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|  | Office of IRB Administration (OIA) **Biomedical Non-Intervention Protocol**  Version Date 12.08.21 |
| 1. **STUDY TITLE** | |
| A Survey of Perceptions of Victims of Violence and System Needs in Caring for Victims of Violence by Providers in Trauma Centers and Associated Rehabilitation Post-acute Trauma Care | |
| **2. PRINCIPAL INVESTIGATOR** | |
| Susan Biffl, MD – Rehabilitation Medicine Department, Rady Children’s Hospital San Diego | |
| **3.** **STUDY RATIONALE** | |
| Experiencing a violent assault can have profound and lasting effects on an individual's life. Unfortunately, there is a scarcity of available data on initiatives aimed at preventing violence among adolescent victims. The quality of care received by victims of violent crime after an injury can significantly impact their physical and psychological recovery from the trauma they have endured.  Whereas admission to a trauma center is covered by Emergency Medical Treatment and Labor Act (EMTALA), transfer to post-acute rehabilitation care is not and thus there is more discretion involved in admission to a post-acute system and there is a greater possibility for provider perceptions to influence acceptance. Many patients who are victims of violence will sustain injuries that significantly impact function and could benefit from post-acute rehabilitation services. Many could benefit from admission to an acute rehabilitation facility, however these facilities are not universally available especially for pediatric patients. Thus a post-acute rehabilitation setting may involve home care skilled nursing facilities or outpatient therapies and rehabilitation medicine care.  In a 2019 study by Patton1, victims of violence were interviewed to understand their perceptions of their care and needs and noted needs specific to their violent injury. They also noted feeling they were treated differently due to the nature of their injury. A Trauma Quality Improvement Program (TQIP) study by Gontarz et al.2 showed trauma victims of violence were more likely to come to the emergency department post discharge suggesting unmet post-discharge needs.    The purpose of this study is to conduct a survey among trauma and post-acute rehabilitation care providers who treat victims of violence in order to identify ongoing differences and disparities in patterns of care and support, specifically targeting the care of victims of violence. Furthermore, this study seeks to identify supports that may increase comfort level of care providers in all centers in caring for this patient population and to shed light on support strategies tailored to different types of traumas experienced by these individuals to improve their care. | |
| **4.** **SPECIFIC AIMS/HYPOTHESES** | |
| **Aims:**  This study aims to examine the existing variations in perceptions of victims of violence by providers in trauma and post acute rehabilitation settings and exposure and supports available within these systems for victims of violence and trauma and rehabilitation providers caring for these patients through surveying representatives of trauma systems and associated rehabilitation systems and the care providers in these systems.  **Hypothesis:**  Our hypothesis suggests that pediatric centers, centers who have a patient population with below-average levels of mechanism of injury involving violent assault and penetrating trauma cases and those with less system-based support to address needs of victims of violence for victims and providers may demonstrate a higher degree of discomfort in providing care for this population | |
| **5. BACKGROUND AND SIGNIFICANCE** | |
| Victimization resulting from violence and is increasingly prevalent among adolescents. Adolescents are specifically of interest as they may be cared for in adult or pediatric settings. A comprehensive phone survey conducted on a sample of 2,000 individuals aged 10 to 16 found that 25% were victims of violence in the preceding year. Acquaintances emerged as the most common perpetrators, while family members constituted another frequent category. Strangers, although less prevalent, still play a role in victimizing adolescents.3 Violence among interpersonal relationships in adolescents is common, with a rate ranging from 20% to 60%.4 This spectrum of partner violence encompasses a wide range of forms, from verbal abuse to sexual assault. Multiple studies have shown that sexual violence among adolescents is predominantly committed by individuals known to the victims. Moreover, a large proportion of adolescents hold the belief that it is acceptable to coerce someone into engaging in sexual activities against their will.4 The prevalence of violence extends beyond interpersonal relationships and sexual assault. A study revealed that approximately 25% of students surveyed had experienced gun-related violence within or around their school.5 Access to weapons among adolescents is alarmingly common, creating an environment conducive to heightened violence. The body of research surrounding the experiences of adolescent victims of violence is lacking, even though 40%-50% of adolescent visits to pediatric emergency departments were attributed to acute injuries resulting from violence.4 A study uncovered that teenagers who were victims of violent crime were ½ as likely to receive follow up instructions and referrals compared to their peers.6  Biases and stereotypes appear to influence the quality of care and follow-up support provided to trauma victims. Some possible factors in the biases found in the care and follow up support of adolescent trauma victims include socio-demographic stereotypes of victims of violence. Healthcare professionals are known to exhibit the same implicit bias as the wider population. Studies have found that biases are likely to have influence over diagnosis and treatment decisions that are made as well as the level of care given. For example, multiple studies evaluating the correlation between Implicit Association Test (IAT) scores and answers to clinical vignettes uncovered a significant correlation between high levels of pro-white implicit bias and treatment responses that favored patients specified as white.7  This study aims to close the gap in research on the biases and obstacles to victims of violence receiving quality treatment and support acutely and throughout the recovery process. In addition, this study will seek to identify strategies for violence prevention through care provider input to ensure that comprehensive interventions are implemented to address biases, remove barriers, and provide the necessary support that is vital to treating victims of violence. | |
| **6. RESEARCH DESIGN AND METHODS** | |
| Upon receiving Institutional Review Board (IRB) approval, this study will begin data collection in a prospective manner from trauma and post-acute care providers who treat victims of violence. Providers consist of physicians, advanced practice practitioners, nurses, case managers, social workers, therapists, etc. This is a multicenter study with Rady Children’s Hospital as the lead site. Trauma centers will be recruited from the institutions involved in the Western Trauma Association (WTA). Recruited facilities will be required to obtain IRB approval for this study and will get access to REDCap.  Each site involved in the study will then send out a link to the survey to their respective trauma and post-acute care providers. The survey will encompass a diverse group of pediatric and adult trauma providers, aiming to gather comprehensive information about the type of trauma centers they represent and the characteristics of the communities and trauma population they serve. It is important to note that no patients will be surveyed for the purposes of this study, and there will be no alterations to their present or future care.  The data collection process will utilize a template on REDCap, which has been designed to encompass the relevant aspects of the survey. Rady Children’s Hospital will be the leading site and oversee recruitment at all centers to facilitate access to the REDCap. There will be a shared REDCap where all the sites will include data from their trauma care providers. The survey form will include a range of questions to be directed towards care providers at various institutions. Participants will receive an email containing a link to access and complete the survey. The survey will be completed in an online format only. The duration of the study participation will be the time it takes for a participant to complete the survey (~15min). Each trauma system and associated rehabilitation system will be identified by a unique number and all associated provider survey will be grouped for analysis. They will be asked to consider their patient population older than 5 years old.  The data to be collected will include various details, such as the characteristics of the trauma center, geographic information, admission details, available support services, evaluation of biases, and demographic information pertaining specifically to victims of violence.  Rady Children’s Hospital will not be transferring clinical data. The excel file imported from REDCap, which contains survey responses, will not contain any identifiable subject or institutional information. These files will be securely stored in a password-protected system on shared network drives, ensuring the confidentiality and privacy of the collected data.  For data analysis, descriptive statistics will be utilized to describe the categories being assessed as described above. Demographic characteristics will be reported as means and standard deviations; medians and ranges; and proportions as appropriate. | |
| **7. RESEARCH PARTICIPANTS** | |
| The participants in this prospective study will be trauma and post-acute care providers willing and eligible to complete an online survey. We plan to include 20 trauma centers across the United States who are members of the Western Trauma Association.  Inclusion Criteria:   1. Employment in an established adult or pediatric trauma center or associated rehabilitation system of care. 2. Providing care and treatment to victims of violence.   Exclusion Criteria:   1. Providing non-trauma related care management. | |
| **8. RECRUITMENT** | |
| We will be recruiting trauma and post-acute care providers from established adult or pediatric trauma care centers across the United States. Trauma centers will be recruited from the institutions involved in the Western Trauma Association (WTA). A link to the REDCap survey will be sent to each site’s providers and completion of the survey will assume consent to participate. No patient information will be collected in this survey and patient care will not be interrupted. | |
| **9. INFORMED CONSENT** | |
| This is a prospective data collection study utilizing a survey via REDCap and does not involve any patient surveys or new data collection that is outside of normal patient care. Participation in the study is optional for all participants. Given the simplicity of the study design, as well as the fact that no patient care is being changed or altered, the only risk associated with this study is loss of confidentiality. Because of these details, we would like to request a waiver of consent and waiver of HIPAA authorization for all aspects of this study.  **Waiver of Consent, Waiver of Documented Consent, Waiver of Individual HIPAA Authorization**  If a *waiver of consent* is being requested, provide a description of how each of the five criteria for granting waiver of consent will be satisfied. The criteria include the following:  1. *The research is minimal risk.* The nature of the research, which is to highlight inequalities of care from victims of violent crime, poses minimal risk to the welfare of patients and care providers and is limited to confidentiality and privacy. Care is not being altered in any way.  2.*The waiver will not adversely affect the rights and welfare of the subjects.* Subjects’ welfare will not be affected. No experimental procedures will be performed for this study. This study only seeks to collect data on usual processes of care and will not interfere with any procedures or decisions made by the doctor or patient. All possible methods to ensure confidentiality will be employed with the collection of survey data.  3.*The research could not practically be carried out without the waiver*. We are not collecting patient health information. The project is designed to document care practices by clinicians. It would not be possible to accomplish this without the waiver.  4.*Whenever appropriate, the subjects will be provided with additional pertinent information after participation.* If desired, participants will be able to access published information on study findings.  5.*If the research involves the use of identifiable private information or biospecimens, the research could not be practicably carried out without the use of identifiers.* N/A  If a *waiver of individual HIPAA authorization* is being requested, this item must clearly and specifically describe how each of the following conditions will be satisfied:  1.*The use of disclosure of PHI involves no more than minimal risk.* This study only poses minimal risk – loss of confidentiality. Section 11 discusses the steps taken to mitigate risk.  2.*Granting waiver will not adversely affect privacy rights and welfare of the individuals whose records will be used.* The patient’s welfare will not be affected. This survey will only be given to care providers to document care practices.  3.The project could not practically be conducted without a waiver. The project is designed to document care practices by clinicians. It would not be possible to accomplish this without the waiver.  4.*The project could not practically be conducted without the use of PHI.* The information we will be collecting will only pertain to the trauma centers that clinicians work for and will be de-identified. No direct patient information will be collected.  5.*An adequate plan to protect identifiers from improper use and disclosure is included in the research proposal*. Only those listed in Section 12 will have access to study. Measures to ensure patient confidentiality will be outlined in Section 11.  6.*An adequate plan to destroy the identifiers at the earliest opportunity, or justification for retaining identifiers, is included in the research proposal.* Any identifiers will be destroyed at the completion of the study.  7.The project plan includes written assurances that PHI will not be re-used or disclosed for other purposes. This project will not re-use or disclose PHI for other purposes.  8.*Whenever appropriate, the subjects will be provided with additional pertinent information after participation.* If desired, participants will be able to access published information on study findings. | |
| **10.**  **BANKING OF INFORMATION/BIOSPECIMENS FOR FUTURE USES** | |
| N/A | |
| **11. MINIMIZATION OF RISK** | |
| **Checkmark with solid fill\_\_\_** Check here if the **only risk** of the research is a breach of confidentiality. If so, no additional information is  required in this section. | |
| **12. PRIVILEGES/CERTIFICATIONS/LICENSES AND RESEARCH TEAM RESPONSIBILITIES** | |
| Susan Biffl, MD – Principal Investigator, Dr. Biffl is a practicing MD at Rady Children’s Hospital in the Rehabilitation Medicine Department. She has medical privileges at UCSD and RCHSD. She will provide support and guidance for the project’s progression as well as data collection, management, and analysis. Dr. Biffl will have full access to study data. **Alyssa Wieand, BS** – ClinicalResearch Coordinator, Alyssa is a Clinical Research Coordinator for the Rehabilitation Medicine Department at Rady Children’s Hospital. She will be involved in all aspects of study progression, data collection, management, and analysis. She will act as the study admin in order to correspond with the IRB.  **Anna Jensen, MA** – Clinical Research Coordinator, Anna is a Clinical Research Coordinator for the Rehabilitation Medicine Department at Rady Children’s Hospital. She will be involved in all aspects of study progression, data collection, management, and analysis. She will act as the study admin in order to correspond with the IRB.  **Talia Soto, BA** – Research Associate, Talia is a Research Associate for the Rehabilitation Medicine Department at Rady Children’s Hospital. She will be involved in all aspects of study progression, data collection, management, and analysis. She will act as the study admin in order to correspond with the IRB. | |
| **13. REFERENCES** | |
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