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Lisa Flowers, MD Date

Empowering Georgia Healthcare Professionals with Knowledge in Identification and Management of Sex Trafficking Victims using a mHealth app Stop SEX Trafficking Now (SSTN): A Grant Proposal to Educate Healthcare Professionals in the Identification and Care of Commercial Sex Exploitation Victims.

By

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Degree to be awarded: Master of Public Health

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An abstract of

A thesis submitted to the Faculty of the Rollins School of Public Health of Emory University in partial fulfillment of the requirements for the degree of Master of Public Health/Master in Prevention Science 2019

Thesis Title: Empowering Georgia Healthcare Professionals with Knowledge in Identification and Management of Sex Trafficking Victims using an mHealth app Stop SEX Trafficking Now (SSTN): A Grant Proposal to Educate Healthcare Professionals in the Identification and Care of Commercial Sex Exploitation Victims.

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Abstract

The US State Department estimates that 26 million individuals worldwide are human trafficking victims. Washington D.C.'s Urban Institute for the U.S. Justice Department reports that between 2003-2007, Atlanta had the largest sex trade revenue of eight major American cities. The violence, abuse, deprivation, physical damage and psychological manipulation experienced by these individuals may cause commercial sex exploitation (CSE) victims to present to the medical community. These victims do not typically self-identify due to shame, fear and close monitoring by the trafficker, leaving it up to the clinician to spot signs suspicious for trafficking. A 2014 survey of CSE victims found that 88 percent had contact with a health care provider at some point while being trafficked. There is very little training for medical professionals in the US, especially among emergency room clinicians, gynecologists, or pediatricians, who are most in contact with these victims. Further, there are no clinically validated screening tools to help medical professionals identify victims in the healthcare setting, or to determine what actions to take once victims actually are identified. This thesis proposes to develop a grant proposal to create and beta test a mobile smartphone app, Stop SEX Trafficking Now (SSTN), designed to educate and better enable clinicians to identify, document and manage CSE victims. Feedback from key informant interviews, in-depth interviews, focus group discussions, and surveys with healthcare professionals, CSE victims and advocacy organizations will be used to inform the design of the app. Once a beta product is designed, it will be piloted among frontline healthcare professionals most in contact with CSE victims (medical staff in the ER, OB/GYN, Pediatric, and Urgent Care clinics). Specifically, this thesis will evaluate the knowledge gain, perceived usefulness of the app, the perceived quality of the content, and the intent to adopt the app among Emergency Medicine clinicians, gynecologists and pediatricians who predominantly provide services to sex trafficking victims and measure increased identification of CSE victims in a Metro Atlanta Safety-net Hospital.

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Chapter I:

Introduction

Defining Sex Trafficking

Sex trafficking is defined by the Trafficking Victims Protection Act of 2000 as "the recruitment, harboring, transportation, provision, or obtaining of a person for the purpose of a commercial sex act" (J. Shandro et al., 2016). It involves the use of force, fraud, or coercion to make an adult engage in commercial sex acts, or if a minor, to cause them to commit commercial sex acts ("Committee opinion no. 507: human trafficking," 2011). This extensive definition also includes stripping, pornography and additional sexually explicit performances (Rabbitt, 2015). With respect to minors and victims under 18 years of age, no proof of fraud, force, or coercion is needed to be considered an act of trafficking (International, 2013). Sex Trafficking does not require transportation of an individual into the US from another country or transportation across state lines (International, 2013). In the US Department of Justice report during the period of 2008-2010, 83% of confirmed sex trafficking victims were US citizens (Banks D, 2011).

The Magnitude of CSE Victims Worldwide and in the US

Despite the passing of legislation outlawing human slavery, it is more widespread today in the form of human trafficking, with sex trafficking of women and children being the most common type (Barrows & Finger, 2008). Over 4 million individuals out of the 40.3 million who are victims of forced labor worldwide are victims of forced sexual exploitation (ILO, 2017). Approximately 1 million are children, generally becoming victims of commercial sexual exploitation (CSE) during their early adolescence (Greenbaum & Crawford-Jakubiak, 2015). Despite the difficulty in acquiring accurate statistics due to low reporting, it is estimated that between 200,000-300,000 children

are at risk for CSE each year in the US (Shandro et al., 2016; Varma, Gillespie, McCracken, & Greenbaum, 2015).

Missed Opportunities for Identification of CSE Victims by HCPs

Recent studies have reported that 28%-50% of trafficking victims had contact with a health care professional in the US who did not recognize the signs (Dovydaitis, 2010; Grace et al., 2014). In a study examining provider knowledge, less than 50% of pediatric emergency room clinicians accurately identified sex trafficking victims and only 42% could correctly decipher a CSE victim from a child abuse victim (Beck, 2015). In addition, 63% of these clinicians had never received formalized training in the identification of CSE victims (Beck et al., 2015). The gaps in awareness and knowledge of CSE victim identification correlated with the clinician's limited experience and training (Beck et al., 2015).

Evidence in the literature has reported that first responders in major medical centers including emergency room, outpatient clinic or urgent care physicians have limited training and therefore limited ability to identify this vulnerable patient population (Grace et al., 2014), (Beck et al., 2015), (Chisolm-Straker, Richardson, & Cossio, 2012) (Macias Konstantopoulos et al., 2013). A study published in the Journal of Health Care for the Poor and Underserved in 2012 reported that 95% of ER doctors and nurses surveyed had never received formal training on human trafficking (Chisolm-Straker et al., 2012) . In this study, only 4.8% were confident in their ability to identify a trafficked patient and 7.7% expressed confidence to treat a trafficked patient (Chisolm-Straker et al., 2012). This is a missed opportunity since the healthcare sector is one of the fields with the highest exposure to trafficking victims (Chisolm-Straker et al., 2012) (Macias-

Konstantopoulos, 2016) (Macias Konstantopoulos et al., 2013). Therefore a need exists in the state of Georgia for Emergency Medicine, Pediatricians and OB/Gyn physicians to receive essential and lifesaving information to assist in the identification of victims of CSE and appropriately intervene through the delivery of needed clinical and mental health services, and actively engage social services and law enforcement to stop the cycle of abuse and improve health outcomes (Macias-Konstantopoulos, 2016; Tracy & Konstantopoulos, 2012). In recognition of the interface between the healthcare setting and trafficking there is a clear need for evidence-based training of health care professionals (HCPs) on human trafficking (HT).

It is our goal to develop a smartphone application which functions as a screening tool to help healthcare providers to CSE victims, perform and document appropriate medical information, and facilitate prompt, direct referral to social and ancillary services to aid in the care and safety of the victim.

Significance of the Study

There are currently no known mobile applications in existence to teach HCPs to identify and manage CSE victims receiving healthcare services. The need for timely information especially in an urgent care setting such as the Emergency Room, is critical when a clinician suspects sex trafficking. Information delivered by the use of mobile devices is more acceptable to health care providers within this generation (Ventola, 2014) and research shows that approximately 17,000 health-related applications have been downloaded for iPhones, Android devices, mobile phones and tablets (Nussbaum et al., 2019) (Yaman et al., 2016) (Perry, Burns, Simon, & Youm, 2017). Current estimates predict that 50% of 3.4 billion tablet or mobile phone users around the world will be

using mHealth applications (apps) (Cisco, 2019). Smartphone access is almost universal among adults in the United States (Nussbaum et al., 2019). A problem of this magnitude requires a solution of similar mass reach. The incorporation of mobile application technology via smartphone and tablet devices has become a natural adjunct to clinical practice for the modern clinician (Franko & Tirrell, 2012; Payne, Wharrad, & Watts, 2012; Perry et al., 2017; Wallace, Clark, & White, 2012; Yaman et al., 2016) . In a study of 197 Ob/Gyn residents in California examining the use of mobile devices for medical knowledge, the entire group reported owning mobile devices (100% smartphones, 74% tablets), and 93% used apps in the medical setting (Perry et al., 2017). Frequently used ob-gyn-related apps were cervical cancer screening algorithms (68%), pregnancy wheels (84%), and contraceptive eligibility guidelines (47%) (Perry et al., 2017). Residents reported mobile technology as a vital clinical tool (92%) that improved their efficiency (89%). Also, the use of mobile apps did not differ by age, gender, or postgraduate year (Perry et al., 2017).

The increased use of these mobile applications by established clinicians and physicians-in-training highlights the shift from dependence on the medical library to the accessible and easy to operate mobile-based technology platforms (Hilgefort et al., 2014). The use of smartphones and apps for clinical care will likely continue to grow, and studies have shown an absence of popular apps of high-quality despite a strong desire among physicians (Franko & Tirrell, 2012). The reliability and ease of use of the mobile app are the main factors in the successful integration of apps into clinical medicine (Franko & Tirrell, 2012). Clearly with the magnitude of the sex trafficking crisis in Atlanta, integration of a screening tool mobile application to improve identification of CSE victims and provide trauma-informed care to these patients is timely. The information available in the mobile app should have information that is accurate and evidence-based,

not solely from the literature but also from the qualitative and quantitative data provided by the CSE victims as well (De Bari et al., 2016).

Theoretical Framework

Healthcare professionals have a poor track record for recognizing clinical signs of sex trafficking or rescuing CSE victims from sex trafficking (Grace et al., 2014) (Baldwin, Eisenman, Sayles, Ryan, & Chuang, 2011) (Chisolm-Straker et al., 2012) (Ross et al., 2015) (H. Stoklosa, MacGibbon, & Stoklosa, 2017) (H. Stoklosa, Grace, & Littenberg, 2015). The reasoning for the lack of recognition by healthcare professionals is related to inadequate education and training tools to assist in identification of CSE victims and differentiate them from individuals presenting with trauma and sexual assault who are not CSE victims. The approach in this proposal will be to conduct key informant interviews (KIIs), in-depth interviews (IDIs) and focus group discussions (FGDs) with CSE victims to acquire information about their experiences with the medical system and missed opportunities by the provider in assisting them to escape. Similar qualitative methods will be used to determine knowledge gaps among healthcare professionals and tools needed to instill confidence in the providers to look through different lenses, those of the CSE victims to increase identification of this population and be intentional in knowing how to manage and provide resources. The next step will be development of the mobile app and testing it among HCPs as an effective educational tool in the identification and management of CSE victims who present for care in the healthcare system.

The theoretical support for the intervention in the proposal will be based on two behavioral theories: Technology Acceptance Model, and Diffusion of Innovation Theory (Sales, Smith, Curran, & Kochevar, 2006).

Technology Acceptance Model

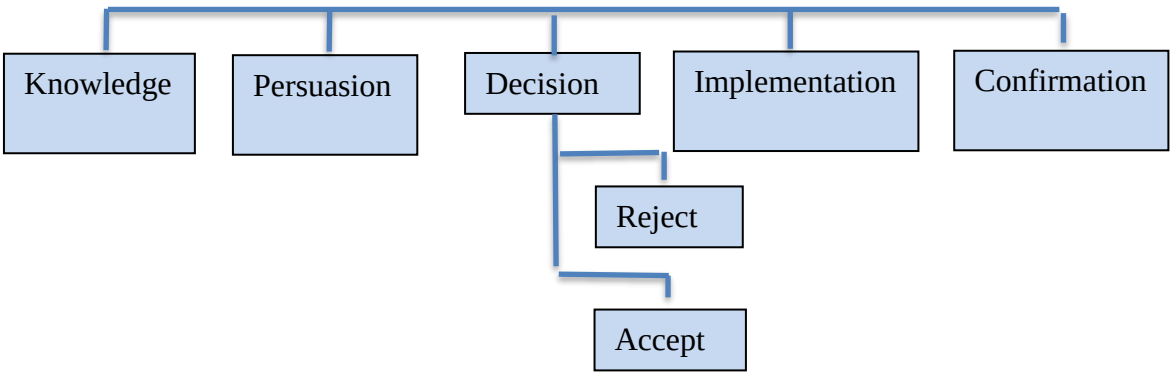
The ultimate reach and impact of the app depends upon its uptake among users, particularly among HCPs. The Technology Acceptance Model (TAM) posits that the perceived usefulness of a new technology and its perceived ease of use together determine an individual's attitude towards a new technology, which in turn affects its likelihood of uptake among new users (Wang & Goh, 2017), (Dou et al., 2017), (Beglaryan, Petrosyan, & Bunker, 2017). A key element of our evaluation of the app, and a proxy for its general acceptability among our larger community, will be the measure of these two variables, the perceived utility and ease of use of the SSTN mHealth app by healthcare professionals.

Diffusion of Innovations Theory

We intend to also use the diffusion of innovations theory to disseminate, beta test and evaluate the mHealth SSTN tool to provide HCPs information quickly. This theory was developed by E.M. Rogers in 1962 to explain over time how a product or idea achieves momentum and disperses through a social system or population (LaMorte, 2018) (Moseley, 2004) (Rogers, 1983). Generally adoption of the product requires the person to view the product, idea or behavior as innovative (LaMorte, 2018) (Rogers, 1983). Those individuals who adopt an innovation quickly have different characteristics than people who are late adopters (LaMorte, 2018) (Rogers, 1983). There are stages and factors that influence individuals to adopt an innovation. The person needs to understand the necessity of the innovation, make a choice to use and evaluate the product or reject it and finally incorporate the product in their daily life (Figure 1) (Walitzer, Dermen, Barrick, & Shyhalla, 2015) (LaMorte, 2018). The factors that play a role in the adoption of a product by the various types of adopters (innovators, early adopters, early majority, late majority, laggards) are relative advantage, compatibility,

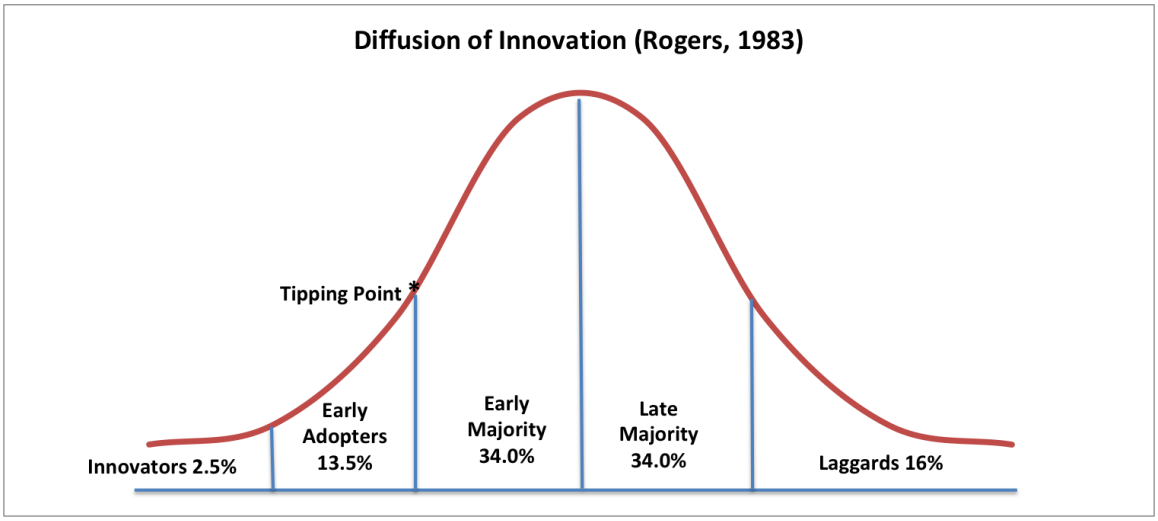
complexity, triability and observability (LaMorte, 2018). Relative advantage addresses how the adopter perceives that the product is superior to what it is replacing in the market (LaMorte, 2018). Compatibility addresses how consistent is the product in delivery the experience expected by the adopter and satisfying their needs (LaMorte, 2018). Complexity is how steep is the learning curve to use the product (LaMorte, 2018). Triability is the limit of product's testing phase before adoption of the product needs to occur and lastly is observability, the level of concrete results produced by the product (LaMorte, 2018). The diffusion curve shows different rates of adoption of new innovations by the various types of adopters (Figure 2) (Haider & Kreps, 2004) (LaMorte, 2018). If the use of the mHealth SSTN tool is beyond the "Tipping Point" then it is more likely to be used by the majority of the population. We anticipate that there will be early adopters of the mHealth SSTN tool especially among technology driven healthcare professionals expressing intent to beta test or to adopt the mHealth SSTN tool if it passes through the beta-testing phase. These early adopters will hopefully engage and promote the mhealth app to the early majority and push the utility of the app past the "tipping point".

Figure 1: Five Stages in the Decision Innovation Process



Source: https://upload.wikimedia.org/wikipedia/en/d/d6/DoI_Stages.jpg

Figure 2: Diffusion of Innovation (Rogers, 1983)



Chapter II Review of the Literature

Magnitude of the Problem

Sex trafficking is an increasingly well-recognized human rights violation that is estimated to involve more than 4 million victims worldwide each year (Toney-Butler & Mittel, 2019), (ILO, 2017). Human trafficking is a 150 billion dollar industry and is the fastest growing area for organized crime providing the 3rd greatest income revenue after narcotics and arms sales (Toney-Butler & Mittel, 2019), (ILO, 2017) (Donahue, 2019). Seventy-one percent of human trafficking victims are women and girls and 29% are men and boys (ILO, 2017). The commercial sex industry accounts for 100 billion dollars of the human trafficking income revenue per year and women and girls account for the majority of CSE victims (ILO, 2017). Published estimates from as far back 2002 have suggested that there may be as many as 325,000 children in the United States who are at risk for commercial sexual exploitation. Since then, cases have been confirmed in all 50 states, in both urban and rural areas, involving girls, boys, and transgendered young people (ILO, 2012) (Toney-Butler & Mittel, 2019) (Group, 2010) (Polaris, 2012). The Center for Public Policy Studies (CPPS) declares that the average age of the commercial

sex market for girls is between 12 and 14 years, but in some cases the girls are introduced through coercion, violence and illegal drugs at even younger ages (Group, 2010). According to the FBI and the National Center for Prosecution of Child Abuse, in Atlanta alone, an estimated 200-300 youth are prostituted each month, while many other organizations believe the number to be much higher than that at approximately 400 girls monthly (Pollard, 2017). According to Washington D.C.'s Urban Institute for the U.S. Justice Department, between 2003 and 2007 Atlanta had the largest sex trade revenue of eight major American cities, generating more than $290 million over that five-year span (Dank, 2014). Additionally, the same study stated that sex traffickers in Atlanta received an average of $33,000 per week from their activities (Dank, 2014). Another unfortunate statistic from the Schapiro group is that 7,200 men buy sex from a minor each month in Georgia, compromising 8,700 sex acts (Group, 2010). In addition, 91% of CSEC in Georgia were enrolled in school during the period of exploitation (Group, 2010). Sadly, 100 juvenile girls on average are exploited every night in Georgia (Project, 2010) (Todres & Clayton, 2014) (Team, 2016) group (Group, 2010).

One of the biggest factors thought to be contributing to sex trafficking in Atlanta is the fact that Hartsfield-Jackson Atlanta International Airport is the world's busiest airport and an important destination for political refugees, making Atlanta a target for predators (Team, 2016). Sixty-five percent of men purchasing sex for young women are conducting their activities in suburban and metro Atlanta (Studies, 2013; Team, 2016) (Group, 2010). Nine percent of these events are occurring near the airport (Studies, 2013). Therefore, being a hub of sex trafficking in the US, Atlanta is the perfect location to pilot an educational mHealth tool to assist health professionals in identifying CSE victims and appropriately managing their care and referring them to resources which can remove them from this dangerous situation.

CSE Victims Health Consequences and Contact with HCPs

The health consequences of CSE bring victims into contact with health systems and healthcare providers, thus providing the potential for identification and intervention. In 2014, Loyola University's Chicago School of Law and the Beazley Institute for Health Law and Policy conducted a study subsequently published in the Annals of Health Law (Lederer LJ, 2014). Over one hundred domestic sex trafficking victims and survivors were surveyed in cities across the United States on a number of topics. The study entailed 11 focus groups conducted in multiple cities across the United States between January 2012 and December 2012 (Lederer LJ, 2014). The ages of the women ranged from 14-60 years of age and all of them were domestic CSE victims (Lederer LJ, 2014). On average, respondents reported being used for sex by approximately thirteen buyers per day, with up to as many as thirty to fifty buyers (Lederer LJ, 2014). Ninety-nine percent of respondents reported some type of health issue, including injuries (69%), dental (54%), neurological (91%), gastrointestinal (62%), and cardiovascular/respiratory symptoms (68%) (Lederer LJ, 2014). More than two-thirds (67.3%) acquired some form of STD/STI, including gonorrhea (27%), chlamydia (39%), and Hepatitis C (15%) (Lederer LJ, 2014). Without accounting for possible underreporting, 71% of respondents reported being pregnant during trafficking with 21% having 5 or more pregnancies (Lederer LJ, 2014). Of the 67 survivors who answered the question of abortion, 55% reported having one abortion, 30% multiple abortions, with a total of 114 abortions among this cohort of survivors (Lederer LJ, 2014). Many of these abortions were forced abortions, very common in the sex trafficking world (Lederer LJ, 2014).
Ninety-eight percent of the survivors reported at least one psychological health issue while being trafficked (Lederer LJ, 2014). Common presenting problems were anxiety

(76%), depression (89%), nightmares (74%), flashbacks (68%), low self-esteem (81%), and emotions of shame or guilt (82%). Several of the survivors were diagnosed with the following psychological disorders: bipolar (30%), multiple personality (13%), borderline personality (13%), depersonalization (20%), acute stress (39%), Post Traumatic Stress Disorder (PTSD) (55) and 42% had attempted suicide (Lederer LJ, 2014). The most troubling statistic is that of those individuals who answered the survey questions about contact with any healthcare providers during their trafficking, 87.8% confirmed having contact with a healthcare provider.

The most frequently reported treatment site was a hospital/emergency room (63%), but survivors were also seen at neighborhood clinics (19%), urgent care (21%), primary care doctors (22%), women's health clinic (19%), and Planned Parenthood (30%) (Lederer LJ, 2014). Just over half of the respondents who answered said that their healthcare providers knew they were "on the street" (Lederer LJ, 2014). The results of this study confirm that a robust healthcare response requires a healthcare workforce that is educated about how to identify and treat affected individuals of sex trafficking in a compassionate, culturally aware, and trauma-informed manner; trained about how to collaborate efficiently with law enforcement, case management, and advocacy partners, and aware of the health impacts of sex trafficking, both long-term and short-term.

A review of survivors' experiences in health care settings provides further support for this initiative. A cross-sectional study of female domestic sex trafficking victims found that 89% reported experiencing physical violence, 80% reported suicidal thoughts, 59% had a sexually transmitted infection, and 58% became pregnant while trafficked (Muftic & Finn, 2013).

The challenge is how health providers can assist in identifying these victims when they present to healthcare facilities and end the cycle of exploitation for many of these victims. As previously mentioned there is a recognized lack of knowledge about identification and management of CSE victims by HCPs in multiple clinical settings (Polaris, 2012) (Polaris, 2014) (Polaris, 2019) (Grace et al., 2014) (Baldwin et al., 2011) Beck (Beck et al., 2015) (Chisolm-Straker et al., 2012) (Macias Konstantopoulos et al., 2013).

There are advocacy organizations that have developed curricula for training in different clinical settings; however, the methodology and materials vary and have not shown to be efficacious (Powell, Dickins, & Stoklosa, 2017). Powell et al. conducted a mixed-method study assessing the strengths and gaps in HT education for HCP using structured interviews with experts in HT education and analysis of information extracted from calls to the National Human Trafficking Resource Center (NHTRC) (Powell et al., 2017). The interviews covered key content areas, barriers and strengths in training HCPs, and NHRTC call database provided trends in calls by HCPs since 2008. The findings in the study supported the need for accurate patient-centered and standardized messaging and information for HCPs.

Characteristics and Risk Factors for CSE Victims

Trafficking victimization and perpetration share risks and consequences associated with child abuse and neglect, intimate partner violence, sexual violence and gang violence (Yates, Mackenzie, Pennbridge, & Swofford, 1991) . Victims can come from all backgrounds and become trapped in different locations and situations (J. Shandro et al., 2016) (Rabbitt, 2015).

- The majority of victims are women and girls, though men and boys are also impacted.
- Victims include all races, ethnicities, sexual orientations, gender identities (lesbian, gay, bisexual, transgender, questioning), citizens, non-citizens, and income levels.
- Victims are trapped and controlled through assault, threats, false promises, perceived sense of protection, isolation, shaming, and debt.

Perpetrators of sex trafficking often target people who are poor, vulnerable, living in an unsafe situation, or searching for a better life (J. Greenbaum & Crawford-Jakubiak, 2015). For example, youth with a history of abuse and neglect or who are homeless are more likely to be exploited (Yates et al., 1991). Associated risk factors and signals of sex trafficking in minors are listed below (Banks D, 2011), (Yates et al., 1991), (Macy & Graham, 2012), (Rabbitt, 2015).

- Homeless Youth
- Youth from group homes and shelters
- LGBTQ Youth
- Frequent runaway episodes
- Frequent Absentee without leaving
- Youth recently relocated or from outside the US separated from supportive social network
- Pregnant teens or teens with multiple abortions
- Teens with unexplained injuries
- Individuals brought in for medical care by unrelated persons who are controlling or “talk for the patient”

- Teens who have gifts, clothing (provocative), money with no justified source or it was given by an older individual
- Youth who "dance" for money
- Youth who use terms used in the sex trade such as "bottom", "the game". "daddy" and "stable"
- Prior history of neglect, sexual abuse or assault, or physical abuse (Child protective services involvement)
- Youth who report not having identification or cell phone has been taken from them
- Branding /Tattoos
- Youth with peers or family members in the sex trade
- Youth with a fearful presentation, anxious, flat affect or submissive behavior
- Medical or demographic information seems recited
- Youth who give false or changing demographic information

The socioecological model can be used to understand how risk factors for CSE within the four levels of the model can influence each other and perpetuate the vicious cycle of CSE (Council, 2013). There is a complex interplay between the different levels: individual, relationship, community and societal (Council, 2013). For instance individual risk factors for CSE are homelessness, being involved in the justice or foster home system, being abused as a child or being a runaway (Council, 2013). For relationship risk factors having a dysfunctional home environment (Council, 2013). Community risk factors would be gang involvement and peer pressure (Council, 2013). Finally societal risk factors would be lack of knowledge about CSE and lack of resources (Council, 2013). This model considers the complex interplay and allows one to understand factors that put individuals at risk for CSE. In order to stop the cycle of CSE and prevent entry and facilitate exiting out, it is imperative to protect potential victims across multiple levels of

the model (Council, 2013). This approach is more likely to sustain prevention efforts over time than any single intervention.

Clinical Consequences of CSE Seen in the Healthcare System

Consequences of sexual violence, including sex trafficking, can be immediate and long term, including physical and relationship problems, psychological concerns, and chronic health outcomes. This type of violence exploits women, men, and children across the United States and around the world (Oram, Stockl, Busza, Howard, & Zimmerman, 2012). CSE victims may present to the healthcare system with multiple medical problems as reported below. (Hossain, Zimmerman, Abas, Light, & Watts, 2010), (Macy & Graham, 2012), (Children, 2013) (Rabbitt, 2015).

- Gynecologic problems including concern for exposure to HIV or other sexually transmitted infections, fertility issues, other diagnosis linked with sexual violence and rape
- Pregnancy
- Physical health issues linked with beatings and rapes (evidence of untreated fractures, cigarette burns, sexual abuse, lacerations, bruises, skin injuries hidden by clothing)
- Self-injury events such as cutting
- Blood-borne infections from brandings and tattoos
- Untreated medical problems
- Mental health issues (post-traumatic stress disorder, anxiety disorders, depression, oppositional behaviors, attachment disorder, aggression, hyperactivity and attention deficit disorder, somatic complaints like headaches or chronic pain associated with chronic trauma and stress)
- Malnutrition (thin or obese)

- Substance abuse (forced by the sex trafficker or as a coping mechanism to deal with the abuse and trauma)

While health care providers are serving this patient population, they do not consistently identify them as victims of sex trafficking. According to Baldwin et al. in 2011, half the survivors surveyed reported that they had visited a physician while in their traffickers' control (Baldwin et al., 2011). In a retrospective study of US-based sex trafficking survivors, out of 173 participants, 68% percent were seen by a healthcare professional during their trafficking experience (Chisolm-Straker et al., 2016). Most survivors reported being seen by ER and urgent care physicians (56%) followed by obstetricians/gynecologists (26%), primary care providers (44%), dentists (26%) and alternative healers (9%) (Chisolm-Straker et al., 2016). Many times, the sex traffickers accompanied the CSE victims to the clinics, filled out the paperwork and spoke with the staff about the presenting medical problems of the CSE victims. Some of the sex traffickers appeared to have relationships with the doctors at the private clinics providing services to the CSE victims (Baldwin et al., 2011). These trafficking victims were prohibited from disclosing their status to health care providers. Shame, fear, language barriers, and restricted interaction with medical personnel were some of the obstacles preventing the disclosure of the CSE victim to the HCPs (Baldwin et al., 2011).

Increasing awareness of human trafficking and modifying practice to facilitate disclosure could improve victim identification. A study by Mumma et al. piloted a program for screening CSE victims in the ER at University of California, Davis, Department of Emergency Medicine using a 14 question survey versus the physician's concern for sex trafficking (Mumma et al., 2017). A positive screen was considered a yes to any question on the survey or if the physician felt that the patient was a CSE victim. This observational

study enrolled 143 patients of which 39 screened positive with 10 actually being accurately identified as CSE victims (Mumma et al., 2017). The sensitivity of the survey for identifying CSE victims was 100% (95% CI: 74%-100%) compared to physician concern which was 40% (95%CI: 12%-74%), a difference of 60%. Specificity was higher for the physician's concern at 91% (95% CI: 85%-95%), better than the survey at 78% (95% CI: 70-85%), a difference of 13%. It demonstrates the lack of knowledge by HCPs on identification of CSE victims and the need of objective screening tools to identify individuals at risk (Mumma et al., 2017).

The Strengths and Weaknesses of Current Screening and Training Tools in Educating HCPs in Identification of CSE victims

There is a significant deficit of knowledge among healthcare professionals who play a critical role in both identifying victims of sex trafficking while they are still in captivity, as well as caring for their mental and physical needs upon release (Ahn et al., 2013). It is imperative that those in the healthcare profession are educated regarding how a sex trafficking victim may present, as well as their unique healthcare needs (Ahn et al., 2013). Unfortunately, medical resources and information are few and clinically validated screening tools to identify victims in the healthcare setting are lacking (Ahn et al., 2013). A factor that complicates the issue is that victims do not typically self-identify due to shame, language barriers, fear and close monitoring by the trafficker, leaving it up to the clinician to spot signs suspicious for sex trafficking (Lederer LJ, 2014) (Baldwin et al., 2011). So, a majority of victims are not identified and a missed opportunity to intervene on behalf of the victim by the clinician occurs.

Sex trafficking is a crime resulting in serious negative health outcomes for the victims. To provide optimal care, thus improving health outcomes, healthcare providers must be

able to identify victims as they seek care for acute and chronic physical illness, communicable diseases, sexually transmitted infections, and mental health disorders (Lederer LJ, 2014) (Oram et al., 2012). Unfortunately, healthcare providers lack appropriate knowledge of clues that would lead to victim identification. This may result in a failure to identify victims (Beck et al., 2015; Ross et al., 2015; Konstantopoulos et al., 2013; Chisolm-Straker et al., 2012).

There is a great need for evidence-based, evaluable training and educational materials to assist HCPs to identify, respond appropriately and refer CSE victims to resources that will help them escape from sex trafficking. A review of educational resources on human trafficking for HCPs conducted between 2011-2012 revealed only 27 resources for HCPs despite the extensive database search (PubMed,/MEDLINE, Global Health, CINAHL, EMBASE, Cochrane Database of Systemic Reviews and Google Scholar website) (Ahn et al., 2013). The inclusion criteria used was English only materials that offer guidance, inform or educate HCPS on human trafficking. The topics covered in these educational materials (toolkits, curricula, guides, workbooks, protocols, and training materials) ranged from definitions of trafficking, victim identification, appropriate treatment, health consequences, referral to services, prevention and safety and legal issues (Ahn et al., 2013). However, many of the materials found did not address behavior change outcomes, most were not found in peer-reviewed publications and lacked any evidence of evaluation (Ahn et al., 2013). The positives about the information extracted from the search was that some of the resources were in a format providing continuing education credit to HCPs, a high yield strategy for optimizing learning among HCPs (Ahn et al., 2013). Other educational training resources provided exams to assess knowledge gain and an assessment of confidence by the provider after completing the training. There were no resources identified in this paper that assessed the effects of training on reporting trafficking events, or the number of victims identified and treated long-term or

content validity. Also, there was minimal assistance on the role of HCPs in prevention of sex trafficking (Ahn et al., 2013).

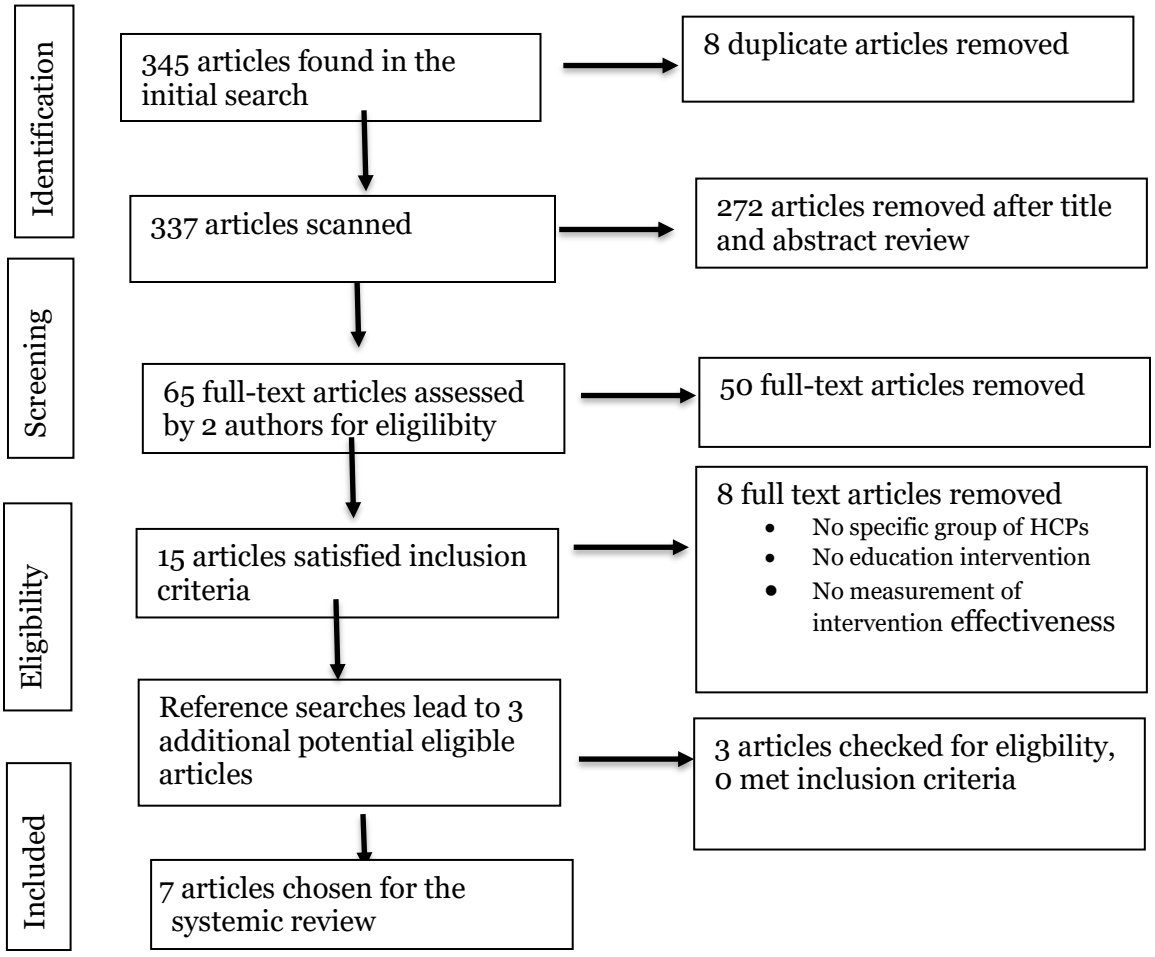
A study by Edyud et al. provided a mandatory educational program to their ER staff (physicians, nurses, social services, registration, radiology, laboratory, and transport) and after the training had the participants complete a survey on knowledge acquired from the training (Egyud, Stephens, Swanson-Bierman, DiCuccio, & Whiteman, 2017). An algorithm was put in place in the ER to facilitate recognition of CSE victims either using medical red flags embedded into the electronic medical record or a silent notification. The outcome measures were any victims identified by either the medical red flags or silent notification (Egyud et al., 2017). At the end of the study 75% of the participants felt they had a higher level of competence in identifying CSE victims and one patient was identified as a CSE victim (Egyud et al., 2017).

Recently Donahue et al. developed an online training module called HTEmergency.com (Donahue, 2017) developed for HCPs in the ER setting (nurses, physician assistants, nurse practitioners, registration and ER technicians) (S. Donahue, M. Schwien, & D. LaVallee, 2019). This 20-minute training module was composed of pretest, educational PowerPoint, identification and treatment guidelines, case studies and post-test. They tested this educational module among ER staff in 2 suburban hospitals in Philadelphia and demonstrated a 93% increase in comprehension on the topic of human trafficking after the intervention among the ER staff compared to less than 50% of the participants reporting an understanding about human trafficking prior to the intervention (S. Donahue et al., 2019). Eighty-nine percent of the participants never received human trafficking education prior to the module but reported a significant increase in their confidence level to identify a human trafficking victim from 4/10 to 7/10 (Steven

Donahue, Michael Schwien, & Danielle Lavallee, 2019). In addition, this training module allowed the clinician to gain CME credits, an incentive to providers.

The evidence of how successful these tools are in identifying CSE victims is lacking and there is still a paucity of screening tools and training or educational materials to assist HCPs in recognizing and helping CSE victims to escape from their imprisonment. A systematic review of educational interventions for HCPs on Human Trafficking was conducted by Fraley et al and published in the Western Journal of Nursing Research in 2019. This study searched 4 databases for peer-reviewed papers published between January 1, 2000-September, 1 2018 following the Cochran Collaboration's Preferred Reporting Items used for Systemic Reviews. The quality of the studies was gauged using the Downs and Black checklist and the validity of the instruments used was measured using the Psychometric Grading Framework (PGF) (Downs & Black, 1998) (Cadorin, Bagnasco, Tolotti, Pagnucci, & Sasso, 2016; Leung, Trevena, & Waters, 2014). The review focused on HCP HT/CSE educational interventions, their implementation and their efficacy. The databases reviewed were MEDLINE, CINAHL, Education Resources Information Center (ERIC) and PsychoInfo (Hannah E. Fraley, Aronowitz, & Stoklosa, 2019). Studies were given points for a total score of 28 (poor <14, fair 15-19, good 20-25 and excellent 26-28) based on Downs and Black Checklist (Downs & Black, 1998). The study summaries and quality appraisal scores for the 7 studies that were included in this review are located in table 1 and figure 3 outlines the stringent screening process of identifying the final articles evaluated in the review (Hannah E. Fraley et al., 2019).

Figure 3 Process for Articles Chosen for Review



The mode of delivery of the intervention varied between studies from face to face to web-based programs. The pooled total of HCPs included in the studies were 1.167 and out of the 7 studies, five utilized mixed methods (H. E. Fraley, Aronowitz, & Jones, 2018). All of the studies examined effectiveness of the interventions using pre- and post-test methodology demonstrating an increase in participant awareness of trafficking and a decrease in negative attitude toward trafficking (Hannah E. Fraley et al., 2019). One study measured confidence in CSE identification and another assessed effectiveness by whether any referrals were made to trafficking agencies by social workers (Hannah E. Fraley et al., 2019). There was an under represented sample of nurses in the cohort of

HCPs in the studies included in this review (Hannah E. Fraley et al., 2019). Also, only one study used a guiding theoretical foundation in creation of the educational curriculum (Hannah E. Fraley et al., 2019). Four of the studies did have formative focus groups with content experts and HCPs and two included input from CSE survivors in the curriculum development phase (Hannah E. Fraley et al., 2019). However, there was a lack of comparison measure across studies (internal consistency, construct, content and discrimination) and four instruments were graded as "weak" per PGF grade (Table 1) (Hannah E. Fraley et al., 2019). Also, the survey response rates and completion of the pre and post-test surveys were low in some studies and many of the study results were not generalizable to the entire population of HCPs. As expected, the authors from this review recommended that future studies should chose to perform a randomized control trial design to truly evaluate the impact of the educational intervention (Hannah E. Fraley et al., 2019).

Table 1 HT HCP Educational Intervention Study Summaries and Quality Appraisal Scores

References (first Author, Year)	Theoretical Foundations	Study Variable(s) Measured	Construct Validity	PGF Grade	Quality Appraisal Downs and Black Checklist Score[a]
Beck et al. (2015)	No specific theory reported	Awareness Attitudes	Awareness posttest compared with intervention group ($p < .001$)	Weak	Fair (Total points = 19)
Donahue et al. (2019)	No specific theory reported	Awareness Knowledge Confidence	Not reported	Very Weak	Poor (Total points = 9)
Ferguson et al. (2009)	Bloom's Taxonomy Andragogical Adult Learning Model	Awareness Attitudes	Awareness posttest compared with pretest significant ($p < .001$) Attitudes posttest compared with pretest significant ($p < .001$)	Adequate	Poor (Total points = 14)
A.M. Grace et al. (2014)	No specific theory reported	Awareness Attitudes	Awareness posttest compared with pretest significant ($p < .001$) Attitudes posttest compared with pretest significant ($p < .001$)	Weak	Fair (Total score = 18)
Lutz (2018)	No specific theory reported	Awareness Knowledge Confidence	Awareness and knowledge posttest compared with pretest significant ($p < .001$)	Weak	Poor (Total score = 10)
McMahon-Howard and Reimers (2013)	No specific theory reported	Awareness Attitudes	Awareness posttest compared with pretest significant ($p < .05$)	Weak	Good (Total score = 21)
Viergever et al. (2015)	No specific theory reported	Awareness Attitudes	Not reported	Very Weak	Poor (Total score = 10)

The key to the success of any program is that any form of training or education about sex trafficking comes from an evidence based, trauma-informed approach, that is patient-centered, and demonstrates proven effectiveness. In addition, the training should address orientation on gender and cultural competencies and allow for survivor input.

Innovation

There is also very little training among medical professionals in the US, especially clinicians in the emergency room, gynecologists, or pediatricians who are mostly in contact with these victims (Grace et al., 2014) (Beck et al., 2015) (Becker & Bechtel, 2015) (Baldwin et al., 2011) (Chisolm-Straker et al., 2012). Many of these professionals feel ill equipped to appropriately question and interview potential victims for fear of putting them more at danger, losing the patient prior to treatment or misjudging the

situation for a human trafficking when it is not (Grace et al., 2014; H. Stoklosa et al., 2015) (Beck et al., 2015) (Baldwin et al., 2011). The following goals are imperative for clinicians: identifying human trafficking victims, recognizing their common medical presentations, understanding approaches to patient interview and exam, acquiring the appropriate documentation and tests for treatment, and providing sources for referral. This is an opportunity to capitalize on using mobile technology or mHealth to disseminate education on the identification and management of sex trafficking to healthcare professionals who are lacking the skills to capture these victims. At present there are no mHealth apps for healthcare professionals to address this educational gap in specialized and standardized training pertaining to the detection and management of CSE victims.

Digital Problem-Based Learning in Health Professions

Whatever the field, smartphone and tablet applications (apps) are quickly becoming a solid resource that the professional cannot do without. Smartphones and tablets already play a huge role in modern medical treatment; they facilitate fast and easy access to medical and test data, patient records, and medical references (T. J. G. Chase et al., 2018). Studies and surveys in 2013 showed that over 87% physicians had adopted smartphone and tablet technology in their practices compared to 99% computer adoption (J. Chase, 2013). Today it is likely closer to the same 99% computer adoption for smart technology. Over 80% of physicians over 55 owned a smart device (J. Chase, 2013).

The major factor driving the adoption of smart mobile device technology is the need for rapid information and communication at the point of care by physicians (Mosa, Yoo, & Sheets, 2012; Wallace et al., 2012). Over 70% of medical school HCPs and students indicated that they generally utilized a smart mobile device and a medical app on a

regular basis and over half on a daily basis (Murfin, 2013; Wallace et al., 2012). Physicians now routinely utilize smart device apps like “UpToDate” and “MedPage Today” to both get medical news and to stay on track with their continuing medical education and training. Smartphone and tablet applications facilitate and deliver on the premise of “learn anywhere.” Device and app technology has advanced to the point that the smartphone has become a “pocket brain,” pocket library, pocket medical record system and most important for this discussion a pocket classroom (Murfin, 2013) (Payne et al., 2012; Wallace et al., 2012).

The smart device has opened the doors to more effective and timelier, less costly and ideally more accepted and embraced forms and methods of learning that support virtual patients, problem-based learning and gamification of scenarios and learning paths. A study in 2012 indicated that physicians that experienced Advanced Life Support Training on a smartphone or tablet had much better scores when tested on cardiac arrest simulators than their peers that trained on other methods (Ozdalga, Ozdalga, & Ahuja, 2012). A cohort of nine randomized controlled trials that involved over 890 health professionals compared face-to-face Problem-Based Learning (PBL) which has been utilized in medical education and training for the past 50 years to digital PBL (DPBL) which is delivered utilizing digital (e.g. computer, online, gamification or mobile smart device) methods (Dunleavy et al., 2019; Semwal et al., 2019; Tudor Car et al., 2019). The studies indicated that Digital Problem-Based Learning and education was at least as effective as traditional PBL face-to-face methods and that DPBL had a higher positive impact on student learning when the DPBL also allowed for full distance learning (Dunleavy et al., 2019; Semwal et al., 2019; Tudor Car et al., 2019). DPBL and PBL were both more effective than traditional classroom and textbook based instruction in increasing medical knowledge and level of skill as well as improving acceptance and

attitudes about the training (Dunleavy et al., 2019; Semwal et al., 2019; Tudor Car et al., 2019). The studies showed that both DPBL and PBL were better at improving skills, long term knowledge retention, higher order thinking, better diagnostic reasoning and overall competence than traditional classroom and textbook methods of training (Dunleavy et al., 2019; Semwal et al., 2019; Tudor Car et al., 2019). Studies showed a higher degree of physician satisfaction with the DPBL training versus the face-to-face PBL (Taradi, Taradi, Radić, & Pokrajac, 2005). The DPBL methodology much like smartphone applications allows for both learning and practice via gamification simulations on virtual reality (Taradi et al., 2005). Learning within the smartphone app style much like the DPBL style in the study allows the students or physicians to train at their own pace, iteratively practice and investigate and self-direct their path through the learning experience (Taradi et al., 2005).

Therefore, with the growth of the use of smartphones, it appears that an appropriate format to educate young HCPs would come from the social media-based arena to increase usability, magnify exposure to other providers and provide easy to access on any smart phone.

This thesis is a grant proposal to create and beta test such a modality: an mHealth app geared to educating healthcare professionals on these issues and evaluating the feasibility, usability, and acceptability of this app among ER or urgent care physicians, gynecologists and pediatricians who predominantly provide services to this hard to identify population - CSE victims. It plans to address a gap in specialized and standardized training pertaining to the detection and management of CSE victims.
An application that can be downloaded and applied universally across various healthcare systems can be standardized for enhanced communication, ease of use and could be

easily employed for statistical and academic evaluation. Such an application can also serve as a data warehouse/ information portal to track patterns and eventually develop targeted prevention and safety techniques perhaps enabling providers to intervene on behalf of patients as a point-of-care modality to improve outcomes.

We plan to create an app that we feel covers these essentials and provides basic information to the provider, included required evaluations, tests, and care when providing medical care to the victim, and reliable and helpful resources to assist in their follow-up and future management. These materials will be evaluated by CSE survivors and CSE advocacy organizations and as well.

Components of the mHealth app for Human Trafficking

Based on my review of the literature to date, it would seem that the major components of the app will minimally include providing the clinicians with: information on the potential red flags or signs of human trafficking, suggestions on how to interview suspected victims of human trafficking, documentation of the medical exam and diagnostic evaluation, and resources for reporting it.

The National Human Trafficking Resource Center created a framework algorithm of how to identify and handle a potential CSE victim with red flags, resources and how to assess for potential danger ((NHTRC), 2010a). This human trafficking protocol for healthcare settings has been modified and used in other educational tools to train HCPs ((NHTRC), 2010a, 2010b, 2012). The National Human Trafficking Resource Center website has several educational tools in the form of fact sheets, PowerPoint, and algorithms. Many studies have used modifications of the materials offered by the NHTRC ((NHTRC), 2010a, 2010b, 2012) as the foundation for their screening and training tools as well as

other resources (Cole et al., 2018; Force, 2013; Hannah E. Fraley et al., 2019; V. J. Greenbaum, Dodd, & McCracken, 2018; Polaris, 2012, 2014, 2019; Powell et al., 2017; J. Shandro et al., 2016; Jamie Shandro et al., 2016; H. Stoklosa et al., 2015; Hanni Stoklosa, Lyman, Bohnert, & Mittel, 2017). Additional examples of resources to be used as a foundation for the educational and training component of the mhealth application for HCPs are listed in table 2.

Table 2: Resources for mHealth App SSTN

NHTRC http://traffickingresourcescenter.org
Polaris https://polarisproject.org
Protocol example from NHTRC https://trafficking resourcecenter.org/resources/human-trafficking-assessment-medical-professionals
Health, Education, Advocacy, Linkage (HEAL) compendium of resources for health care providers http://healtrafficking.org/education/educational-programs http://healtrafficking.org/medical-literature/
International Organization for Migration's handbook for health care providers (Trafficked Persons Guidance for Healthcare Providers) http://publications.ion.int/system/files/pdf/ct_handbook.pdf
Brief Webinar training for health professionals on Trafficking http://traffickingresourcscenter.org/resources/recognizing-and-responding-human-trafficking-healthcare-context
Department of Health and Human Services: Rescue and Restore Campaign materials for health professionals http://www.acf.hhs.gov/programs/endtrafficking/resource/rescue-restore-campaign-tool-kits
National Health Collaborative on Violence and Abuse 2014 Webinar
APSAC Practice Guidelines: The Commercial Sexual Exploitation of Children- The Medical Provider's Role in Identification, Assessment, and Treatment. https://www.apsac.org/guidelines
Human Trafficking the role of the health care provider http://nhcva.org/2014/04/15/webina-human-trafficking/

The initial steps involve suspicion of human trafficking by the clinical presentation, historical factors, and the physical exam. Common findings on clinical presentation can be evidence of acute sexual assault, suicide attempt, unexplained or poorly explained physical injury, a child accompanied by a domineering adult who appears to be intimidating or frightening to the child, and an adult who is not the guardian. Other findings can be changing or false demographic and historical information given by the child, a withdrawn, fearful, or submissive child, a child who is intoxicated and an adult with the child who pays in cash for the visit.

Historical factors can be frequent use or misuse of drugs, history of multiple sex partners or sexually transmitted infections, history of running away from home (>3 times over the past year), history of child protective services involvement (domestic violence in the home, caregiver with criminal history or drug use, history of maltreatment), history of pregnancy or multiple abortions, truancy or poor performance in school, and an older boyfriend.

The physical exam may exhibit signs of inflicted injury, tattoos with sexually provocative words, evidence of old injuries or broken limbs, inexplainable bruises or injuries.

Table 3. Potential Features of the SSTN APP (Temporary Name)

Feature/Content	SSTN APP
Definition of CSE and General Statistics	✓
Stages of Entrapment	✓
At Risk Populations	✓
Red Flags or Signs of CSE	✓
Screening tools	✓
Methods of Interviewing	✓
Clinical Presentations	✓
Documentation of the medical exam	✓
Diagnostic Evaluation	✓
Referral Resources and Exit Plans	✓
Real Life Case Studies	✓
Health Consequences and Implications	✓

Tips on interviewing potential human CSE victims will also be in the SSTN App.

Definition of Terms

SSTN: Stop Sex Trafficking Now

HCP: Healthcare professionals

CSE: Commercial sexual exploitation

mHealth: The use of mobile devices to deliver public health.

App: Application

HT: Human Trafficking

CINAHL: Cumulative Index to Nursing and Allied Health Literature

LGBTQ = lesbian, gay, bisexual, transgender or Queer

Chapter III: Methodology

NoVo Foundation Life Story Grants

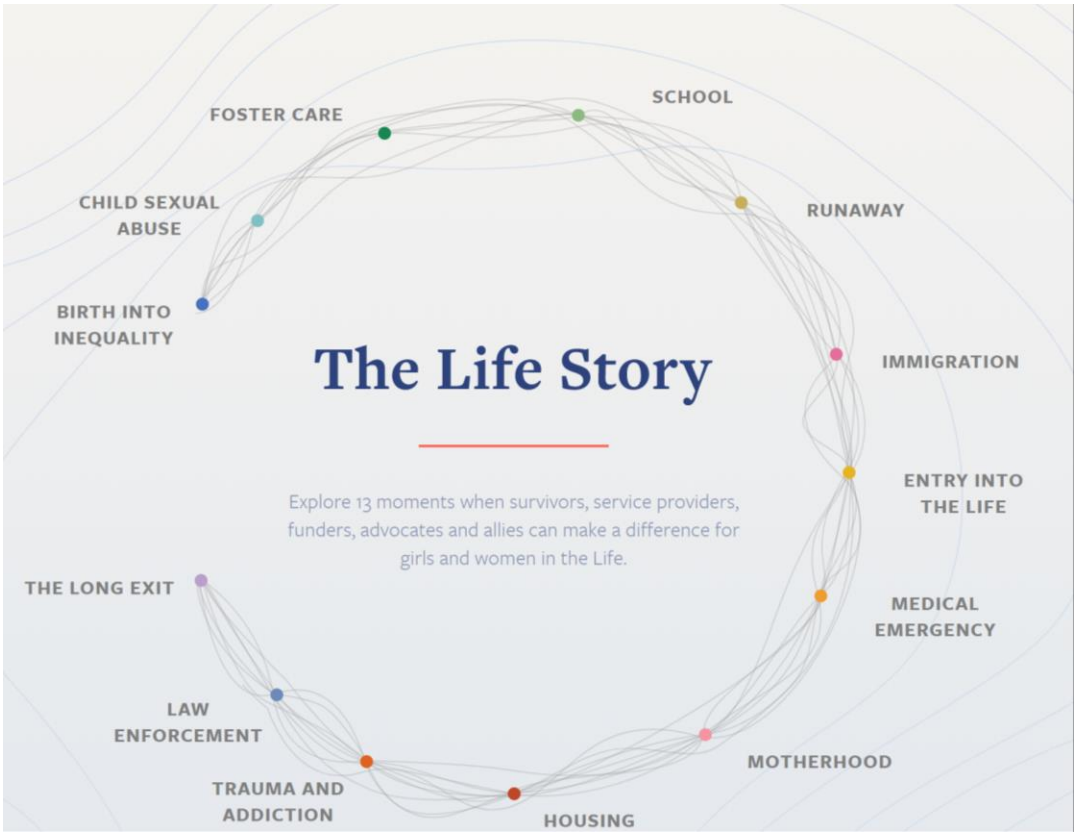


Figure 4 https://novofoundation.org/ending-violence-against-girls-and-women/strategic-approach/cse/the-life-story-grants/

The purpose of the NoVo Foundation Life Story Grant program is to fund initiatives that are system-focused strategies to block on-ramps into commercial sexual exploitation while building more opportunities to exit from CSE. The communities that are a priority for the grant are women of color, immigrant girls and women, indigenous girls and women, trans girls and women, and gender-nonconforming individuals who are disproportionately affected by this type of violence. They believe that system failures call for systems-based solutions and are interested in strategies that address opportunities to assist CSE victims from exiting the system such as the healthcare system where many

HCPs come into contact with CSE victims. The founders of the NoVo Foundation are Jennifer and Peter Buffett and it's a social justice foundation focused on catalyzing a change in global society to move from a culture of exploitation and domination to one of partnership and equality. This grant is up to 3 years with a minimum amount of $100,000 per year with a maximum grant size of $600,000 per year. It will provide funding to cover the concept development, planning and conducting of the key informant interviews, structured interviews, focus groups and surveys with the CSE victims, healthcare professionals and CSE advocacy organizations to develop the critical educational and resource materials, development and piloting of the mhealth app to the healthcare professionals.

Purpose of the Thesis Project

The purpose of this thesis project is to develop a smartphone application that functions as a screening tool to help healthcare providers identify commercial sexual exploitation (CSE) victims, perform and document appropriate information, facilitate prompt, direct referral to social and ancillary services to aid in care and provision of safety of the victim. This application, which can be downloaded and applied universally across various healthcare systems, can be standardized for enhanced communication, ease of use and could be easily employed for statistical and academic evaluation. Such an application can also serve as a data warehouse/ information portal to track patterns and eventually develop targeted prevention and safety techniques perhaps enabling providers to intervene on behalf of patients to improve outcomes.

Aim 1: Design-an mHealth app to provide critical lifesaving information on CSE victims for providers' use on a cross-platform framework compatible with multiple electronic devices (e.g., smartphones and tablet computers running both Apple iOS and Android operating systems).

Feedback from key informant interviews, in-depth interviews, focus group discussions and surveys with healthcare professionals, CSE victims and CSE advocacy groups will be aggregated and synthesized to inform the design of the app in response to salient themes critical for detection, documentation, care and referral of CSE victims. The primary outcome will be the development of a beta model of the app.

Aim 2: Pilot test and refine the mHealth app to measure healthcare professionals' knowledge about the detection and management of sex trafficking within a large academic and community healthcare network.

Once a beta product is designed, it will be first reviewed by the CSE victims and the CSE advocacy leadership using focus group discussions and surveys. Recommended revisions will be applied and the beta product piloted among frontline HCPs most in contact with CSE victims (medical staff in the ER or urgent care centers, OB/GYN and Pediatric clinics). The primary outcome measure will be increased knowledge on identification and management of CSE victims using pre and post-test based on educational materials taught within the app and performance during clinical scenarios to assess the application of learned concepts using DPBL.

Aim 3: Conduct a retrospective feasibility, usability, and acceptability assessment for the mHealth sex trafficking app among healthcare providers in a large academic and community health network.

3a: Determine factors associated with variance in feasibility, usability, and acceptability among specific provider specialty subgroups.

3b: Measure differential uptake and use patterns among specialty providers via application of established behavioral theory (i.e., Diffusion of Innovations).

Eligibility for the Grant

Eligible projects must support system-focused strategies that help with closing on-ramps into commercial sexual exploitation in addition to building more exit ramps. In the current funding opportunity, they are seeking approaches to address 6 specific systems in the US: Medical Needs, Housing, Law Enforcement, Trauma and Mental Health Systems Impacting Youth and Immigration.

This grant is addressing medical needs which is one of the critical systems. This grant is up to 3 years with a minimum amount of $100,000 per year with a maximum grant size of $600,000 per year.

Study Design

Key Informant Interviews (KIIs)

The purpose of key informant interviews will be to delve into the perspectives, beliefs, and knowledge of people who are close to the community we are intending to impact (e.g. organizations focused on bettering the lives and outcomes of persons living with CSE victims). These community experts, with their particular knowledge and understanding, will be able to provide valuable insight on the nature of issues in the community and give recommendations on the presentation of CSE victims. We will conduct 8 Key Informant Interviews with individuals involved in three integral organizations conducting work in Atlanta, Georgia on identifying CSE victims to develop a better understanding of the needs of the target population. Key Informant Interviews will last approximately 1.5 hours and will be audio recorded to ensure all data is collected. A trained qualitative interviewer will conduct all key informant interviews using a semi-structured interview guide to ensure appropriate methods are utilized and qualitative probing is implemented in effort to gather pertinent information and data that may provide answers for questions related to the research. Preliminary analysis of data collected in key informant interviews will be used to inform the development of in-

depth interviews and focus group discussion guides to ensure that pertinent questions and topics are covered during qualitative research with non-key informant participants of the project.

In-Depth Interviews IDIs

During the first year of the project we will conduct 15 in-depth interviews with HCPs, CSE victims and CSE advocacy leadership (total of 45 IDI) to uncover gaps in knowledge, individual views, attitudes, perspectives of a mHealth focused app aimed to increase detection and assist with management of CSE victims. We will also question HCPs on their concerns, gaps in knowledge, and quality of information desired related to sex trafficking. Interviews will include questions intended to gain an understanding of their personal desires and needs for this focused application. Year one in-depth interviews will focus on identifying the needs and desires of healthcare professionals to feel proficient in identify CSE victims after evaluating educational materials and gaming scenarios for the mhealth app and the methods to integrate and meet these needs in the mHealth app. During year two, we will conduct 15 more in-depth interviews after participants have been introduced to the developed app. Interviews will be with individuals not previously involved in year one qualitative research activities. The goal of year two in-depth interviews will be to gain perspectives of the users of the developed mHealth app. These interviews will focus on uncovering the participants' views of the app, their perceived usefulness of the app, their perceived benefit of the app, and any iterative changes that participants might encourage or desire.

The project will employ a team of qualitative interviewers that are thoroughly trained in procedures and protocols for the project to ensure accurate collection of data. Alongside the training that each interviewer will participate in, interviewers will use a semi-structured interview guide with pre-determined probes and questions to uncover

information pertinent to the research topic. In-depth interviews will last between 1- 1 ½ hours depending on the questioning and probing pattern of the interviewer and the participants' responses.

Participants for both years of qualitative activities will be recruited from partnering organizations in the metro-Atlanta area who are advocacy organizations for CSE victims.

Focus Group Discussions (FGDs)

Focus group discussions provide in depth information and understanding to social issues in a group context. Through the use of focus groups, we will be able to gather a more holistic and complete view and understanding of the needs and desires of HCPs in reference to a mHealth application focused on improving detection and management of CSE victims in Atlanta. We will conduct 9 focus groups per project year with no more than 10 participants in each focus group (assuming that there will be an average of 9 participants per focus group). The research team will develop semi-structured focus group discussion guides to be used during focus group discussions. The guides will be structured in a way to ensure that complex ideas, concepts, and topics are elaborated by participants to develop an understanding of the nuanced needs and desires of the population. As with in-depth interviews, the research team will use trained qualitative researchers with experience conducting focus group discussions for this aspect of the project. This team of interviewers will be informed and trained of all procedures and protocols related to the focus group discussions and any needed training or certification for interviewers will be attained (e.g. CITI, HIPPA, etc.). It is expected that focus group discussions will last 1 – 1 ½ hours depending on the questioning, probing, and activities included in the focus group. Participants for focus group discussions during both years of the project will be recruited with assistance from academic health institutions and CSE advocacy organizations.

Surveys

Participants (HCPs, CSE victims, CSE advocacy organizations) not previously involved in the KII, IDI or focus group discussions will complete a pre-survey to determine learning needs for the HCPs community. A pre-education or baseline knowledge survey and a post-education survey will be distributed to the HCPs to examine the effectiveness of the mhealth educational program. The information extracted from the pre- and post-education surveys will collected using Survey Monkey or a Qualtrics questionnaire. The surveys sent to HCPs will collect general demographic data (age, sex, race/ethnicity, socioeconomic status/SES etc.), profession, years of medical experience, type of practice (private, Health Maintenance Organization (HMO) or academic institution) and their practice hospital. It will also question the HCPs on a previous history of CSE training and if the participants perceived that they had a comprehensive and thorough understanding of CSE. The survey will also use Likert Scale questions to measure each participant's confidence in identifying and managing potential CSE victims. The questions in the pre-education survey and post-education survey will be identical to track improvement of the mhealth intervention.

Development of education materials

Drs. Lisa Flowers, Nancy Fajman, Kalinda Woods, Sandra Ford will oversee the development of evidence-based educational materials in response to initial KIIs, IDI and focus-group feedback, drawing on the health professional experience with CSE victims. We will also use materials provided by the literature, CSE advocacy and hotline websites and webinars as a starting point to receive input from the CSE survivors and HCPs. Dr. Flowers, will adapt these materials to follow a scaffolded, approachable pedagogical design (Simpson, 2016). The scaffolded content design builds upon previous participant

knowledge and draws connections with read-world and relatable examples, fostering understanding and empowerment through education.

App Development

For app development, we are partnering with Cygnis Media. They will assist in the development of native apps capable of accepting updatable content compatible for download on devices using a variety of operating systems (e.g. Apple iOS, Android and HTML-5). Enabling download on these most widely-used operating systems will maximize compatibility with many types of mobile devices including smartphones, tablets and embedded browsers with HTML-5 compatibility. The apps will be "published" on Apple store, google play store, health department websites, physicians' websites, etc. to be available for download. We have selected this multi-platform modality in order to optimize the flexibility and longevity of the applications while allowing us to easily make changes as new issues arise.

The intervention to be developed through this project will be a native app designed for use on the Apple iPhone and Android-based operating systems, as these two systems are market share leaders. The app and all essential content will reside on the device, and routine updates (e.g., dynamic content updates, pushed messages) will be applied to the app when there is network connectivity. Having the core elements of the app reside on the device will provide continuity of service in the event of limited network connectivity in the event of a public health emergency or any other type of network shutdown.

The information contained within the app will be searchable (using keyword searches) and browsable, both through a general menu of topics as well as a more granular list of topics.

The study team will have access to an app "dashboard" that can be used for near real-time updates of the app, including updates of dynamic content. To maintain engagement

with the app, a “Message of the Week” will be sent through the dashboard; this message can be used to provide updates regarding sex trafficking information which will appear as a notification within the app. In the absence of a specific issue, messages will be chosen by the study team for promulgation through the “Message of the Week” function. Additionally, this type of engagement will serve to ensure that users have the most up-to-date content in their personal copy of the app. Typically, when apps are updated, updates are applied once the app is opened. As the app will need to be accessed to read these Messages of the Week, dynamic content updates will occur.

The dashboard will also provide counts of how frequently the app is accessed and frequencies of specific queries to the study team. This dashboard informatics can be used to evaluate patterns of sex trafficking concerns among HCPs as well as provide data on app usage to incorporate into the data analysis.

The app will be able to push out short (two to three question) feedback requests (e.g., to assess SSTN app usability, to assess willingness to use the app) where information can be transmitted back to the study team through the app.

Since smartphones do not have a large screen size in comparison to a tablet, notebook or computer, text and images presented on the app should be scaled for readability. Menu items and search lists will appear as pop-up selection tools, to increase visible presence on the screen, to aid in both viewing materials and selecting the desired choice.

The app will be able to be updated, with updates made available for download when available, as necessary. Users will have the option to allow the app to automatically update when a new version is available, to eliminate the need to actively update the app. App version updates will be created to address issues within the app (e.g., software functionality problems; response to “bug reports” from users) as well as to deliver the most up-to-date information on sex trafficking (e.g. statistics in the area, resources,

required medical documentation) and the best ways to report and refer cases to the appropriate authorities.

Initial system specifications will be provided to the app development team early in the study period while formative research is occurring, to allow sufficient time for initial development processes that can be refined following pilot testing. These specifications will address preliminary design issues, system compatibility, and user interface, and will allow Cygnis Media staff to begin designing the core features and layout of the application system. Through the initial development process, internal usability testing by Cygnis Media staff will be supplemented with testing by members of the study team. Results of usability testing and documentation of modifications to the app based on this testing will be tracked by the developer and provided to the study team for reference. Continuous internal quality control checks by Cygnis Media staff with secondary quality control checks by members of the research team will be incorporated to verify application system accuracy and functionality.

Resource Linkage

Community resources: Local experts will develop a list of local community resources, including help sources for CSE victims and screening health professionals. For the beta-version of the app, only local Atlanta resources will be included. Future versions of the app will collect information from local health departments, safe houses, and CSE victim assistance services to create a map of resources.

Provider connection: A key function of the app will be the ability to communicate directly with providers and local health experts. The app will employ a dedicated team of clinicians and CSE experts to monitor an open forum for questions and discussion of sex trafficking concerns by healthcare professionals.

App evaluation, Modification, and Preliminary Testing

We expect the initial development process to take 4-6 months, resulting in a test product. This test product will then undergo a second iteration through the community evaluation process. Stakeholders (HCPs, CSE victims and members of CSE advocacy organizations) who participated in the initial focus groups will be given the opportunity to explore the app, and will rate the function, appeal and relevance of the app on surveys utilizing a Likert scale. The HCPs, CSE victims and members of the CSE advocacy organizations will rate their satisfaction with the design process and the extent to which they felt their voices were represented in the design and the design met their identified needs and preferences, also utilizing a Likert scale for satisfaction. In addition, the initial design will be given to a representative group of primary care providers, social workers, and public health experts from the community, who will rate the app content for educational value, comprehensiveness, and perceived relevance to their population. Focus groups will be conducted through years 1 and 2 of the study as described in the community needs analysis section above. Feedback from surveys and focus groups will be aggregated and sent to the developer for improvement. The developer then estimates that a period of 14 weeks will be required to integrate modifications based on community feedback. After integrating these modifications, a beta version of the app will be delivered to the research team.

Final design testing and dissemination

Our strategy for dissemination of the intervention builds upon opinion leadership and early adopters. Healthcare professional opinion leaders that can be identified from our current relationships with Emory University Healthcare Systems, Grady Memorial Hospital Healthcare Systems and Children's Healthcare of Atlanta to hold social influence within their networks; a downstream diffusion of thought and behavior in the healthcare professional community extending from these leaders can thus be leveraged

to promote new innovations. To identify opinion leaders in our healthcare community, brief surveys will be administered to healthcare professionals.

Once the beta version of the app is completed, identified healthcare professionals and community opinion leaders will be provided with an opportunity to download and experiment with the app. They will be allotted a period of 6 weeks for testing of the app. Opinion leaders will be provided with an incentive for piloting and providing feedback on the app, but not for recruitment of peers to engage with the app. They will be told they can "spread the word" via word of mouth, social networks and social media, and that the app is publicly available for download; in addition, the beta version of the app will include a "refer a friend" function, to permit ease of download. It is important, however, not to incentivize the spread of the app as we wish to model its real-world diffusion among the community.

App developers will be able to monitor downloads and interface time with the app as described above. In addition, push notifications will enable users to rate their satisfaction with the app in real-time. At the end of the trial period, quantitative measures will include number of new downloads, number of referrals sent and downloaded, overall app satisfaction rating, and time spent engaging with app content. Additionally, users will be given the opportunity to complete a brief survey on their experience with the app in exchange for a small monetary incentive. Surveys will assess appeal, usability, and relevance of the app, as measured on a 5-point Likert scale.

Data management

We will transcribe observation notes and audio recordings from all KIIs, IDIs and FGDs and all transcriptions and audio recordings will be stored on a secure, password-protected, limited access server. Research staff will play each audio recording after transfer to the server to ensure audio file fidelity; after confirming that the server-stored

audio recording is complete we will delete the file from the recorder. Once transcription of all audio recordings is complete and verified, we will delete the audio file from the server. Transcriptions and observation notes will be de-identified and tracked by anonymous ID codes.

Survey data will be collected via the app. The study team will have access to survey data via the app dashboard. De-identified survey data will be linked to participants to provide a measurement of the amount of time spent interfacing with the app in order to determine the extent to which time spent engaging with the app resulted in overall score improvement. Study data will be downloadable to a HIPAA-compliant, password protected Redcap form for analysis.

Qualitative Data Analysis

We will utilize a standard qualitative data analysis software (e.g. NVivo or MaxQDA) for all qualitative data analysis. We will utilize the constant comparative approach within the grounded theory process model (Cooney, 2011; Gelling, 2011; Harris, 2015; Hunter, Murphy, Grealish, Casey, & Keady, 2011; Licqurish & Seibold, 2011). This approach uses both deductive and inductive methods for thematic and pattern identification. All IDI transcripts will be coded according to emerging patterns and these codes will be further refined through a series of iterative cycles used in team-based qualitative data analysis (Macqueen, McLellan, Kay, & Milstein, 1998). Two members of the project team will conduct observational data coding, and coding will be compared for consistency with the achievement of inter-coder reliability at Kappa ≥ .70, which is considered a minimally acceptable inter-coder agreement level (Elliot, 2007).

Themes, as identified, will be summarized for application in the development of the app. Within the existing framework of materials, we will identify clear areas of need from the qualitative-based observational data and update the app content accordingly. Following

refinement of materials, focus group discussions with CSE victims, healthcare professionals and CSE advocacy organizations and community stakeholders will be conducted to obtain content feedback, acceptability, and usability of the materials. Using an iterative approach, the study team will revise and refine intervention materials accordingly.

Quantitative data analysis

Survey data will be analyzed using SAS v9.4. We will assess frequency counts of the responses to the Likert scales, collapsing relevant categories (e.g. “Strongly agree” and “Agree” into one category) to allow more parsimonious outcome assessment. Response proportions and associated 95% confidence intervals will be computed and compared between the original opinion leaders and the network contacts for whom they provided access to the app to determine the extent of acceptability among potential early adopters and other potential later adopters.

For the impact assessment, mean scores will be treated as a continuous variable, and pre and post intervention means will be compared. The primary outcome measures will be change in 1.) mean CSE identification awareness, 2.) mean CSE knowledge scores, and 3.) mean CSE victim referral knowledge. We expect baseline CSE awareness and knowledge to be less than 30% in healthcare professionals based on the paucity of data. Given the possibility of a total score range of 0 to 29 across all measures, we hypothesize a mean knowledge score of 14.5 and standard deviation of 10. Using a one-way ANOVA comparison of two means for pre-post comparison, we would need to enroll and retain 79 individuals to detect an increase in mean knowledge score of approximately 30% (a mean score increase from 14.5 to 19) following exposure to the app. To account for up to

30% attrition, we would need to enroll 113 individuals to use the app for the initial impact assessment.

Summary of the Grant Funding Announcement

Types of Grant Funding Agencies

Review of the Types of agencies that fund health education mhealth projects are

1. **The NoVo Foundation/The Life Story Grants:** The mission of this organization is ending the vulnerability of girls and women to all forms of exploitation and violence. They believe that "system failures call for systems-based solutions to create lasting change—and that's where we see an untapped opportunity for anyone who wishes to improve the lives of marginalized girls and women" (Novofoundation.org, 2019). In the current funding opportunity, they are seeking approaches to address 6 specific systems in the US: **Medical Needs**, Housing, Law Enforcement, Trauma and Mental Health, Systems Impacting Youth and Immigration. They are requesting letters of inquiry for grant submissions to address one of these six key points of entry or exit that CSE victims may come in contact (https://novofoundation.org/wp-content/uploads/2019/02/The-Life-Story-Grants_Request-for-Letters-of-Inquiry_NoVo-2019.pdf). Many healthcare professionals in critical systems come into contact with people in sexual exploitation. Their focus is to use promote initiatives that help healthcare professionals to understand the CSE victim and be aware of resources and use the opportunity to close an on-ramp to sexual exploitation—or open an exit ramp**.** Letters of Inquiry will be accepted until Friday, April 19, 2019, 3pm Eastern time, via this online submission form: novofoundation.force.com.

2. **Change a Path Organization:** This organization supports organizations that fight sex trafficking through grants to non-profit organizations working to address the crisis of global sex trafficking crisis by protecting and supporting

children and women at risk for sex trafficking and prosecuting traffickers. https://changeapath.org/. No grant deadline

3. **US Department of Health and Human Services, Office on Trafficking in Persons, An Office of the Administration for Children & Families**. The ACF is committed to preventing human trafficking and working towards ensuring that victims of every form of human trafficking has access to the services they require. Much of the work that they do to forge pathways to freedom for victims and those at risk of human trafficking is with the help of our grantees. They oversee and coordinate the governing of anti-trafficking grant programming on behalf of the Department of Health and Human Services (HHS). https://www.acf.hhs.gov/otip
4. **Department of Justice.** The Department of Justice solicit grants at various times during the year to address this topic. At present they are not soliciting grants. www.justice.gov.
5. **National Institute of Health (NIH):** NIH has several mhealth grant opportunities through Fogarty International Center (FIC), National Cancer Institute (NCI), National Institute of Biomedical Imaging and Bioengineering (NIBIB), National Institute on Deafness and Other Communication Disorders (NIDCD), National Institute of Mental Health (NIMH), Office of Behavioral and Social Sciences Research (OBSSR), and

   Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD). These opportunities at present are focusing on low to middle income countries and chronic diseases. However previous requests were appropriate for this topic.

6. **Grants.gov:** Grants.gov is a portal for grants offered by government, private sector and foundation sources.
   https://www.grants.gov/web/grants/search-grants.html?keywords=sex%20trafficking%27
7. **Mobile App Fund:** Mobile App Fund is an organization which solicits mobile application ideas and give a wide range of support from imitation to full scale development, marketing and deployment.
   https://www.mobileappfund.com/how-the-fund-works/.

Protection of Human Subjects

Risks to Human Subjects

Human Subjects Involvement, Characteristics, and Design

The project, Empowering Georgia Healthcare Professionals with Knowledge in Identification and Management of Sex Trafficking Victims using an mHealth app Stop SEX Trafficking Now (SSTN): will focus on development of an mhealth app to educate health professionals to identify CSE victims who present for medical care. We plan to engage previous CSE victims via in-depth interviews and focus groups. Also, HCP representatives from pediatrics, emergency medicine, urgent care centers, and obstetrics and gynecology will also undergo in-depth interviews and focus groups to provide input in the mhealth app SSTN. We anticipate that many of the CSE victims will be female and suffer from post-traumatic stress disorder therefore social workers and psychologists will be present for support as needed by the participants. The study team is diverse and bilingual to address the diversity of potential study participants (CSE victims) and consents will also be bilingual (English and Spanish versions). In addition, the app will be bilingual, and all content will be presented in both English and Spanish.

Human Subjects Sources of Materials

All data will be securely managed and stored on HIPAA-compliant network drives at the Emory University School of Medicine, Emory Rollins School of Public Health, Grady Memorial Hospital and Children's Healthcare of Atlanta. Data collection through web and smartphone surveys will be securely encrypted during data entry, storage, and transmission. All collected data will be used only by designated study staff and will be accessible via on-site secured computers. Personal identifying data will be stored in a separate, encrypted, and password-locked file, as will collected health information and vaccination information obtained from the state immunization registries. Based on existing study protocols, we believe this will be a "minimal risk" study even though the demographic and behavioral data will be linked to the outcomes of this project. Any breach in security or risk of disclosure from materials (personal identifying information or other sensitive data) will be reported immediately to the Emory University School of Medicine Institutional Review Boards (IRB), which will serve as the multisite IRB of record for this study. All security incidents will be thoroughly documented and follow-up reports sent to the IRB.

Potential Risks

The foreseeable risks to participants are minimal. The primary risk will be breach of confidentiality or breach of security related to data transfer. Because participants have provided personally identifying information through the mobile app, including name, address or geolocation, date of birth, and phone and email contacts, there is a risk that these data could be unintentionally disclosed to someone not authorized to access the data, compromising the privacy of the participant despite our best efforts. We will also collect sensitive health information from the CSE victims who participate in the focus groups, semi-structured interviews and surveys. This may cause anxiety for the CSE victims which will be addressed with the victims prior to their participation in activities

to assist in app development. Although data are heavily secured, it is possible that persons who provided information used in this study may experience a sense of shame or ostracization if what they disclosed in confidence is inadvertently made public. To minimize this risk, the CSE victims will be well counseled about the intent of the focus groups, interviews, and surveys; and CSE advocacy support groups and advocates will be available during the activities.

Recruitment and Informed Consent – English and Spanish

For the aims of this study we will recruit CSE victims from our CSE advocacy organizations (Street Grace) and health professionals from the Departments of Obstetrics and Gynecology, Emergency Medicine, and Pediatrics from Emory University, Grady Memorial Hospital, and Children's Healthcare of Atlanta. Participants will receive information about the study and will be asked questions to verify that they understand the risks and benefits involved with being in this study. Screening, consent, and focus groups/in-depth interviews will be conducted at the study site with staff fluent in the participant's preferred language (English or Spanish). Screening may also be conducted via phone interviews with study staff. The informed consent form will be given to the participant in their preferred language (English or Spanish) and will be emailed to potential participants after screening or in person based on the participant's preference. Enrollment will occur after return of the signed consent form through email, fax, mail or in person. All staff involved in the screening, consent, and focus group/interview process for Spanish speaking participants must be fluent in Spanish and English as demonstrated by certification and/or written and oral proficiency assessments.

Protection Against Risks

Study data will be provided with all appropriate physical and operational security protection measures. Critical security measures required by Emory University School of Medicine will be strictly observed to protect study data and minimize risks to

confidentiality. Data entry through web and smartphone surveys will be securely encrypted during data entry, storage, and transmission in compliance with HIPAA standards. All data will be stored in electronically and physically secure locations at Emory University and Children's Healthcare of Atlanta, and all study personnel will be assigned unique identifying login IDs and passwords to perform their tasks. Electronic data will be encrypted and password-protected on these secure servers. Access to identifying data will be restricted to only the essential study staff and investigators working with the data to complete their study-related analyses. Participants will be assigned a study ID to be used in all datasets, and the key file linking participant ID to personally identifying information (name, address, contact information, date of birth) will be stored in a separate encrypted and password-locked file. Sensitive health information on HIV and vaccination status will be stored in another separately encrypted and password-locked file, linked only to participant ID. All published analyses (including geospatial analyses) will aggregate participant data to ensure participants are not identifiable. All staff will be trained in confidentiality procedures and sign a statement regarding nondisclosure of participant information.

Potential Benefits of the Proposed Research to Subjects and Others

The potential benefit of the mHealth app is development of an educational mobile application which can assist healthcare professionals in detection and management of CSE victims. The findings from this study will provide valuable information for healthcare professionals and hopefully assist CSE victims from escaping their traffickers and receiving critically needed assistance. Additionally, we will be addressing a national public health crisis in a direct and tangible way.

Importance of the Knowledge to be Gained

Healthcare professionals lack the information required to appropriately identify CSE victims. Findings from this study will improve the knowledge gap among healthcare

professionals in the frontline of care for CSE victims. This new information will aid the development of an mhealth app to improve CSE identification, management and referral to support services when in contact with healthcare professionals. Therefore, the knowledge gained will help ensure that strategies developed from this project are salient to the reduction of missed opportunities of identification of CSE victims within the healthcare system.

Vertebrate Animals

N/A

Select Agent Research

N/A

Data Safety Monitoring Plan

The Data Safety Monitoring Plan (DSMP) outlined below will ensure the safety of the participants and will verify the validity and integrity of the data of study protocols conducted under the program. An IRB-approved written informed consent (available in both English and Spanish) will be obtained from each potential subject prior to enrollment and initiation of study procedures. The elements of the informed consent will include an information and consent form provided through the web survey platform and (focus groups, usability testing, surveys, and interviews) screening and consent will proceed through phone or in- person interviews at the study site. The components of consent will include: (a) having the potential subject review the study consent form; (b) having the investigators or study staff meet with the potential subject to review the consent, confirm understanding, and answer any questions; and (c) obtaining signed consent, in the presence of a witness, from individuals who wish to participate. The data management coordinator will review data collection forms on a weekly basis and track data accuracy from collection sites. The Principal Investigators (PIs) will review all

collected data at least annually for completeness and accuracy of the data as well as protocol compliance.

Participant Safety Data Examination, Monitoring Procedures/Oversight

The safety of study participants will be monitored by the Principal Investigators, co-investigators and study coordinators on a regular basis. The research coordinators will be responsible for recording all clinical data and information taped during the semi-structured interviews and focus groups. As these are collected, all adverse events (AEs) will be identified and reported to the Principal Investigators and Emory University IRB. Because post-traumatic stress disorder (PTSD), shame, grief, and/or stigma could be a major risk to participants, possible AEs will be monitored actively by encouraging participants to self-report if they perceive that they have been affected. All AEs will be graded as to their attribution (unrelated to protocol, possibly, probably, or definitely related to protocol). The CIN computerized database system will then be used by all investigators to report all adverse events (AE) and serious adverse events (SAE) that may occur during the conduction of any semi-structured interview or focus group. For the purpose of this application, an SAE will be defined as any experience of a participant that suggests a significant hazard, such as events which: a) are fatal, b) are life threatening, c) results in permanent disability.

Potential ("Expected") Adverse Events and Plan for Detecting Problems and Minimizing Subject Risk During this Program

PTSD, shame, grief, and stigma are the main AE that participants may directly experience during the study. These potential side effects will be monitored and support CSE advocates will be available during the focus groups and interview.

Procedures for Minimizing Risks

We will work closely with CSE community organizations, as all of our proposed studies require community input in order to be sensitive and culturally appropriate. Staff will be trained to handle sensitive topics regarding private health information and potentially upsetting CSE adverse events. All persons will be over the age of 18, and therefore must be able to read, understand, and sign the consent forms in English or Spanish. Bilingual study personnel will be available for the duration of the study to answer and translate study procedures and confidentiality requirements as required. Participants will be assured that refusal to participate in the study will not affect their future treatment at that health facility or relationship with the university. All data will be securely encrypted during collection through web or app surveys, while stored locally, and when transmitted to study personnel. All collected data will be stored on secure encrypted network servers operated by Emory University, and access will be restricted to approved study staff. Results of data analyses will report aggregated participant data, and no personally identifiable data will be published.

Plans for Transmission of Temporary or Permanent Suspension Actions

N/A

Plans for Protecting Subject Confidentiality

All information and materials obtained as a result of the research will be kept in strict confidence. Confidentiality will be assured by the use of subject codes rather than personal identifiers. The specific study database will be password protected on secure servers, and information will only be entered using subject identifier codes rather than personal identifiers. One document connecting identifier codes to personal identifiers will be password protected and saved on a secure, password-protected server. Only staff

on the data team will have access to the identifying document. Electronic communication will involve only coded, unidentifiable information.

NIH Certificate of Confidentiality

The research team will comply with all new NIH COC rules for maintaining confidentiality of all identifiable information collected by research team members and research partners. Identifying information will be collected over the course of the study period, including disease status (e.g., depression) and contact information, in order to ensure that the study is run properly. By obtaining a certificate of confidentiality, we will further ensure the privacy of study participants so that private identifying information is not disclosed to individuals outside of the research team. We expect individuals to be more open and willing to disclose both their own behavior and that of others if the fear of a privacy violation is minimal. With the certificate of confidentiality, individuals will be more willing to participate or provide quality information.

Plans for Assuring Data Accuracy and Protocol Human Safety Compliance

The above detailed DSMP should assure data accuracy and human safety protocol compliance. All study activities will be required to include computerized secured database management and IRB oversight.

Proposed Budget

Table 4 Proposed Budget

	Aim 1/Year 1	Aim 2/Year 2	Aim 3/ Year 3
Faculty	**Stipends**		
Dr. Lisa Flowers Gynecologist	35,000	35,000	35,000
Dr. Kalinda Wood Adolescent Gynecology Specialist	30,000	30,000	30,000
Dr. Nancy Fajman Pediatrician	30,000	30,000	30,000
Emergency Room Physicians	30,000	30,000	30,000
Emergency Room Nurses	10,000	10,000	10,000
Jordan Greenbaum CHOA	30,000	30,000	30,000
Dabney Evans MPH, PhD, Director Center for Humanitarian Emergencies at Emory	30,000	30,000	30,000
Linelle Blais Associate Director, Executive MPH Program	15,000	15,000	15,000
JoAnna Hillman Director of Research and Evaluation	15,000	15,000	15,000
Sandra Ford Consultant	30,000	30,000	30,000
Social Worker	7,000	7,000	7,000
Psychologist	10,000	5,000	5,000
Research Coordinator	57,000	58,000	59,000
Program Director	40,000	40,000	40,000
Key Informant Interviews, indepth interviews Costs	8,000	12,000	12,000
Software Development/App Development	50,000	20,000	20,000
Focus Group Coordination and Management Contract	30000	30000	30000
Focus Group Participant and Survey Distribution Costs	8,000	12,000	12,000
Street Grace	30,000	30,000	30,000
International Institute of Human Trafficking	25,000	25,000	25,000
Statistician and Analysis	50,000	50,000	50,000
Promotion Activities and Distribution of mobile App	10,000	10,000	10,000
Total	580,000	554,000	555,000
			1,689,000

Proposed Timeline

Figure 5a Proposed Timeline

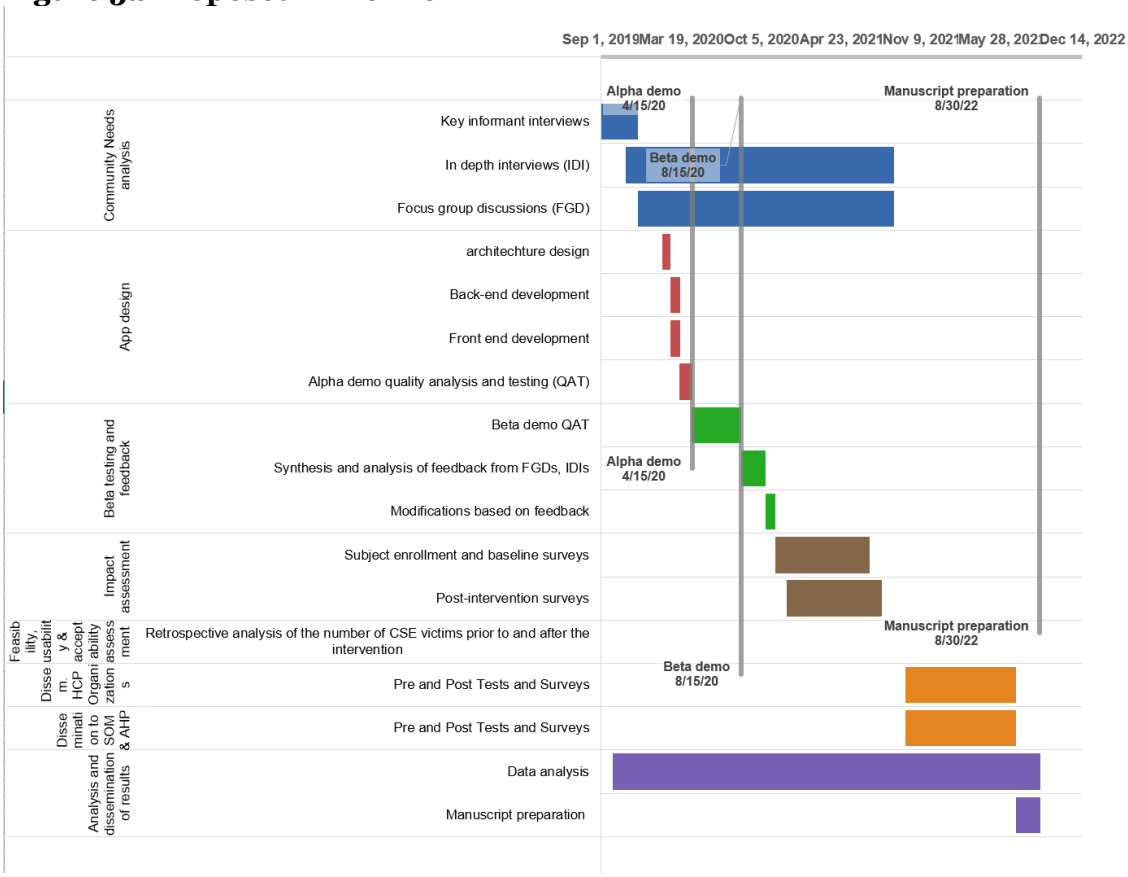


Figure 5b Proposed Timeline

		Project Start	9/1/19		columns used to create the chart						
CATEGORY	TASK	START	END	COLOR	Start	Blue	Red	Green	Brown	Orange	Purple
Community Needs analysis	Key informant interviews	9/1/19	12/1/19	Blue	9/1/19	92	0	0	0	0	0
	In depth interviews (IDI)	11/1/19	8/30/21	Blue	11/1/19	669	0	0	0	0	0
	Focus group discussions (FGD	12/1/19	8/30/21	Blue	12/1/19	639	0	0	0	0	0
App design	architechture design	2/1/20	2/21/20	Red	2/1/20	0	21	0	0	0	0
	Back-end development	2/21/20	3/15/20	Red	2/21/20	0	24	0	0	0	0
	Front end development	2/21/20	3/15/20	Red	2/21/20	0	24	0	0	0	0
	Alpha demo quality analysis ar	3/15/20	4/15/20	Red	3/15/20	0	32	0	0	0	0
Beta testing and feedback	Beta demo QAT	4/14/20	8/15/20	Green	4/14/20	0	0	124	0	0	0
	Synthesis and analysis of feed	8/15/20	10/15/20	Green	8/15/20	0	0	62	0	0	0
	Modifications based on feedba	10/15/20	11/8/20	Green	10/15/20	0	0	25	0	0	0
Impact assessment	Subject enrollment and baselin	11/8/20	7/1/21	Brown	11/8/20	0	0	0	236	0	0
	Post-intervention surveys	12/8/20	8/1/21	Brown	12/8/20	0	0	0	237	0	0
Feasibility, usability & acceptability assessment	Retrospective analysis of the n	7/30/21	2/8/20	Orange	7/30/21	0	0	0	0	-537	0
Dissem. HCP Organizations	Pre and Post Tests and Surve	9/30/21	6/30/22	Orange	9/30/21	0	0	0	0	274	0
Dissemination to SOM & AHP	Pre and Post Tests and Surve	9/30/21	6/30/22	Orange	9/30/21	0	0	0	0	274	0
Analysis and dissemination of results	Data analysis	10/1/19	8/30/22	Purple	10/1/19	0	0	0	0	0	1065
	Manuscript preparation	7/1/22	8/30/22	Purple	7/1/22	0	0	0	0	0	61
	Insert new rows above this one										

MILESTONE LABEL	DATE	Margin Bottom	Margin Top
Alpha demo	4/15/20	50%	95%
Beta demo	8/15/20	25%	95%
Manuscript preparation	8/30/22	30%	95%

External Reviewers for the Grant Proposal

Sandra Elizabeth Ford, MD, MBA, FAAP

President and Chief Executive Officer, Sandra Elizabeth Ford, MD, MBA, FAAP, is a Board-Certified Pediatrician with more than 15 years of public health experience at both the state and local levels. Dr. Ford is currently the District Health Director for DeKalb County, Georgia, a diverse community of over 750,000 citizens where more than 120 languages and dialects are spoken. She has also served as Georgia's State Health Officer and Acting Director of the Division of Public Health in Georgia's Department of Human Resources. Dr. Ford sits on a number of boards, most notably United Way of

Greater Atlanta, NACCHO (National Association of County and City Health Officials), and ARCHI--the Atlanta Regional Collaborative Health Initiative.

Dr. Ford received her BA in Psychology from Stanford University, and her Medical Degree from Howard University's College of Medicine. She also holds a Masters of Business Administration in Healthcare Services from Howard University's Graduate School of Business. She is in charge of a Task Force addressing Sex Trafficking in Atlanta, Georgia. This July, Dr. Ford took office as the Vice-President of NACCHO.

Nancy Nost Fajman, MD. MPH

Dr. Fajman is an Associate Professor in the Department of Pediatrics at Emory School of Medicine and lead physician for Stephanie V. Blank Center for Safe and Healthy Children at Hughes Spalding Children's Hospital. She is involved with the Sex Trafficking education at Children's and was the Medical Director of the Child Protection program at Egleston Children's Hospital.

Kecia Harris, A.M., Ph.D.

Dr. Harris is a Biomedical Scientist, Medical and Wellness Consultant, and Speaker with more than fifteen years of research and health consultant experience with the Centers of Disease Control and Prevention and the pharmaceutical industry. Her background includes expertise in infectious and chronic disease research and oncology education. Additionally, her training and work as a former middle and high school teacher significantly contributes to her ability to make the most complicated, technical information understandable. Dr. Harris is the Founder and Principal Manager of KD2 Consultants, LLC, a company focused on training on emerging, critical health issues and policies for government, health and medical organizations.

Dr. Harris earned her B.S. in Chemistry from Spelman College in Atlanta, GA, and a Master's degree in Science Education from the University of Michigan, Ann Arbor. She

also earned her Doctor of Philosophy degree in Biomedical Sciences from Morehouse School of Medicine, Atlanta, Georgia. She is currently completing her Executive Education Certification from Emory University in Leadership and Strategy.

Kalinda Dennis Woods, MD

Dr. Woods is a board-certified obstetrician gynecologist with subspecialty certification and interest in pediatric and adolescent patients. She is involved in research assessing knowledge gaps in appropriate identification and treatment of young women involved in human trafficking in the city of Atlanta. She received her Bachelors of Science from Howard University and her medical degree from Meharry Medical College. Her residency was at Brigham & Women's/Mass General Hospital under Harvard Medical School. She works with the pediatric population at CHOA and received the Dean's Faculty Excellence Award. boundless given the electronic nature and universality of our screening tool.

Chapter IV: Incorporation of Reviewer Comments

I would like to thank all of my reviewers for taking the time to read my thesis and provide constructive criticism and verbal support. I am eternally grateful to all of your suggestions and help through this process.

Reviewer 1 comments: Kecia Harris, A.M., Ph.D.

Comment 1: I suggest that you create a table with ALL providers in the beginning of the thesis. This table should include the type of provider and percentages if patients seen. You can focus on the top three, but also capture and create awareness of all providers types who are most likely seeing patients unknowingly. Charting this in the thesis beginning creates ongoing awareness and engagement of the reader regarding the number of providers types whom these children encounter.

Response to comment 1: I have noted the providers that we are targeting in the text. The focus will be on ER and physicians in urgent care clinics, OB/Gyn and Pediatricians. I agree that if there was a long list of providers a table should be used. Thanks so much and I will consider that if we decide to expand the list.

Comment 2: Please further highlight the importance of distinguishing familial child abuse that doesn't involve the selling of services, from sex trafficking. It would be important to include a separate section within the app (a checklist, of sorts) to ensure that this distinction is made, both for the child's emotional health and any ongoing therapy.

Response to comment 2: This is very critical and I agree that the two need to be separate. I will make sure that this distinction is noted in the educational component of the app and discussed during the KIIs, IDIs and focus group discussions.

Reviewer 2 comments: Sandra Ford MD, MBA

Comment 1:

Did you decide not to add the GPS tracking? Even if you can't get it done with this iteration of the app, it's definitely worth mentioning as a future project

Response to comment 1: I agree that GPS tracking is an important tool to have in this area. I will ask questions about the utility of the GPS during the KIIs, IDIs and focus group discussion and take the suggestions given to the app builders so they can discuss feasibility and cost.

Comment 2: I know NOVO funding is for women, but trafficking is an issue among young boys as well, and you don't mention them much in your thesis.

Response to comment 2: It is true that men and boys are CSE victims as well, and under-represented in the statistics. However, since the majority of CSE victims are women and girls I felt it was best to focus on this population for my thesis which was written for the NoVo grant. I will however include information about clinical presentations of CSE in men and boys and resources for this population in the mhealth app.

Comment 3: I would make sure you state definitively that you plan to include victims of trafficking as SMEs in the development of the app. They will provide invaluable insight.

Response to comment 3: Thank you for this comment. I have prioritized the importance of having CSE victims as stakeholders and important contributors to the development of the app.

Comment 4: Think about including acute care centers (doesn't Emory have some of those?) as part of the study. Those docs probably see quite a few victims as well and miss them.

Response to comment 4: Thank you for this comment. Emory has started to set up urgent care clinics throughout Metro Atlanta and I feel that we will be able to capitalize

on this growth. Therefore, I have added urgent care clinicians as one of the HCPs that will be asked to participate in the piloting of the app.

Reviewer 3 comments: Nancy Fajman MD, MPH

Comment 1: There seems to be an assumption here that the information on determining victims of CSE is known – it just needs to be disseminated, taught. I'm not convinced we do know those things very well – unless it's an obvious situation. It appears to me that part of your project, e.g., with interviewing victims, is to also better understand how we can identify risk factors and manners of presentation and add that information to the already known observations.

Response to comment 1: I stressed the importance of having CSE victim input into the development of the app and increased the KII, IDI and focus groups to have more of their involvement in the process

Comment 2: A list of grammatical corrections.

Response to comment 2: All suggested grammatical corrections fixed.

Reviewer 4 comments: Kalinda Woods, MD

Comment 1: The magnitude of the problem of sex trafficking in the Atlanta metro area cannot be overstated and the ability for health providers to identify and appropriately triage services to victims is woefully lacking as demonstrated by the evidence presented in this thesis. A major strength of this proposal lies in the evidence supporting the statement of need. In essence, this project will employ the use of smartphone technology, a novel concept which has not been applied to study this vulnerable group. This technology offers an intangible benefit of privacy and discretion which is essential when handling individual's personal health information in a clinical setting. A rigorous and I believe, successful attempt at qualifying and legitimizing this technology as a useful

research tool has been thoroughly demonstrated in the thesis. The impact factor of the study alone would place it at a level of outstanding/ excellent.

Response to comment 1: Thank you for your comments

Chapter V: The Final Version of the Proposal

Thesis Title: Empowering Georgia Healthcare Professionals with Knowledge in Identification and Management of Sex Trafficking Victims using an mHealth app Stop SEX Trafficking Now (SSTN): A Grant Proposal to Educate Healthcare Professionals in the Identification and Care of Commercial Sex Exploitation Victims.

Abstract

The US State Department estimates that 26 million individuals worldwide are human trafficking victims. Washington D.C.'s Urban Institute for the U.S. Justice Department reports that between 2003-2007, Atlanta had the largest sex trade revenue of eight major American cities. The violence, abuse, deprivation, physical damage and psychological manipulation experienced by these individuals may cause commercial sex exploitation (CSE) victims to present to the medical community. These victims do not typically self-identify due to shame, fear and close monitoring by the trafficker, leaving it up to the clinician to spot signs suspicious for trafficking. A 2014 survey of CSE victims found that 88 percent had contact with a health care provider at some point while being trafficked. There is very little training for medical professionals in the US, especially among emergency room clinicians, gynecologists, or pediatricians, who are most in contact with these victims. Further, there are no clinically validated screening tools to help medical professionals identify victims in the healthcare setting, or to determine what actions to take once victims actually are identified. This thesis proposes to develop a grant proposal to create and beta test a mobile smartphone app, Stop SEX Trafficking Now (SSTN), designed to educate and better enable clinicians to identify, document and manage CSE victims. Feedback from key informant interviews, in-depth interviews, focus group discussions, and surveys with healthcare professionals, CSE victims and advocacy organizations will be used to inform the design of the app. Once a beta product is designed, it will be piloted among frontline healthcare professionals most in contact with CSE victims (medical staff in the ER, OB/GYN, Pediatric, and Urgent Care clinics). Specifically, this thesis will evaluate the knowledge gain, perceived usefulness of the app, the perceived quality of the content, and the intent to adopt the app among Emergency Medicine clinicians, gynecologists and pediatricians who predominantly provide services to sex trafficking victims and measure increased identification of CSE victims in a Metro Atlanta Safety-net Hospital.

Aim 1: Design-an mHealth app to provide critical lifesaving information on CSE victims for providers' use on a cross-platform framework compatible with multiple electronic devices (e.g., smartphones and tablet computers running both Apple iOS and Android operating systems).

Feedback from key informant interviews, in-depth interviews, focus group discussions and surveys with healthcare professionals, CSE victims and CSE advocacy groups will be aggregated and synthesized to inform the design of the app in response to salient themes critical for detection, documentation, care and referral of CSE victims. The primary outcome will be the development of a beta model of the app.

Aim 2: Pilot test and refine the mHealth app to measure healthcare professionals' knowledge about the detection and management of sex trafficking within a large academic and community healthcare network.

Once a beta product is designed, it will be first reviewed by the CSE victims and the CSE advocacy leadership using focus group discussions and surveys. Recommended revisions will be applied and the beta product piloted among frontline HCPs most in contact with CSE victims (medical staff in the ER or urgent care centers, OB/GYN and Pediatric clinics). The primary outcome measure will be increased knowledge on identification and management of CSE victims using pre and post-test based on educational materials taught within the app and performance during clinical scenarios to assess the application of learned concepts using DPBL.

Aim 3: Conduct a retrospective feasibility, usability, and acceptability assessment for the mHealth sex trafficking app among healthcare providers in a large academic and community health network.

3a: Determine factors associated with variance in feasibility, usability, and acceptability among specific provider specialty subgroups.

3b: Measure differential uptake and use patterns among specialty providers via application of established behavioral theory (i.e., Diffusion of Innovations).

Eligibility for the Grant

Eligible projects must support system-focused strategies that help with closing on-ramps into commercial sexual exploitation in addition to building more exit ramps. In the current funding opportunity, they are seeking approaches to address 6 specific systems in the US: Medical Needs, Housing, Law Enforcement, Trauma and Mental Health Systems Impacting Youth and Immigration.

This grant is addressing medical needs which is one of the critical systems. This grant is up to 3 years with a minimum amount of $100,000 per year with a maximum grant size of $600,000 per year.

Study Design

Key Informant Interviews (KIIs)

The purpose of key informant interviews will be to delve into the perspectives, beliefs, and knowledge of people who are close to the community we are intending to impact (e.g. organizations focused on bettering the lives and outcomes of persons living with CSE victims). These community experts, with their particular knowledge and understanding, will be able to provide valuable insight on the nature of issues in the community and give recommendations on the presentation of CSE victims. We will conduct 8 Key Informant Interviews with individuals involved in three integral organizations conducting work in Atlanta, Georgia on identifying CSE victims to develop a better understanding of the needs of the target population. Key Informant Interviews will last approximately 1.5 hours and will be audio recorded to ensure all data is

collected. A trained qualitative interviewer will conduct all key informant interviews using a semi-structured interview guide to ensure appropriate methods are utilized and qualitative probing is implemented in effort to gather pertinent information and data that may provide answers for questions related to the research. Preliminary analysis of data collected in key informant interviews will be used to inform the development of in-depth interviews and focus group discussion guides to ensure that pertinent questions and topics are covered during qualitative research with non-key informant participants of the project.

In-Depth Interviews IDIs

During the first year of the project we will conduct 15 in-depth interviews with HCPs, CSE victims and CSE advocacy leadership (total of 45 IDI) to uncover gaps in knowledge, individual views, attitudes, perspectives of a mHealth focused app aimed to increase detection and assist with management of CSE victims. We will also question HCPs on their concerns, gaps in knowledge, and quality of information desired related to sex trafficking. Interviews will include questions intended to gain an understanding of their personal desires and needs for this focused application. Year one in-depth interviews will focus on identifying the needs and desires of healthcare professionals to feel proficient in identify CSE victims after evaluating educational materials and gaming scenarios for the mhealth app and the methods to integrate and meet these needs in the mHealth app. During year two, we will conduct 15 more in-depth interviews after participants have been introduced to the developed app. Interviews will be with individuals not previously involved in year one qualitative research activities. The goal of year two in-depth interviews will be to gain perspectives of the users of the developed mHealth app. These interviews will focus on uncovering the participants' views of the

app, their perceived usefulness of the app, their perceived benefit of the app, and any iterative changes that participants might encourage or desire.

The project will employ a team of qualitative interviewers that are thoroughly trained in procedures and protocols for the project to ensure accurate collection of data. Alongside the training that each interviewer will participate in, interviewers will use a semi-structured interview guide with pre-determined probes and questions to uncover information pertinent to the research topic. In-depth interviews will last between 1- 1 ½ hours depending on the questioning and probing pattern of the interviewer and the participants' responses.

Participants for both years of qualitative activities will be recruited from partnering organizations in the metro-Atlanta area who are advocacy organizations for CSE victims.

Focus Group Discussions (FGDs)

Focus group discussions provide in depth information and understanding to social issues in a group context. Through the use of focus groups, we will be able to gather a more holistic and complete view and understanding of the needs and desires of HCPs in reference to a mHealth application focused on improving detection and management of CSE victims in Atlanta. We will conduct 9 focus groups per project year with no more than 10 participants in each focus group (assuming that there will be an average of 9 participants per focus group). The research team will develop semi-structured focus group discussion guides to be used during focus group discussions. The guides will be structured in a way to ensure that complex ideas, concepts, and topics are elaborated by participants to develop an understanding of the nuanced needs and desires of the population. As with in-depth interviews, the research team will use trained qualitative researchers with experience conducting focus group discussions for this aspect of the project. This team of interviewers will be informed and trained of all procedures and

protocols related to the focus group discussions and any needed training or certification for interviewers will be attained (e.g. CITI, HIPPA, etc.). It is expected that focus group discussions will last 1 – 1 ½ hours depending on the questioning, probing, and activities included in the focus group. Participants for focus group discussions during both years of the project will be recruited with assistance from academic health institutions and CSE advocacy organizations.

Surveys

Participants (HCPs, CSE victims, CSE advocacy organizations) not previously involved in the KII, IDI or focus group discussions will complete a pre-survey to determine learning needs for the HCPs community. A pre-education or baseline knowledge survey and a post-education survey will be distributed to the HCPs to examine the effectiveness of the mhealth educational program. The information extracted from the pre- and post-education surveys will collected using Survey Monkey or a Qualtrics questionnaire. The surveys sent to HCPs will collect general demographic data (age, sex, race/ethnicity, socioeconomic status/SES etc.), profession, years of medical experience, type of practice (private, Health Maintenance Organization (HMO) or academic institution) and their practice hospital. It will also question the HCPs on a previous history of CSE training and if the participants perceived that they had a comprehensive and thorough understanding of CSE. The survey will also use Likert Scale questions to measure each participant's confidence in identifying and managing potential CSE victims. The questions in the pre-education survey and post-education survey will be identical to track improvement of the mhealth intervention.

Development of education materials

Drs. Lisa Flowers, Nancy Fajman, Kalinda Woods, Sandra Ford will oversee the development of evidence-based educational materials in response to initial KIIs, IDI and focus-group feedback, drawing on the health professional experience with CSE victims. We will also use materials provided by the literature, CSE advocacy and hotline websites and webinars as a starting point to receive input from the CSE survivors and HCPs. Dr. Flowers, will adapt these materials to follow a scaffolded, approachable pedagogical design (Simpson, 2016). The scaffolded content design builds upon previous participant knowledge and draws connections with read-world and relatable examples, fostering understanding and empowerment through education.

App Development

For app development, we are partnering with Cygnis Media. They will assist in the development of native apps capable of accepting updatable content compatible for download on devices using a variety of operating systems (e.g. Apple iOS, Android and HTML-5). Enabling download on these most widely-used operating systems will maximize compatibility with many types of mobile devices including smartphones, tablets and embedded browsers with HTML-5 compatibility. The apps will be "published" on Apple store, google play store, health department websites, physicians' websites, etc. to be available for download. We have selected this multi-platform modality in order to optimize the flexibility and longevity of the applications while allowing us to easily make changes as new issues arise.

The intervention to be developed through this project will be a native app designed for use on the Apple iPhone and Android-based operating systems, as these two systems are market share leaders. The app and all essential content will reside on the device, and routine updates (e.g., dynamic content updates, pushed messages) will be applied to the

app when there is network connectivity. Having the core elements of the app reside on the device will provide continuity of service in the event of limited network connectivity in the event of a public health emergency or any other type of network shutdown.

The information contained within the app will be searchable (using keyword searches) and browsable, both through a general menu of topics as well as a more granular list of topics.

The study team will have access to an app "dashboard" that can be used for near real-time updates of the app, including updates of dynamic content. To maintain engagement with the app, a "Message of the Week" will be sent through the dashboard; this message can be used to provide updates regarding sex trafficking information which will appear as a notification within the app. In the absence of a specific issue, messages will be chosen by the study team for promulgation through the "Message of the Week" function. Additionally, this type of engagement will serve to ensure that users have the most up-to-date content in their personal copy of the app. Typically, when apps are updated, updates are applied once the app is opened. As the app will need to be accessed to read these Messages of the Week, dynamic content updates will occur.

The dashboard will also provide counts of how frequently the app is accessed and frequencies of specific queries to the study team. This dashboard informatics can be used to evaluate patterns of sex trafficking concerns among HCPs as well as provide data on app usage to incorporate into the data analysis.

The app will be able to push out short (two to three question) feedback requests (e.g., to assess SSTN app usability, to assess willingness to use the app) where information can be transmitted back to the study team through the app.

Since smartphones do not have a large screen size in comparison to a tablet, notebook or computer, text and images presented on the app should be scaled for readability. Menu

items and search lists will appear as pop-up selection tools, to increase visible presence on the screen, to aid in both viewing materials and selecting the desired choice.

The app will be able to be updated, with updates made available for download when available, as necessary. Users will have the option to allow the app to automatically update when a new version is available, to eliminate the need to actively update the app. App version updates will be created to address issues within the app (e.g., software functionality problems; response to "bug reports" from users) as well as to deliver the most up-to-date information on sex trafficking (e.g. statistics in the area, resources, required medical documentation) and the best ways to report and refer cases to the appropriate authorities.

Initial system specifications will be provided to the app development team early in the study period while formative research is occurring, to allow sufficient time for initial development processes that can be refined following pilot testing. These specifications will address preliminary design issues, system compatibility, and user interface, and will allow Cygnis Media staff to begin designing the core features and layout of the application system. Through the initial development process, internal usability testing by Cygnis Media staff will be supplemented with testing by members of the study team. Results of usability testing and documentation of modifications to the app based on this testing will be tracked by the developer and provided to the study team for reference. Continuous internal quality control checks by Cygnis Media staff with secondary quality control checks by members of the research team will be incorporated to verify application system accuracy and functionality.

Resource Linkage

Community resources: Local experts will develop a list of local community resources, including help sources for CSE victims and screening health professionals. For the beta-version of the app, only local Atlanta resources will be included. Future versions

of the app will collect information from local health departments, safe houses, and CSE victim assistance services to create a map of resources.

Provider connection: A key function of the app will be the ability to communicate directly with providers and local health experts. The app will employ a dedicated team of clinicians and CSE experts to monitor an open forum for questions and discussion of sex trafficking concerns by healthcare professionals.

App evaluation, Modification, and Preliminary Testing

We expect the initial development process to take 4-6 months, resulting in a test product. This test product will then undergo a second iteration through the community evaluation process. Stakeholders (HCPs, CSE victims and members of CSE advocacy organizations) who participated in the initial focus groups will be given the opportunity to explore the app, and will rate the function, appeal and relevance of the app on surveys utilizing a Likert scale. The HCPs, CSE victims and members of the CSE advocacy organizations will rate their satisfaction with the design process and the extent to which they felt their voices were represented in the design and the design met their identified needs and preferences, also utilizing a Likert scale for satisfaction. In addition, the initial design will be given to a representative group of primary care providers, social workers, and public health experts from the community, who will rate the app content for educational value, comprehensiveness, and perceived relevance to their population. Focus groups will be conducted through years 1 and 2 of the study as described in the community needs analysis section above. Feedback from surveys and focus groups will be aggregated and sent to the developer for improvement. The developer then estimates that a period of 14 weeks will be required to integrate modifications based on community feedback. After integrating these modifications, a beta version of the app will be delivered to the research team.

Final design testing and dissemination

Our strategy for dissemination of the intervention builds upon opinion leadership and early adopters. Healthcare professional opinion leaders that can be identified from our current relationships with Emory University Healthcare Systems, Grady Memorial Hospital Healthcare Systems and Children's Healthcare of Atlanta to hold social influence within their networks; a downstream diffusion of thought and behavior in the healthcare professional community extending from these leaders can thus be leveraged to promote new innovations. To identify opinion leaders in our healthcare community, brief surveys will be administered to healthcare professionals.

Once the beta version of the app is completed, identified healthcare professionals and community opinion leaders will be provided with an opportunity to download and experiment with the app. They will be allotted a period of 6 weeks for testing of the app. Opinion leaders will be provided with an incentive for piloting and providing feedback on the app, but not for recruitment of peers to engage with the app. They will be told they can "spread the word" via word of mouth, social networks and social media, and that the app is publicly available for download; in addition, the beta version of the app will include a "refer a friend" function, to permit ease of download. It is important, however, not to incentivize the spread of the app as we wish to model its real-world diffusion among the community.

App developers will be able to monitor downloads and interface time with the app as described above. In addition, push notifications will enable users to rate their satisfaction with the app in real-time. At the end of the trial period, quantitative measures will include number of new downloads, number of referrals sent and downloaded, overall app satisfaction rating, and time spent engaging with app content. Additionally, users will be given the opportunity to complete a brief survey on their

experience with the app in exchange for a small monetary incentive. Surveys will assess appeal, usability, and relevance of the app, as measured on a 5-point Likert scale.

Data management

We will transcribe observation notes and audio recordings from all KIIs, IDIs and FGDs and all transcriptions and audio recordings will be stored on a secure, password-protected, limited access server. Research staff will play each audio recording after transfer to the server to ensure audio file fidelity; after confirming that the server-stored audio recording is complete we will delete the file from the recorder. Once transcription of all audio recordings is complete and verified, we will delete the audio file from the server. Transcriptions and observation notes will be de-identified and tracked by anonymous ID codes.

Survey data will be collected via the app. The study team will have access to survey data via the app dashboard. De-identified survey data will be linked to participants to provide a measurement of the amount of time spent interfacing with the app in order to determine the extent to which time spent engaging with the app resulted in overall score improvement. Study data will be downloadable to a HIPAA-compliant, password protected Redcap form for analysis.

Qualitative Data Analysis

We will utilize a standard qualitative data analysis software (e.g. NVivo or MaxQDA) for all qualitative data analysis. We will utilize the constant comparative approach within the grounded theory process model (Cooney, 2011; Gelling, 2011; Harris, 2015; Hunter et al., 2011; Licqurish & Seibold, 2011). This approach uses both deductive and inductive methods for thematic and pattern identification. All IDI transcripts will be coded according to emerging patterns and these codes will be further refined through a series

of iterative cycles used in team-based qualitative data analysis (Macqueen et al., 1998). Two members of the project team will conduct observational data coding, and coding will be compared for consistency with the achievement of inter-coder reliability at Kappa ≥ .70, which is considered a minimally acceptable inter-coder agreement level (Elliot, 2007).

Themes, as identified, will be summarized for application in the development of the app. Within the existing framework of materials, we will identify clear areas of need from the qualitative-based observational data and update the app content accordingly. Following refinement of materials, focus group discussions with CSE victims, healthcare professionals and CSE advocacy organizations and community stakeholders will be conducted to obtain content feedback, acceptability, and usability of the materials. Using an iterative approach, the study team will revise and refine intervention materials accordingly.

Quantitative data analysis

Survey data will be analyzed using SAS v9.4. We will assess frequency counts of the responses to the Likert scales, collapsing relevant categories (e.g. “Strongly agree” and “Agree” into one category) to allow more parsimonious outcome assessment. Response proportions and associated 95% confidence intervals will be computed and compared between the original opinion leaders and the network contacts for whom they provided access to the app to determine the extent of acceptability among potential early adopters and other potential later adopters.

For the impact assessment, mean scores will be treated as a continuous variable, and pre and post intervention means will be compared. The primary outcome measures will be change in 1.) mean CSE identification awareness, 2.) mean CSE knowledge scores, and

3.) mean CSE victim referral knowledge. We expect baseline CSE awareness and knowledge to be less than 30% in healthcare professionals based on the paucity of data. Given the possibility of a total score range of 0 to 29 across all measures, we hypothesize a mean knowledge score of 14.5 and standard deviation of 10. Using a one-way ANOVA comparison of two means for pre-post comparison, we would need to enroll and retain 79 individuals to detect an increase in mean knowledge score of approximately 30% (a mean score increase from 14.5 to 19) following exposure to the app. To account for up to 30% attrition, we would need to enroll 113 individuals to use the app for the initial impact assessment.

Protection of Human Subjects

Risks to Human Subjects

Human Subjects Involvement, Characteristics, and Design

The project, Empowering Georgia Healthcare Professionals with Knowledge in Identification and Management of Sex Trafficking Victims using an mHealth app Stop SEX Trafficking Now (SSTN): will focus on development of an mhealth app to educate health professionals to identify CSE victims who present for medical care. We plan to engage previous CSE victims via in-depth interviews and focus groups. Also, HCP representatives from pediatrics, emergency medicine, urgent care centers, and obstetrics and gynecology will also undergo in-depth interviews and focus groups to provide input in the mhealth app SSTN. We anticipate that many of the CSE victims will be female and suffer from post-traumatic stress disorder therefore social workers and psychologists will be present for support as needed by the participants. The study team is diverse and bilingual to address the diversity of potential study participants (CSE victims) and consents will also be bilingual (English and Spanish versions). In addition, the app will be bilingual, and all content will be presented in both English and Spanish.

Human Subjects Sources of Materials

All data will be securely managed and stored on HIPAA-compliant network drives at the Emory University School of Medicine, Emory Rollins School of Public Health, Grady Memorial Hospital and Children's Healthcare of Atlanta. Data collection through web and smartphone surveys will be securely encrypted during data entry, storage, and transmission. All collected data will be used only by designated study staff and will be accessible via on-site secured computers. Personal identifying data will be stored in a separate, encrypted, and password-locked file, as will collected health information and vaccination information obtained from the state immunization registries. Based on existing study protocols, we believe this will be a "minimal risk" study even though the demographic and behavioral data will be linked to the outcomes of this project. Any breach in security or risk of disclosure from materials (personal identifying information or other sensitive data) will be reported immediately to the Emory University School of Medicine Institutional Review Boards (IRB), which will serve as the multisite IRB of record for this study. All security incidents will be thoroughly documented and follow-up reports sent to the IRB.

Potential Risks

The foreseeable risks to participants are minimal. The primary risk will be breach of confidentiality or breach of security related to data transfer. Because participants have provided personally identifying information through the mobile app, including name, address or geolocation, date of birth, and phone and email contacts, there is a risk that these data could be unintentionally disclosed to someone not authorized to access the data, compromising the privacy of the participant despite our best efforts. We will also collect sensitive health information from the CSE victims who participate in the focus groups, semi-structured interviews and surveys. This may cause anxiety for the CSE victims which will be addressed with the victims prior to their participation in activities

to assist in app development. Although data are heavily secured, it is possible that persons who provided information used in this study may experience a sense of shame or ostracization if what they disclosed in confidence is inadvertently made public. To minimize this risk, the CSE victims will be well counseled about the intent of the focus groups, interviews, and surveys; and CSE advocacy support groups and advocates will be available during the activities.

Recruitment and Informed Consent – English and Spanish

For the aims of this study we will recruit CSE victims from our CSE advocacy organizations (Street Grace) and health professionals from the Departments of Obstetrics and Gynecology, Emergency Medicine, and Pediatrics from Emory University, Grady Memorial Hospital, and Children's Healthcare of Atlanta. Participants will receive information about the study and will be asked questions to verify that they understand the risks and benefits involved with being in this study. Screening, consent, and focus groups/in-depth interviews will be conducted at the study site with staff fluent in the participant's preferred language (English or Spanish). Screening may also be conducted via phone interviews with study staff. The informed consent form will be given to the participant in their preferred language (English or Spanish) and will be emailed to potential participants after screening or in person based on the participant's preference. Enrollment will occur after return of the signed consent form through email, fax, mail or in person. All staff involved in the screening, consent, and focus group/interview process for Spanish speaking participants must be fluent in Spanish and English as demonstrated by certification and/or written and oral proficiency assessments.

Protection Against Risks

Study data will be provided with all appropriate physical and operational security protection measures. Critical security measures required by Emory University School of Medicine will be strictly observed to protect study data and minimize risks to

confidentiality. Data entry through web and smartphone surveys will be securely encrypted during data entry, storage, and transmission in compliance with HIPAA standards. All data will be stored in electronically and physically secure locations at Emory University and Children's Healthcare of Atlanta, and all study personnel will be assigned unique identifying login IDs and passwords to perform their tasks. Electronic data will be encrypted and password-protected on these secure servers. Access to identifying data will be restricted to only the essential study staff and investigators working with the data to complete their study-related analyses. Participants will be assigned a study ID to be used in all datasets, and the key file linking participant ID to personally identifying information (name, address, contact information, date of birth) will be stored in a separate encrypted and password-locked file. Sensitive health information on HIV and vaccination status will be stored in another separately encrypted and password-locked file, linked only to participant ID. All published analyses (including geospatial analyses) will aggregate participant data to ensure participants are not identifiable. All staff will be trained in confidentiality procedures and sign a statement regarding nondisclosure of participant information.

Potential Benefits of the Proposed Research to Subjects and Others

The potential benefit of the mHealth app is development of an educational mobile application which can assist healthcare professionals in detection and management of CSE victims. The findings from this study will provide valuable information for healthcare professionals and hopefully assist CSE victims from escaping their traffickers and receiving critically needed assistance. Additionally, we will be addressing a national public health crisis in a direct and tangible way.

Importance of the Knowledge to be Gained

Healthcare professionals lack the information required to appropriately identify CSE victims. Findings from this study will improve the knowledge gap among healthcare

professionals in the frontline of care for CSE victims. This new information will aid the development of an mhealth app to improve CSE identification, management and referral to support services when in contact with healthcare professionals. Therefore, the knowledge gained will help ensure that strategies developed from this project are salient to the reduction of missed opportunities of identification of CSE victims within the healthcare system.

Vertebrate Animals

N/A

Select Agent Research

N/A

Data Safety Monitoring Plan

The Data Safety Monitoring Plan (DSMP) outlined below will ensure the safety of the participants and will verify the validity and integrity of the data of study protocols conducted under the program. An IRB-approved written informed consent (available in both English and Spanish) will be obtained from each potential subject prior to enrollment and initiation of study procedures. The elements of the informed consent will include an information and consent form provided through the web survey platform and (focus groups, usability testing, surveys, and interviews) screening and consent will proceed through phone or in- person interviews at the study site. The components of consent will include: (a) having the potential subject review the study consent form; (b) having the investigators or study staff meet with the potential subject to review the consent, confirm understanding, and answer any questions; and (c) obtaining signed consent, in the presence of a witness, from individuals who wish to participate. The data management coordinator will review data collection forms on a weekly basis and track data accuracy from collection sites. The Principal Investigators (PIs) will review all

collected data at least annually for completeness and accuracy of the data as well as protocol compliance.

Participant Safety Data Examination, Monitoring Procedures/Oversight

The safety of study participants will be monitored by the Principal Investigators, co-investigators and study coordinators on a regular basis. The research coordinators will be responsible for recording all clinical data and information taped during the semi-structured interviews and focus groups. As these are collected, all adverse events (AEs) will be identified and reported to the Principal Investigators and Emory University IRB. Because post-traumatic stress disorder (PTSD), shame, grief, and/or stigma could be a major risk to participants, possible AEs will be monitored actively by encouraging participants to self-report if they perceive that they have been affected. All AEs will be graded as to their attribution (unrelated to protocol, possibly, probably, or definitely related to protocol). The CIN computerized database system will then be used by all investigators to report all adverse events (AE) and serious adverse events (SAE) that may occur during the conduction of any semi-structured interview or focus group. For the purpose of this application, an SAE will be defined as any experience of a participant that suggests a significant hazard, such as events which: a) are fatal, b) are life threatening, c) results in permanent disability.

Potential ("Expected") Adverse Events and Plan for Detecting Problems and Minimizing Subject Risk During this Program

PTSD, shame, grief, and stigma are the main AE that participants may directly experience during the study. These potential side effects will be monitored and support CSE advocates will be available during the focus groups and interview.

Procedures for Minimizing Risks

We will work closely with CSE community organizations, as all of our proposed studies require community input in order to be sensitive and culturally appropriate. Staff will be trained to handle sensitive topics regarding private health information and potentially upsetting CSE adverse events. All persons will be over the age of 18, and therefore must be able to read, understand, and sign the consent forms in English or Spanish. Bilingual study personnel will be available for the duration of the study to answer and translate study procedures and confidentiality requirements as required. Participants will be assured that refusal to participate in the study will not affect their future treatment at that health facility or relationship with the university. All data will be securely encrypted during collection through web or app surveys, while stored locally, and when transmitted to study personnel. All collected data will be stored on secure encrypted network servers operated by Emory University, and access will be restricted to approved study staff. Results of data analyses will report aggregated participant data, and no personally identifiable data will be published.

Plans for Transmission of Temporary or Permanent Suspension Actions

N/A

Plans for Protecting Subject Confidentiality

All information and materials obtained as a result of the research will be kept in strict confidence. Confidentiality will be assured by the use of subject codes rather than personal identifiers. The specific study database will be password protected on secure servers, and information will only be entered using subject identifier codes rather than personal identifiers. One document connecting identifier codes to personal identifiers will be password protected and saved on a secure, password-protected server. Only staff

on the data team will have access to the identifying document. Electronic communication will involve only coded, unidentifiable information.

NIH Certificate of Confidentiality

The research team will comply with all new NIH COC rules for maintaining confidentiality of all identifiable information collected by research team members and research partners. Identifying information will be collected over the course of the study period, including disease status (e.g., depression) and contact information, in order to ensure that the study is run properly. By obtaining a certificate of confidentiality, we will further ensure the privacy of study participants so that private identifying information is not disclosed to individuals outside of the research team. We expect individuals to be more open and willing to disclose both their own behavior and that of others if the fear of a privacy violation is minimal. With the certificate of confidentiality, individuals will be more willing to participate or provide quality information.

Plans for Assuring Data Accuracy and Protocol Human Safety Compliance

The above detailed DSMP should assure data accuracy and human safety protocol compliance. All study activities will be required to include computerized secured database management and IRB oversight.

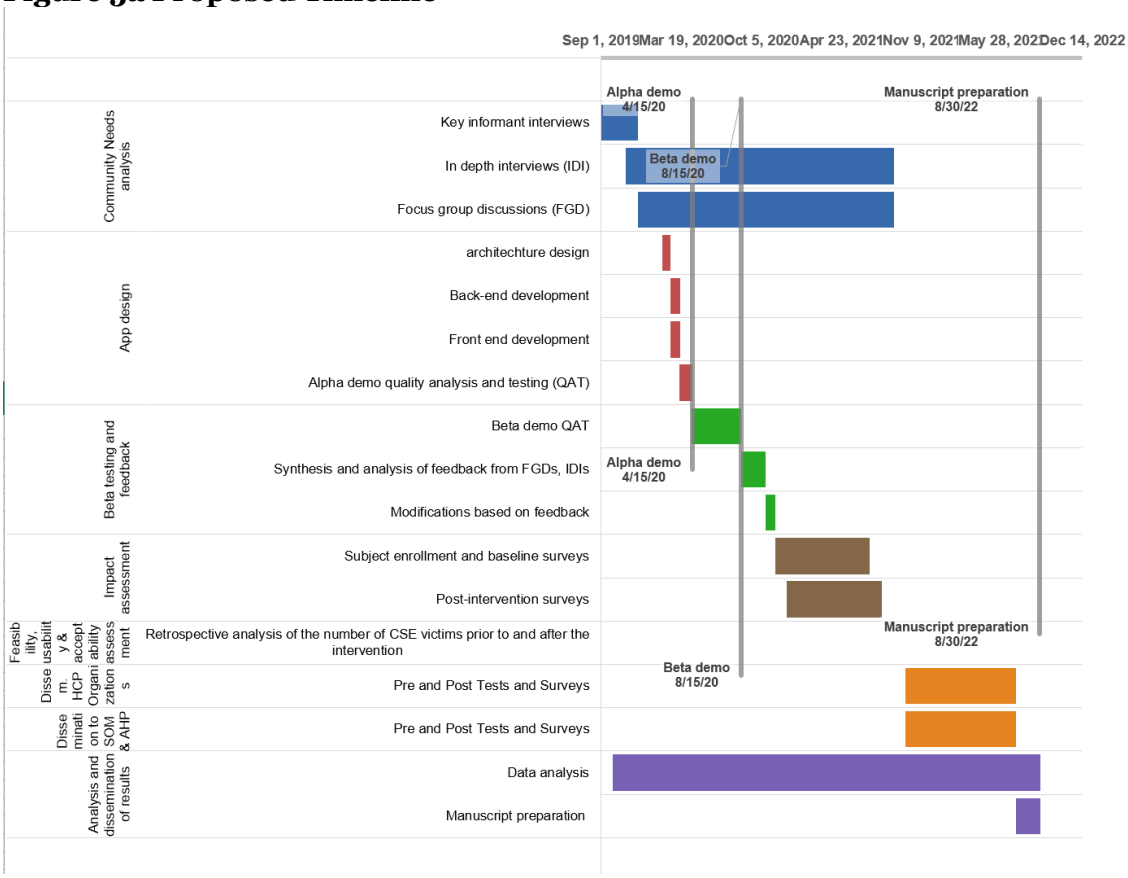
Proposed Budget

Table 4 Proposed Budget

	Aim 1/Year 1	Aim 2/Year 2	Aim 3/ Year 3
Faculty	**Stipends**		
Dr. Lisa Flowers Gynecologist	35,000	35,000	35,000
Dr. Kalinda Wood Adolescent Gynecology Specialist	30,000	30,000	30,000
Dr. Nancy Fajman Pediatrician	30,000	30,000	30,000
Emergency Room Physicians	30,000	30,000	30,000
Emergency Room Nurses	10,000	10,000	10,000
Jordan Greenbaum CHOA	30,000	30,000	30,000
Dabney Evans MPH, PhD, Director Center for Humanitarian Emergencies at Emory	30,000	30,000	30,000
Linelle Blais Associate Director, Executive MPH Program	15,000	15,000	15,000
JoAnna Hillman Director of Research and Evaluation	15,000	15,000	15,000
Sandra Ford Consultant	30,000	30,000	30,000
Social Worker	7,000	7,000	7,000
Psychologist	10,000	5,000	5,000
Research Coordinator	57,000	58,000	59,000
Program Director	40,000	40,000	40,000
Key Informant Interviews, indepth interviews Costs	8,000	12,000	12,000
Software Development/App Development	50,000	20,000	20,000
Focus Group Coordination and Management Contract	30000	30000	30000
Focus Group Participant and Survey Distribution Costs	8,000	12,000	12,000
Street Grace	30,000	30,000	30,000
International Institute of Human Trafficking	25,000	25,000	25,000
Statistician and Analysis	50,000	50,000	50,000
Promotion Activities and Distribution of mobile App	10,000	10,000	10,000
Total	580,000	554,000	555,000
			1,689,000

Proposed Timeline

Figure 5a Proposed Timeline



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