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Project Summary

Evidence of Injury Following Sexual Assault: A Research Proposal

By

Brea Echard

July 2017

The prosecution of rape in the United States often relies on the evidence of genital injury. However, because rape is a crime of lack of consent, evidence should only be used to corroborate a storyline rather than to prove or disprove consent. The objective of this incidence density case-control study examining participants after consensual intercourse as well as victims of rape is to prove that both groups have an equally low prevalence on genital injury. Participants will include 300 victims on non-consensual sexual intercourse and 300 participants of consensual sexual intercourse interviewed and examined for genital injury using macrovisualization, speculum, colposcopy, and toluidine blue dye by Sexual Assault Nurse Examiners. Study participants must be over the age of 18 but premenopausal, present with absence of menses or pregnancy, and have participated in penile-vaginal intercourse within 72 hours of examination. Main outcomes are proportion and odds ratio of injury among both groups.

Evidence of Injury Following Sexual Assault: A Research Proposal

By

Brea Echard

B.S., GEORGIA STATE UNIVERSITY

A Capstone Submitted to the Graduate Faculty
of Georgia State University in Partial Fulfillment
of the
Requirements for the Degree

MASTER OF PUBLIC HEALTH

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Approval Page

Evidence of Injury Following Sexual Assault: A Research Proposal

By

Brea Echard

Approved:

Richard Rothenberg, MD, MPH
Committee Chair

Sarah Pederson, RN, BSN, SANE-A, SANE-P
Committee Member

July 20, 2017
Date

Author's Statement Page

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Table 1. Review of Literature for Injury Prevalence

Author, Year	Study Type	Sample Size	Injury definition	Injury Findings	Recruitment	Methods
Maguire, W (2008)	Cross-sectional	153	Bruise, abrasion, and/or laceration to vaginal & anal areas	39% in SA	Secondary data from previously done sexual assault exams Ages 13+	Macroscopic visualization, colposcopy and speculum
Zilkens, R (2017)	Cross-sectional	1266	Bruise, abrasion, laceration, stab wound and/or burn to vaginal & anal areas	24.5% in SA	Sexual assaults only – less than 10 days since assault, had to be penile-vaginal intercourse Ages 13+	Macroscopic visualization and speculum
Slaughter, L (1997)	Case-control	311 – cases 75 – controls	Redness, swelling, bruises, abrasions, and tears to vaginal & anal areas	68% cases 11% controls	Retrospective data for cases, Prospective data for controls Ages 11-85	Macroscopic visualization and colposcopy
McLean, I (2011)	Case - control	500 – cases 68 – controls	Bruise, abrasion, and laceration to vaginal & anal areas	22.8% cases 6% controls	Retrospective data for the SA Prospective data for control; penile-vaginal intercourse; within 48h Ages 18+	Macroscopic visualization and speculum with magnification
Lincoln, C (2013)	Prospective cohort	41 – cases 81 – controls	Bruise, abrasion and/or laceration	53.7% cases 10% controls	72 hours after penile-vaginal intercourse; sexual assault reports to	Macroscopic visualization and speculum

			to vaginal area only		police for cases and regular/sick gyn check-ups for controls Ages 18-45	
Sommers, M (2006)	Matched case-control	40 – cases 80 – controls	Bruise, tear, abrasion, redness, and swelling to vaginal & anal areas	Adj OR = 4.30 95% CI (1.09-25.98)	Used data of sexual assault victims within 72 hours of assault; Ages <40-50+	Macroscopic visualization, colposcopy, and toluidine blue due staining

CHAPTER I: INTRODUCTION

1.1 Public Health Concern

The Georgia department of public health estimates that 1 in 4 girls and 1 in 7 boys will experience sexual violence before their 18th birthday (Sexual Violence Prevention, 2017).

While the prevalence of sexual assault on males and females of all ages has decreased since 1993, the lifelong effect of sexual assault for more than 300,000 Americans over the age of twelve makes sexual assault a public health concern (About Sexual Assault, 2016).

Sexual assault can subsume many actions involving sexual intention such as rape, attempted rape, fondling or non-consensual touching. Between 2006 and 2010 it was determined that rape is the most underreported violent crime in the country, with 65% of rapes during those 4 years being unreported to police (Walsh, 2016). While rape has always been viewed as a heinous crime, the definition of rape has evolved over time. Rape historically referred to penetration ‘by force’, yet is legally now understood as ‘without consent’. Consent in itself requires active participation.

Drug-facilitated sexual assault (DFSA) is an important topic alone. At just one hospital-based Sexual Assault Center (SAC), the estimated incidence of drug- or alcohol-facilitated sexual assault made up over 50% of their victim population in 2015. Data from this organization found that involuntary DFSA increased 8% within 2 years (Richer, 2017). DFSA is also less likely to be reported than rape by physical force, as often the

victims of DFSA don't know how to define their experience or don't remember the event occurring (Walsh, 2016). With many sexual assault centers serving the non-reporting population, it is feasible to curb this limitation of underreporting.

1.2 Forensic Nursing

Owing to the criminal offense of sexual assault, forensic examination and evidence collection should be performed by a physician or specially trained nurse. SANE (Sexual Assault Nurse Examiner) programs across the nation serve to deliver this care. Law enforcement, victim advocates, and health care providers involved in the immediate response to sexual assault are called SART (Sexual Assault Response Team). The SART members attend regular training to keep up-to-date on the protocols to execute a seamless delivery of care for victims of sexual assault. Local jurisdictions make mandates for their area on how and when to perform a sexual assault forensic exam. The more equipment and education in forensic medicine employed, the more high quality exams can be performed.

In the event of a sexual assault report, the law enforcement investigators will bring the patient to a sexual assault center or hospital to perform the exam if still within the jurisdictions designated presentation window between assault and exam. The presentation window is traditionally 72 hours, but more areas are moving toward almost one week (US DOJ, 2013). Many programs customarily have a victim advocate with them as well for the exam. That individual will aid the victim through the process, paperwork, and

resources for longer term care as a result of the assault, such as: shelter, legal aide, counseling, etc. A traditional Sexual Assault Forensic Exam would include: collection of consent forms, medical history, personal information, details of the assault, and any information that may lead the exam in collection of evidence; the physical examination; and STI prophylaxis and Plan B dispense. The forensic exam record should be kept separate from the medical records to maintain confidentiality (US DOJ, 2013).

The statement and details of the event are important factors in guiding the SANE through the exam and should be thorough and precise. They also give the patient an emotional and psychological release to express their side of the story to medical individuals who have no legal position; this also gives the advocates an opportunity to assess the patient's immediate nonmedical needs and ensure patient safety at home and work. Collection of clothing and blood samples may be at the discretion of the SANE and/or investigating officer. Once paperwork and assault details have been collected, the physical exam begins. Like most of the exam, the procedures used may be determined by the examiner, the program protocol, and equipment available. Forensic photography, however, is customary throughout the entire physical examination to document injuries. As stated in the National Protocol for Sexual Assault Medical Forensic Examination, the combination of evidence collected, the statement given, and the injury seen during the exam hold four purposes: "to identify the suspect, to document recent sexual contact, to document force, threat, or fear, and to corroborate the facts of the assault (US DOJ, 2013)."

Injury documented during the Sexual Assault Forensic Exam includes any bodily injuries such as bruises, scratches, ligature marks, swelling, and lacerations to any part of the body outside the genitals as well as genital injuries such as redness, swelling, bruises, abrasions, and lacerations to the buttocks, perianal skin, anal folds, rectum, vaginal walls, cervix, perineum, labia majora, labia minora, clitoral hood and surrounding area, periurethral tissue/urethral meatus, hymen, fossa navicularis, and posterior fourchette (Kelly, 2013; US DOJ, 2013).

Many Emergency Department physicians do not have extensive training in forensic evidence collection or have time in an ER shift to give so much attention to one patient exam, making a SANE a necessity (Campbell, 2007). These nurses may have to testify in court, which means having proper training and experience in sexual assault cases, having the flexibility to attend court, and intently studying the sometimes four hour exam details is extremely important in the legal arena when testifying as an expert witness.

1.3 Legal Implications

Many researchers will agree that the legal implications for forensic exam findings need to be carefully interpreted with the current definition of rape, yet many studies find a correlation between conviction and genital injury findings. While non-genital injuries, as well as specimen collection, can very helpful in identifying sexual contact and corroborate a victim and/or assailant's story, if sexual contact is not in question the conviction weighs on the determination of "consent" (Ingemann-Hansen, 2008 & 2013).

This can make it more difficult to prove rape beyond reasonable doubt. In fact, RAINN (Rape, Abuse, & Incest National Network) estimates that only 6 out of every 1000 rapists are actually imprisoned (The Criminal Justice System: Statistics, 2016). For this reason, many studies have tried to find either a difference in proportions of genital trauma, severity of trauma, or pattern of trauma to physically distinguish between consensual and non-consensual sexual contact. However, forensic physician Graeme Walker points out, “the idea that the question of consent can even be dependent on presence, pattern, or severity of genital injury which most studies aim to find, is based on the very old definition of rape being by force” (Walker, 2015).

Regardless, studies still find a significant relationship between genital trauma and conviction rates (Gray-Eurom, 2001); and the difference in examination methods, participant recruitment, definitions of injury, and lack of control for possible confounding variables found in the current literature do not help. Not all sexual exams are performed with the same equipment or methods and different methods can reveal different findings. The National Protocol for Sexual Assault Medical Forensic Examinations suggests that more equipment and more methods increase the opportunity for “state-of-the-art” exams, but these standards are determined within each jurisdiction. It is important for a jury to understand that biologically, the vaginal canal was developed for intercourse, and the patterns or presence of genital injury should not sway a conviction. The increase of alcohol- and drug-induced sexual assaults can also have a large impact on the findings of

injury in both populations, which has yet to be examined. Combined with lack of injury, the lack of memory leaves the victim less credible to a jury.

1.4 Study Objectives

While current studies aim to find significant difference in prevalence of injury between non-consensual victims and consensual participants, this study aims to identify an equally low prevalence of injury between the statuses of consent. Current research lacks clinical studies of consensual vs non-consensual prospective frequency matched controls to cases that still controls for examiner and other variables to make reliable claims generalizable to the US population. The primary objective of this study is to identify prevalence of genital injury following penile-vaginal intercourse measuring injury count using naked eye visualization (macrovisualization), colposcopy, toluidine blue dye, and speculum to better educate the sexual assault victims, community, SART, attorneys, and prosecutors. The secondary objective is to identify prevalence of genital injury based on possible confounding variables such as exam method, alcohol/sedative use, lubrication use, race, and exam presentation time frames to better inform SART on how to address these population differences in the future.

CHAPTER II: REVIEW OF THE LITERATURE

2.1 Injuries Following Non-Consensual Sexual Intercourse

Two cross-sectional studies of distinction have been completed to analyze the injuries and related factors associated with the sexually assaulted population. The first major study by Maguire, et al. identifies if a relationship to assailant, alcohol use, or age, could be significantly correlated with physical injury (Maguire, 2008). Retrospectively analyzing 153 genital exams on women aged 13 and older with police reports done between 2002 and 2006, this study they found that 39% of victims had documented injury. Genital injury was defined as bruises, abrasions, lacerations, burns and stab wounds in the genital and anal regions with both speculum and colposcopy. Only 85% were examined within 72 hours of the assault and they included bodily injury in their proportions. While they are the only study to stratify for alcohol use in sexual assault, they did not find any relationship between injury and alcohol use and did not have this variable incorporated in any tables or graphs. They did however find that age is the greatest risk factor for sexual assault and that victims with a lack of sexual experience had a greater number of genital injuries (anal and/or vaginal) than sexually active women. Some major weaknesses of this study included only examining women who reported to the police. This lacks generalizability to the population that does not report rape, which could be due to their lack of injury. Overall, they identified age as the biggest risk factor for sexual assault because 44% of their complainants were 20 years of age or younger.

However, the age of consent in Northern Ireland prior to 2008 was age 17 (Sex and the Law, 2014). Therefore it is expected that using only police reported sexual assault, there may be a higher proportion in ages under 20 years of age due to the legal obligation to report rape for that population.

The more recent cross-sectional study by Zilkens, et al. analyzed a much larger population of victims only using macroscopic visualization with speculum (Zilkens, 2017). At this point in time, the forensic community has identified use of colposcopy and toluidine blue dye as best methods to identify genital injuries (Zink, 2010). This study's recruitment included victims, ages 13 and older, who reported to the Emergency Department or to police (69% were police reports). They did require them to be post-puberty but used patients whose exams were done within 10 days, rather than standard recommendation of 72 hours to find most evidence (Maguire, 2008; Adams, 2001). They also were one of the only studies to separate vaginal and anal injuries in their methods. They found genital (vaginal and/or anal) bruises, abrasions, lacerations, incised wounds, penetrating (stab) wounds and burns in 24.5% of women reporting alleged vaginal penetration. They claimed that the number of different penetrant types increased anogenital injury frequency; however the odds ratio confidence interval starts at 1.1, showing the potential of only a slight difference in injury for single penetration versus multiple penetration exposure. They did mention a possible limitation is that more women with injuries may either report to police or be referred to the SAC by emergency providers or

police. Since this study goes into the detailed characteristics of factors contributing to injuries, if injuries are sustained at all, it is important for the reader to interpret with caution in order not to confuse increased odds of injury with merely the odds of specific characteristics given injury (Zilkens, 2017).

The purpose and direction of those studies was to find factors significantly associated with genital injury. Taken at face value, these can have significant implications in court, without emphasis on the lack of injury found in majority of patients. These studies make predictions on what injuries should look like if they occur.

2.2 Injuries Following Consensual Sexual Intercourse

A study purposed to describe the genital injuries sustained in consensual intercourse done by Astrup, et al. concluded that genital lesions alone should not be used in court to corroborate rape (Astrup, 2012). This study most directly relates to the purpose of the proposed study, without comparing any findings between actual victims and those who volunteered to be evaluated. This study found in women ages 19-40 that 34% of lesions were seen with the naked eye, 49% were seen with colposcopy, and 52% were seen with toluidine blue dye and subsequent colposcopy. The term “lesion” was used to describe bruises, abrasions, and lacerations. They also studied duration of lesions, having interesting findings that survival time of lesions was: 24h with the naked eye, 40h with colposcopy, and 80h using toluidine blue dye. This shows us the importance of comparison between studies using similar methods because of the large variation in

findings. Ideally, studies should be consistent with the most advanced forensic exam recommendations. It could be argued however, that these methods have been identified as ideal for different types of lesions, so one method may not be appropriate for identifying every type of lesion. Strength in this study was that the same five physicians saw all of the patients, though they did not note inter-examiner bias as a possible limitation. Furthermore, the recruitment was potentially biased as the patients were instructed to have sexual intercourse 48 hours before exam, changing the intentions and possibly desire in which intercourse would naturally occur. They did however mention that a limitation of their study was sample size (Astrup, 2012).

2.3 Injuries Following Consensual vs Non-Consensual Sexual Intercourse

Within the last 20 years, four studies have been the most-cited for sexual assault injury (Slaughter, 1997; McLean, 2011; Astrup, 2013; Lincoln, 2013). These case-control studies compare the injuries found within the population of alleged non-consensual penile-vaginal intercourse and consensual penile-vaginal intercourse. The first two (Slaughter, 1997; McLean, 2011) have a larger sample population for cases as they are retrospectively using previously collected data from sexual assault exams to compare to new recruits for their control group. The older of the two studies by Slaughter et al. from 1997, found 68% of the 311 reported rape victims reported between 1985 and 1993 had genital injury (Slaughter, 1997). They claim to only use a colposcopy for visualization, which was announced as a new method for forensic examiners at that time. The

definition of “injury” included vaginal and anal tears, ecchymosis, abrasions, redness, and swelling. Most studies do not include nonspecific injuries such as redness and swelling. This study has a large number of limitations: 36% of victims reported “unsure” if any sexual acts even occurred, at least 6 women were identified originally as having injuries which were later found to be persistent vascular anomaly, and a few women were menstruating at the time with no mention that abrasions identified could be due to tampon insertion. Their recruitment for the consensual group, which consisted of 75 women, included 48 who were initially rape victims but later admitted to consent according to police and 6 who were minors, making the term ‘consent’ debatable. Using these patients as controls is a serious weakness as we did not know the reason for these women recanting their original statement.

The second study, McLean et, al. more specifically identifies vaginal intercourse (McLean, 2011). This study also uses retrospective cases and prospective controls, which allows for greater inter-examiner bias. The cases were drawn from previous exams done between 1997 and 2001, while the controls were examined between 2003 and 2005. In the eight year time span it is possible that protocols for evidence collection had changed, as well as examiner expertise. This could lead to inter-examiner bias as the practitioners examining the controls were not the same as those whom examined the cases previously. They included only female cases and controls over the age of 18, presenting to examination within 48 hours of assault. Injuries were defined as bruises,

abrasions, and lacerations examined by magnified light only. Their results were very different from the first study, in that they only found 23% of all cases to have at least one genital injury though their comparison group only had 6%. This study did mention the limitations in recruiting more controls which was necessary to meet their sample size requirements given 95% confidence interval width +/-5%. They also mentioned the vast presentation time gap and age gap between the two groups. Most of their cases were examined within 11 hours of assault compared to most of the controls who were examined 12-48 hours following intercourse, and 28% of their consensual group was over age 45, while only 8% of their non-consensual group was of comparable age.

Two more recent studies (Astrup, 2013; Lincoln, 2013) have such small sample sizes that there is limited generalizability. However, these are currently the most cited studies in sexual assault injury. Both 2013 studies are prospective case-controls. The first, Astrup et.al, used 39 cases and 98 controls to confirm different patterns of injury among cases vs controls (Astrup, 2013). The control participants were volunteer college students who were given a questionnaire and then were examined by different examiners. Patients were instructed to have vaginal intercourse 48 hours before final exam, creating a bias in the intent of having sex for this study knowing what was being examined. The only significant difference between the cases and controls in injury prevalence was among the injury type of abrasion, which was only found on 5% of controls and 15% of cases. The articles does site that different methods give different results and that “no technique in

itself is superior when distinguishing trauma patterns.” They conclude that the frequency of having at least one injury was “strikingly” similar between both groups especially after toluidine blue use. Cases may have larger lacerations and abrasions than controls which may not be seen with the naked eye after consensual intercourse.

The second also highly popular study, conducted by Lincoln, et al. used 41 cases and 81 controls of women aged 18-45 years (Lincoln, 2013). They chose to only use speculum for injury detection. They clearly defined injury as bruises, abrasions, and lacerations. They concluded that 53.7% of cases had vaginal injury as compared to only 9.9% of controls and believe their results to be generalizable even after excluding dark pigmented women and women that had unclear memory of assault. Both of these excluded groups may very likely have no injury either due to differences in skin plasticity or submissiveness due to drug- or alcohol-facilitated rape. While this study’s method is most similar to the proposed study, they did mention the lack of appropriate sample size over the six year study period. The recruitment of the consensual group draws the most attention, because they chose to recruit women attending their general practitioner or ob/gyn within various settings (Lo, 2014; Astrup, 2013). While they state all providers were forensically trained to use the same protocol, the doctors examining the controls were not primarily forensic medical examiners. However, the women presenting to the hospitals for forensic sexual assault exams were seen by forensic medical officers and all were police-reported incidents. The consensual group could very likely have an

established relationship with their provider who has their medical history and would be able to exclude any regular abnormalities that would less likely be attributed to sexual contact. Weaknesses mentioned included lack of alcohol-use information for the consensual group as its effect on injury is debatable, as well as the match of consent group time between intercourse and exam.

None of these studies controlled or stratified for alcohol incorporation in the abuse. It is unclear if alcohol reduces or increases genital injury, but both have been hypothesized by accidental findings in clinical trial (Zilkens, 2017; Maguire, 2008; Lincoln, 2013). It is our hypothesis that alcohol or sedative means of force reduce injury findings greatly. With the increased use of alcohol in sexual assault, this could mean very different results in new studies which control for such.

2.4 Methods for Specific Populations

Many research studies focus on difference in injury following sexual assault within specific populations found in the previous more general studies. These factors are imperative to consider when designing a study to ensure proper control measures.

One matched retrospective cohort study from Sommers, et al. identifies an association between race (black versus white) and genital injury (Sommers, 2005). They concluded that white individuals were four times more likely to have genital injury than black individuals when defining injury as tears, ecchymosis, abrasions, redness, or swelling.

They mentioned that this could likely be due to difficulties in a SANE's ability to identify injury in different skin pigmentations. They were not however able to conclude any relationship between age and injury. A study weakness was in their age group recruitment, since they claimed hormonal changes likely cause differences in age-specific injury rates. The labels of premenopausal, perimenopausal, and postmenopausal were based on age alone and not actual medical documentation of hormonal stages.

However, another study on postmenopausal injury following sexual assault from Jones, et al. found a significant increase in the proportion of postmenopausal women, 50 years and older, with ano-genital injuries when compared to premenopausal women, 18 to 49 years (Jones, 2009). They also chose to define injuries as tears, ecchymosis, abrasions, redness, and swelling. A weakness in this study was that they excluded victims who "could not recall details of the assault," which may exclude much of the younger population that were victims of DFSA. Of course, this could have caused an even greater difference if the younger population had even lower prevalence than reported.

CHAPTER III: METHODS

3.1 Study Design & Methodology

The proposed study would use an incidence density case-control study design with frequency matching on possible confounders: race, age, and residential area by zip code. An incidence density design gives the best ability to utilize the same examiners, methods, and examiner judgement with comparable person-years for each study group. In identifying cases and controls as they occur within the same risk pool, the odds ratio can be an unbiased estimate of the risk ratio, greatly strengthening the results and their application to our study population. To use retrospective cases we would be limited to the information collected and equipment used in previous exams. Using the United States female population as the target research population, the sampling frame should be a heterogeneous sample of females within the Sexual Assault Center (SAC) service area. The outcome variable being studied of penile-vaginal intercourse is defined by patient declaration of consent (control group) or lack of consent (case group) at time of examination.

The exposure variable of injury will not include nonspecific injuries such as redness and swelling. Injuries should be defined as follows:

Bruise-discoloration due to damaged blood vessels below an intact epidermis

Abrasion-scrape or exposure of epidermis with or without bleeding

Laceration-tear or discontinuity of epidermis or dermis with or without bleeding

Injuries should be documented on a genital body diagram (Appendix: Genital Injury Documentation). Injuries should be documented as present or not for each method and participant individually. Variables such as alcohol/drug use, age, race, zip code, time of presentation to exam, and lubricant use should be defined categorically and documented during patient interview (Appendix: Interview for Vaginal Injury following Intercourse). Last menstrual period, medication, and surgical history will be used by the SANE to interpret injury based on menstrual cycle, medication use, and possible previous injuries due to surgery. Alcohol consumption should be no more than six hours before sexual intercourse based on alcohol metabolic rate.

All exams, both consensual and non-consensual, should take place within the same SAC to maintain internal validity for equipment use. Blinding examiners is important to limit intra-examiner bias. If examiners do not know whether the exam is for the consensual or non-consensual group, they are less likely to introduce potential subconscious bias when assessing of injury. To reduce patient discomfort and avoid legal risk of both examiners being subpoenaed (exposing the patient as part of a research study), only a secondary examiner reviewing examinations will be blinded. It is also important that each SANE performs exams across both the consensual and non-consensual groups. This can greatly reduce inter-examiner bias we see in many current study results, since each examiner may interpret findings differently.

The non-consensual group will be initiated and examined as usual SAC protocol except for the genital examination. After the initial exam proceeding, the patient will be given the consent form for study and interview questions will be addressed if the items have not already been addressed during the initial sexual assault exam proceedings (Appendix: Consent Form and Interview for Vaginal Injury following Intercourse). The designated SANE performing the genital exam will collect evidence and take photographs as they would for any sexual assault exam to maintain proper documentation of injuries and/or findings at each step of the exam. Any study interview and injury documentation will be completely separate from any official case exam records as not to be part of possible subpoena and risk identification of patient in research study.

Consensual group patients will be screened over telephone for inclusion and exclusion criteria and asked to come to the SAC to be interviewed and examined in a SANE exam room. One of the designated SANES for the research study will conduct the interview and genital exam. Due to the lack of criminal investigation, controls will only be asked to participate in the genital exam. Lack of evidence collection and assault details allows the initial examination SANE to know which study group these patients belong. The SANE will take genital photographs as they would for any sexual assault exam to maintain proper documentation of injuries and/or findings at each step of the exam.

To introduce examiner blinding, a second SANE who is not performing any genital exams for the study will review injury documentation and photography for each case

without knowing which study group the patient belongs. They may add any injuries findings that they believe were missed during initial exam.

Each exam must follow the same strict genital exam routine and order. Digital photographs for injury detection using a forensic camera may be used in place of, or in conjunction with, colposcopy in below steps. Photography must be used after toluidine blue dye as well for secondary evaluation. Swabbing of evidence per jurisdiction protocol may be taken as deemed necessary for cases only at any step in the examination as listed below:

1. Initial findings of genital presentation and injuries with macroscopic visualization.
2. Colposcopy of external genitalia and perineal area: perineum, labia majora, labia minora, clitoral hood and surrounding area, perurethral tissue/urethral meatus, hymen, fossa navicularis, and posterior fourchette.
3. Apply toluidine blue on external genitalia using Forensic Blue Swabs, produced by National Forensic Nursing Institute.
4. Speculum insertion and examination for internal genitalia: vaginal canal and cervix.
5. Colposcopy with speculum inserted.

No previous studies examining consensual patients alongside non-consensual victims have used all three methods to examine their patients. These three methods have been identified as beneficial in examining sexual assault and injuries (White, 2013; Kelly,

2013). The order in which these are to be used is of great importance. It has been suggested that toluidine blue dye should be used last as it can reduce the visibility of bruises, however in forensic investigation it is standard to use toluidine blue dye before speculum insertion to confirm any lacerations found with toluidine blue dye were not caused by insertion (Zink, 2007; Lincoln, 2013).

3.2 Study Population & Recruitment

To be eligible for study inclusion, all patients must be over the age of 18 but pre-menopausal, present with absence of menses or pregnancy, and having participated in penile-vaginal intercourse 72 hours before the exam. Menses can make it difficult for examiners to identify genital injury that is undoubtedly from intercourse rather than tampon use. For patient safety during speculum exams, pregnant participants are also excluded. Cases will also be excluded if consensual intercourse occurred between assault and exam presentation.

The victim may or may not have clear memory of sexual assault as long as there is minimal doubt of vaginal penetration as determined by research leads or examiner, based on sexual contact details and/or medical symptoms prior to physical exam. As stated previously, research suggests that 72 hours is optimal time frame to detect injury, but according to National Protocol for Sexual Assault Medical Forensic Examination, many jurisdictions have larger windows of examination. Seventy-two hours is more

generalizable to those presenting to SAC and also gives the research team a better opportunity to recruit enough participants.

The difference of proportions formula for case-control studies was used to calculate sample size.

$$N = (r+1/r) * [(p) (1-p) (Z_{\beta} + Z_{\alpha/2})^2 / (p_1 - p_2)^2]$$

The difference of proportions to disprove would be an assumed baseline prevalence of 10% of women having injury after consensual sexual intercourse and 18% of injury after rape with a minimum odds ratio of 2 and sufficient power (80%) at 0.05 significance.

The sample size requirement is about 300 participants for each group.

A Sexual Assault Center covering Northwest Atlanta averages 15 victims a month, indicating that this study could take at least 20 months to complete. This would also depend on examiners availability to complete an average of 30 examinations per month.

Controls will be frequency matched to cases based on age, race, and zip code of residence. This consensual group will be recruited from local fertility and women's health clinics presenting for any procedure that does not include a genital exam. Patients will be given information on inclusion criteria and an opportunity to contact the research team for telephone screening. Screening will ensure that the patient meets the inclusion criteria and that the intercourse commenced prior to knowledge of study. The patient will

need to present to the SAC within the 72-hour time frame for interview with research team and genital exam by designated SANE.

Cases are those that present to the SAC either by police report or non-report (without police report, voluntarily initiated exam).

3.3 Data Management & Analysis

Data will be recorded on paper. Participants will be assigned a random study ID number and no patient identification will be recorded. Interview questions will be recorded as categorical values to ensure quality assurance, and injury documentation must be drawn on genital body diagrams. Once data is reviewed by the second SANE, it cannot be edited once that examiner is made aware of participants study group. Injury presence will be determined after completion of examination and review. If injury is detected in either phase, injury is determined as present.

Data will be entered into secure database and statistical software by research team after all examinations have been completed. Single entry of data will require validation by research lead. Only non-SANE research team will have study IDs matched to participant group to prevent second SANE reviewer internal bias.

Participants who wish to withdraw their consent from the study should be replaced with a comparable participant. Any participant who wishes not to give demographic information needed should also be removed from analysis and reported as attrition.

The primary statistical endpoint is difference in proportion and prevalence odds ratio of injury between the two groups calculated from the number of participants with injury documented on the injury documentation forms from each group. The secondary endpoints will include the odds ratio of injury for each variable based on number of participants with injury based on injury documentation forms as well as interview questionnaire and demographic information.

3.3.1 Univariate analysis

Proposed analysis of descriptive statistics will include univariate analysis of variables composing case and control groups to ensure comparability between them.

Table 1. Characteristics of study participants

Variable	Category	Cases		Controls	
		N	%	N	%
Age	18-19				
	20-29				
	30-39				
	40+				
Race	White				
	Black				
	Hispanic				
	Other				

Zip Code	<i>dependent on SAC service area</i>				
Presentation Time	0-23 24-47 48-72				
Alcohol/Drug Use	Yes No				
Lubricant Use	Yes No				

3.3.2 Bivariate analysis

To compare the odds of injury for consent vs non-consent, the prevalence odds ratio for each group will be calculated.

The odds ratio confidence intervals will be analyzed to identify the significance of injury to study group.

Two-proportion z test will also be utilized to compare the equality of proportions between the consensual and non-consensual proportions of injury using a two-tailed test, with a significance level of 0.05.

Null hypothesis: $P_1 = P_2$

Alternate hypothesis: $P_1 \neq P_2$

Table 2. Prevalence of any genital injury for cases and controls

	Non-Consensual	Consensual	Total	Odds Ratio (95% CI)	P-value
Injury					
No Injury					
Total					

To compare the prevalence of injury in relation to specific variables, the odds ratio of the odds of injury among each strata and group will be calculated along with the 95% confidence interval.

Table 3A. Prevalence of severe injury for cases and controls

Injury Severity	Non-Consensual	Consensual	Total	Odds Ratio (95% CI)	P-value
Required medical attention					
Did not require medical attention					
Total					

Table 3B. Prevalence of injury found at each phase of study

	Non-Consensual	Consensual	Total	Odds Ratio (95% CI)	P-value

Initial Exam					
Review of Exam					
Total					

Table 3C. Prevalence of total genital injury found by different methods from exam and review

Method			Total	Odds Ratio (95% CI)	P-value
	Non-Consensual	Consensual			
Naked Eye Visualization				1.0 (Ref)	
Toluidine Blue					
Colposcopy					
Speculum					
Total					

Table 3D. Prevalence of total genital injury by race

Race			Total	Odds Ratio (95% CI)	P-value
	Non-Consensual	Consensual			
White				1.0 (Ref)	
Black					

Hispanic					
Other					
Total					

Table 3E. Prevalence of total genital injury by age

Age			Total	Odds Ratio (95% CI)	P-value
	Non-Consensual	Consensual			
18-19				1.0 (Ref)	
20-29					
30-39					
40+					
Total					

The variable of alcohol/drug consumption was determined in study design as a possible confounding factor that could not be matched in study sampling and must be addressed in analysis by stratification. The Cochran–Mantel–Haenszel test will be used to determine the odds ratios.

Table 4A. Prevalence of total genital injury for cases verses controls stratified by substance use

	Total (T)	Odds Ratio	P- value

				(95% CI)	
		Non- Consensual	Consensual		$OR_{M-H} = \frac{\sum_j a_j d_j / T_j}{\sum_j b_j c_j / T_j}$
Alcohol/Drug Use	Injury	A ₁	B ₁		
	No Injury	C ₁	D ₁		
No Alcohol/Drug Use	Injury	A ₂	B ₂		
	No Injury	C ₂	D ₂		

Because the consensual group can confirm that penile-vaginal penetration occurred, it is also important to compare alcohol's possible confounding effects on this group alone.

This can identify that alcohol in fact affects the body's response to trauma rather than the possibility that those intoxicated in rape may have differing rates of injury due to reasons they cannot remember and are not a direct consequence of physiological response to substances.

Table 4B. Prevalence of total genital injury for substance use in each group

		Alcohol/Drug Use	No Alcohol/drug Use	Total (T)	Odds Ratios (95% CI)	P-value
Consensual	Injury	A ₁	B ₁			
	No Injury	C ₁	D ₁			
Non-Consensual	Injury	A ₂	B ₂			
	No Injury	C ₂	D ₂			

The variables lubricant use and presentation time following sexual assault are both possible effect modifiers for finding injury and will thus be stratified. Testing for the heterogeneity of effects for these variables is also important to understand their effect on injury rate.

Table 5A. Prevalence of any genital injury for cases vs controls stratified by exam presentation time frame.

		Non-Consensual	Consensual	Stratified OR	OR*
Presentation ≤48h	Injury				
	No Injury				
Presentation	Injury				

>48h	No Injury				1.0 (Ref.)
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*no injury & >48h as reference

Table 5B. Prevalence of any genital injury for cases vs controls stratified by lubricant use.

		Non-Consensual	Consensual	Stratified OR	OR*
Lubricant Use	Injury				
	No Injury				
No Lubricant Use	Injury				
	No Injury				1.0 (Ref.)

*no injury & no lubricant use as reference

3.3.3 Multivariate analysis

Using a stepwise logistic regression model with χ^2 statistic 0.05 for inclusion, we can assess the relationship between changes in consent status, age, race, method, presentation time, alcohol and lubricant use on occurrence of injury. Alcohol and lubricant use pose the risk of interaction, and thus their interaction will be examined in relation to injury as well.

$$\text{Log Odds: } \ln(p/1-p) = \beta_0 + \beta_1\text{CONSENT} + \beta_2\text{AGE} + \beta_3\text{RACE} + \beta_4\text{METHOD} + \beta_5\text{TIME} + \beta_6\text{ALCOHOL} + \beta_7\text{LUBRICANT} + \beta_8\text{ALCOHOL}*\text{LUBRICANT}$$

3.4 Ethics and Informed Consent

Each patient should be given a chance to read and discuss written and verbal detailed information about the study prior to consent. Example of consent and information form can be found in the Appendix. SANEs must also explain procedures with patients as the examination is being done to ensure patient comfort and continued verbal consent.

Patients from both groups are encouraged to discuss with their examiner the findings during exam or photos taken as the exam is under their control and direction. All patients will be advised to follow-up with a women's health provider following examination. For safety considerations, if the examiner notices a health risk to the patient during exam, the patient will be informed of concern and referred to their regular provider for follow-up care.

To maintain patient privacy, all data will be de-identified and stored securely where only the research team has access. The dissemination of results will never include any patient identifying information or photographs. All patients must be made aware how any evidence and information will be tracked and when it will be destroyed.

To maintain quality assurance, interview and diagram forms should be easily read and interpreted. All variables indicated are categorical. SANEs are allowed to review their documentation post exam, until the second SANE begins their review.

SANEs administering the genital exam may not review their documentation with another examiner with any intention to alter findings based on peer review. Furthermore, all examiners should have the same baseline training and ideally continued education in colposcopy, SANE-A, and toluidine blue dye use.

To maintain evidence integrity for each case, SANE must never leave sight of evidence and follow jurisdiction policy for drying, packaging, labeling, and sealing any evidence. Photos of control patients must be deleted and destroyed at end of research study as agreed upon with study participant.

3.5 Limitations

Limitations to this study design are recall bias relying on both patient groups to give the correct information. This may be particularly prevalent in the case group because we are not following the police cases to identify if the alleged sexual assault cases are confirmed or prosecuted.

Adding DFSA cases decreases the bias of exclusion of a very important variable when identifying injury in rape due to the possible physiological component these substances have during trauma. However, if memory is compromised, we cannot be certain that penetration was with a penis.

Selection bias for controls is also a possibility based on the socioeconomic status of the women that may regularly visit a women's health provider or fertility clinic for certain procedures or volunteer for a genital exam study.

The last obvious limitation is trying to examine natural intercourse without interference within 72 hours. Recruitment for the consensual group is therefore difficult. Research has mentioned the limitations found in the volunteer being approached both prior and post sexual intercourse, as this can alter the natural sexual encounter events and thus the findings. Approaching women post sexual intercourse has been defined as decreasing this bias (Astrup, 2015).

CHAPTER IV: CONCLUSION

4.1 Public Health Implications

The implications of these results have the potential to change the way injury is portrayed in the legal arena. Due to strength of the study design, the odds ratio obtained for the primary objective of genital injury found in consensual and non-consensual patients can estimate the ratio of risk of genital injury found in victims of rape to participants of consensual intercourse. Exposure to injury can occur in either group, but identifying the significance and probability to be able to quantify the likelihood of consent status given injury in a court of law would be substantial. However, if we fail to reject the null hypothesis that there is no significant difference between the proportions of injury among either consent group, then we can confirm that injury or lack thereof cannot predict consent status.

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APPENDIX:

Document 1. Consent and Information Form

Vaginal Injury after Sexual Intercourse Research Study Consent

You are being asked to take part in a research study of vaginal injury after vaginal intercourse. We are asking you to take part because you were identified as an ideal candidate for the study. Please read this form carefully and ask any questions you may have before agreeing to take part in the study.

What is the study about? The purpose of this study is to identify the prevalence of vaginal injury after consensual versus non-consensual intercourse. This will assist in educating our research, clinical, and legal community when assessing and interpreting the injury or lack of injury in sexual assault victims.

Participants must:

- Be over the age of 18
- Pre-menopausal
- Not currently menstruating or pregnant
- Have had penile-vaginal intercourse within the last 72 hours

What we will ask you to do: If you agree to be in this study, we will conduct an interview and genital exam. The interview will include questions about the sexual contact, your demographics, and your medical history. The genital exam will include a colposcopy, speculum exam, toluidine blue dye, “evidence” collection and digital photography with a forensic camera. The examiner is trained in forensic medical exams and is blinded to the patient group in which you are assigned. She will perform the genital examination exactly the same for a consensual intercourse volunteer as she would for a sexual assault victim.

Colposcopy – A colposcope is a magnifying and illuminating device which the examiner will use to magnify your external vaginal area as well as your cervix, vagina, and vulva. This allows the examiner to see any injuries much closer than she would with the naked eye.

Speculum – A speculum is a hollow cylindrical tool inserted into the vagina to expand the vaginal walls. This allows the examiner to better view your vagina and cervix & to collect any swabs from the cervix (much like is used for a pap smear).

Toluidine Blue dye – Toluidine Blue is a nuclear staining dye; which means it gets absorbed by a cell's nucleus. Most superficial vaginal cells, however, do not have nuclei. After removal of the dye, if any cells are stained this means a tear or injury is present, exposing your deeper cells which do have nuclei.

Forensic Photography – With a mega-pixel camera used in forensic investigation, examiners may take photographs of injuries they see in your external and internal vaginal area. Much like the colposcope, this acts as a source of magnification for the examiner.

Risks and Benefits: There is a risk you may find questions about your personal sexual history to be sensitive and the physical exam uncomfortable.

The benefit is peace of mind by being examined for genital injury by a certified professional in women's sexual health.

Your answers will be confidential and any photographs destroyed at conclusion of study.

The records of this study will be kept private. Any published report will not include any information that will make it possible to identify you. Research records will be stored in a locked file and only the research team and examiners will have access.

Taking part is voluntary: Taking part in this study is completely voluntary. If you decide you do not want to take part in this study, it will not affect your relationship with your current health care provider or facility. If you decide to take part, you may stop the exam and withdraw at any time.

If you have questions: Please ask any questions you have now. If you have questions later please contact the research team.

Statement of Consent: I have read the above information, and have received answers to my questions I asked. I consent to take part in the study.

Signature _____ Date _____

Printed Name _____ Date _____

In addition to agreeing to participate, I authorize the forensic-medical examiner to perform the procedures described above. I understand I can withdraw my consent at any time.

Signature_____ Date_____

Signature of person obtaining consent_____ Date_____

Printed Name of person obtaining consent_____ Date_____

Document 2. Interview Questionnaire

Interview for Vaginal Injury following Intercourse

Research Group: _____ Research ID: _____

Date/time of Exam: _____

Patient Information:

Age: _____

Race: _____

Zip code of residence: _____

Surgical/Medication History:

LMP: _____

Sexual Contact Information:

Date/time of intercourse: _____ Presentation time frame: _____

Was alcohol or drugs consumed prior to intercourse: YES / NO

Was lubricant used? YES / NO

INTERVIEWER Signature: _____ **Date:** _____

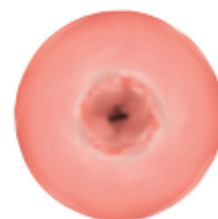
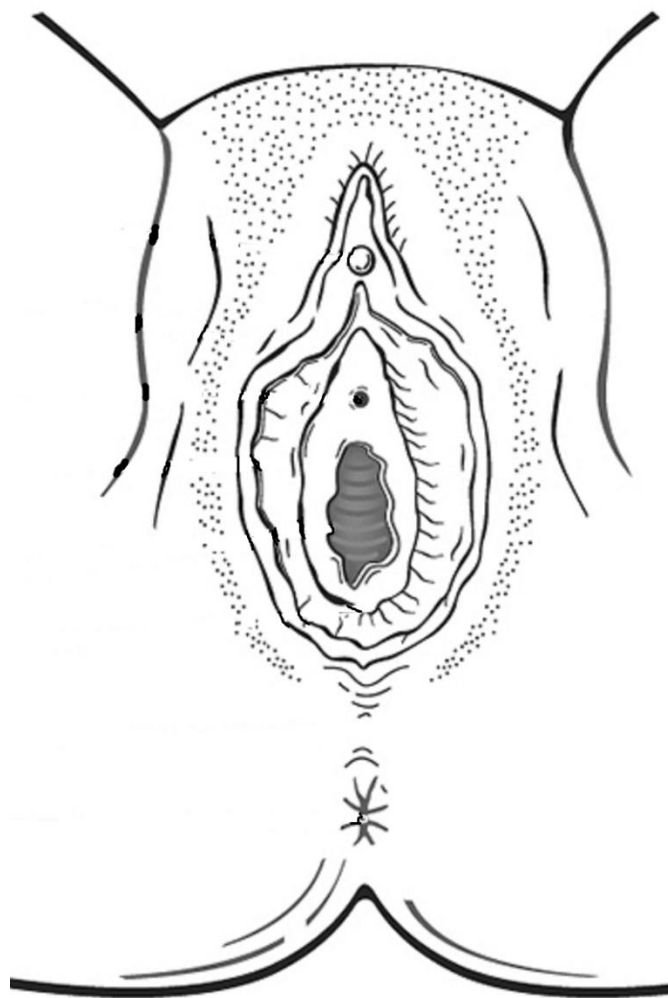
INTERVIEWER Printed Name: _____ **Date:** _____

Document 3. Genital Exam Injury Documentation

Genital Injury Documentation

Study# _____

1 of 4 - NAKED-EYE VISUALIZATION



Circle one: Initial Exam / Review of documentation

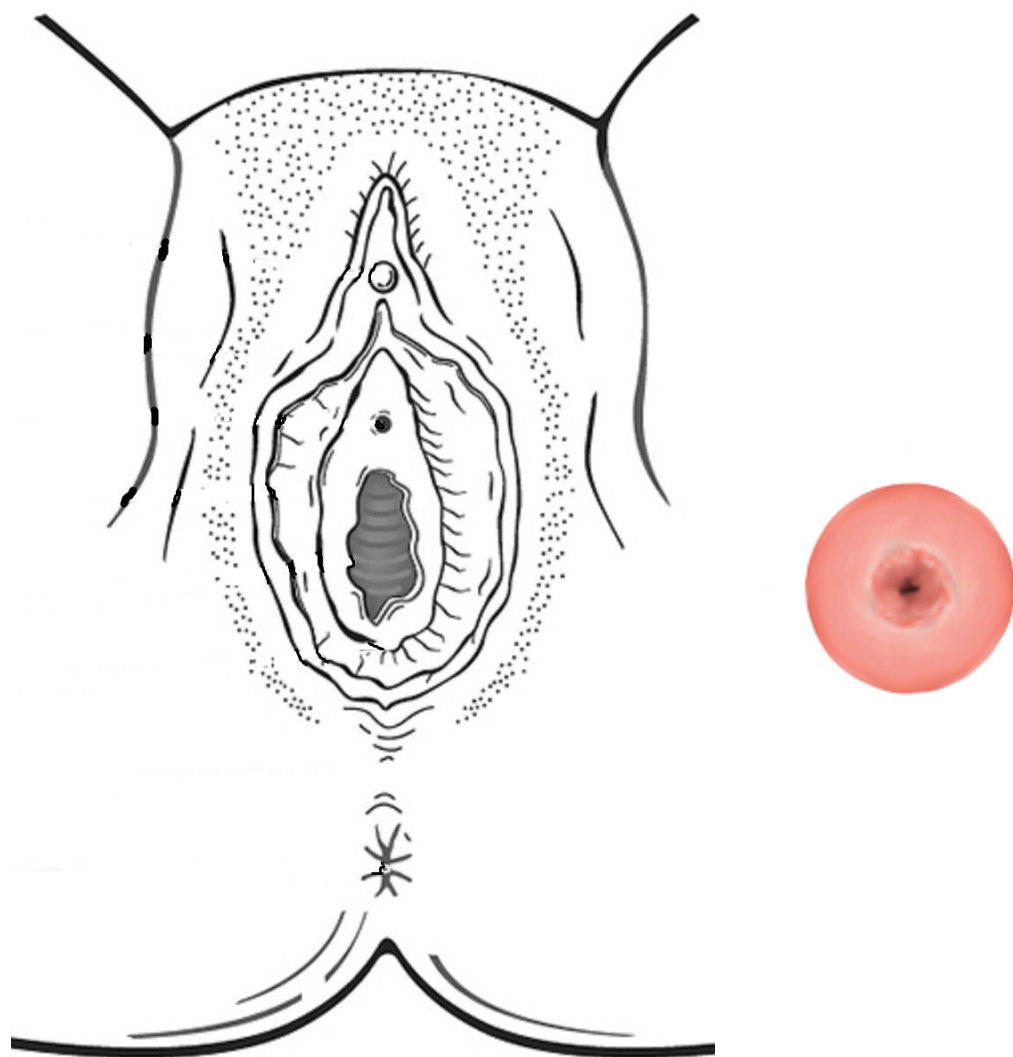
Injury detected with naked eye? YES / NO

Injury requires medical attention? YES / NO

Genital Injury Documentation

Study# _____

2 of 4 – COLPOSCOPY



Circle one: Initial Exam / Review of documentation

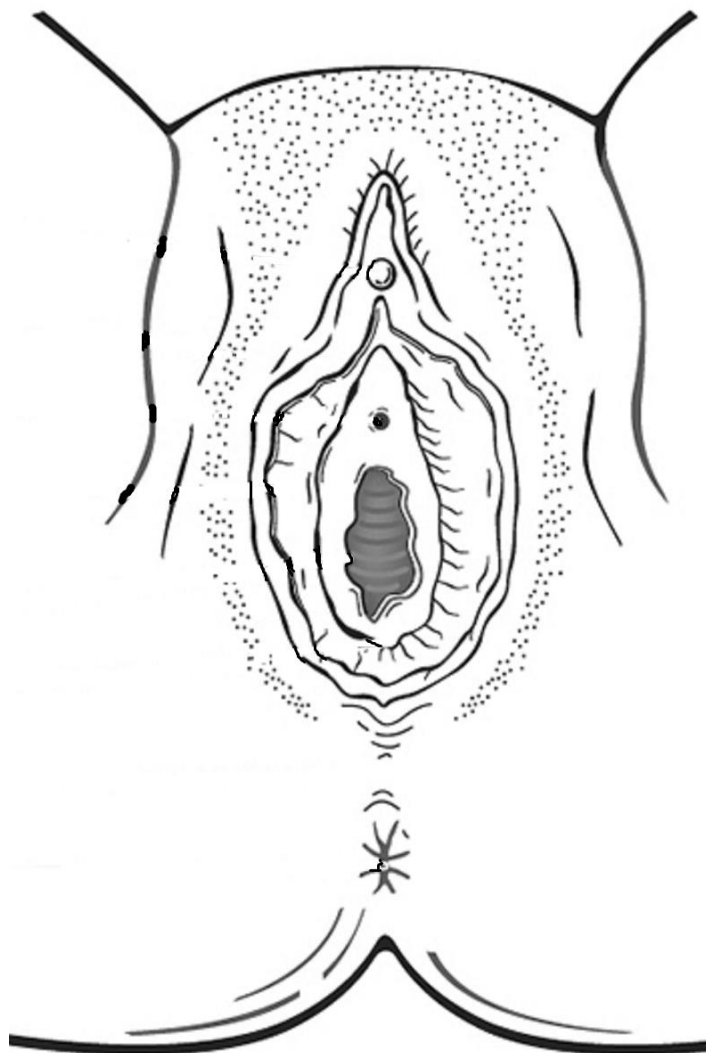
Injuries detected w/colposcope ONLY, after naked-eye and speculum? YES / NO

Injury requires medical attention? YES / NO

Genital Injury Documentation

Study# _____

3 of 4 – TOLUIDINE BLUE DYE



Circle one: Initial Exam / Review of documentation

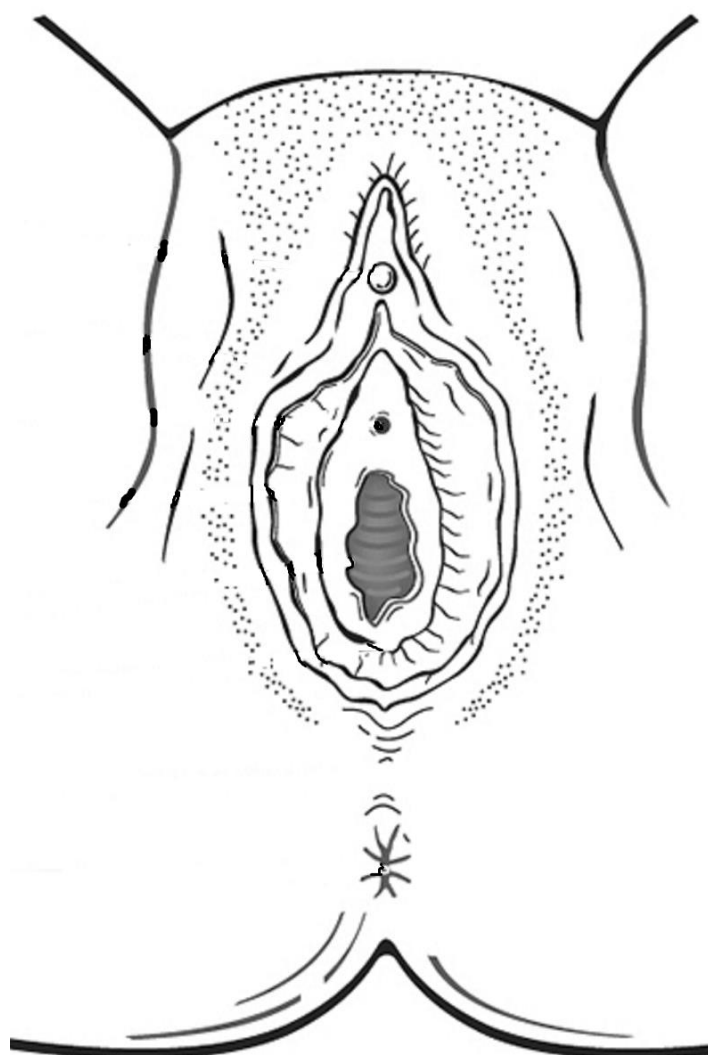
Injuries detected w/toluidine blue dye ONLY? YES / NO

Injury requires medical attention? YES / NO

Genital Injury Documentation

Study# _____

4 of 4 – SPECULUM



Circle one: Initial Exam / Review of documentation

Injuries detected w/speculum ONLY? YES / NO

Injury requires medical attention? YES / NO