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The Practical Journal for Emergency Physicians

Emergency Medicine Reports

Volume 23, Number 6 March 11, 2002

Evaluating Pediatric Sexual Abuse in the Emergency Department

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Sexual abuse affects children irrespective of age, sex, socioeconomic class, or geographic location.[1,2,3] In 1999, there were approximately 1.07 million substantiated cases of child maltreatment. Of the substantiated cases, 46% were due to neglect, 18% to physical abuse, and 9% to sexual abuse.[4] In 1998, more than half of sexually abused children were abused by males.[5] Heterosexual males who are known to their victims continue to constitute the majority of pediatric sexual abuse perpetrators.[6,7]

Although fewer than 1% of victims die as a result of sexual abuse, the long-term effects of sexual abuse are far-reaching.[5,8] The investigation of the association between childhood sexual abuse and adult health risk behaviors has been examined in the primary care setting. Increased numbers of childhood exposures to abuse have been correlated with multiple risk factors for the leading causes of death in adults.[9] Moreover, abused children become adults who often die prematurely because of disproportionate health risk behaviors.[9,10] (See Figure 1.) Among conditions linked to childhood sexual abuse, such common disorders as adulthood depression, morbid obesity, ischemic heart disease, cancer, and chronic lung disease have been shown to have a graded relationship with childhood maltreatment exposures.[10]

The emergency department (ED) evaluation of a child for sexual abuse can be extremely anxiety-provoking and intimidating for the victim, the child's family, and the ED staff. The consequences of misdiagnosis of sexual abuse can be damaging from two perspectives: over-diagnosis and failure to diagnose. Over-diagnosis of sexual abuse has been correlated with the inexperience of the practitioner performing the evaluation and can be devastating to everyone involved.[11,12] On the other hand, failure to recognize signs and symptoms of sexual abuse can result in increased risk for further abuse and injury to the child.[12,13]

As a result, knowledge and awareness of the behavioral and physical signs and symptoms of sexual abuse is critical to the detection of sexual abuse in the emergency setting. Accordingly, emergency physicians should be familiar with techniques for pediatric forensic evidence collection as well as basic principles of pediatric genital evaluation. Knowledge of prophylaxis and treatment recommendations for sexually transmitted disease (STD) in children also is mandatory.

With these issues in focus, the purpose of this review is to provide a systematic approach to the diagnosis, evaluation, and management of children suspected of having been victims of sex-

ual abuse. The objective is to outline strategies for assessment and intervention that make it possible for emergency physicians to provide compassionate and comprehensive care to a sexually abused child.

— The Editor

Definition of the Problem

C. Henry Kempe is credited with the astute recognition of child sexual abuse as a significant hidden pediatric problem.[14] Sexual abuse was originally defined as the involvement of dependent, developmentally immature children and adolescents in sexual activities that they do not fully comprehend, to which they are unable to give informed consent, or that violate the social taboos of family roles.[1] Current definitions of child sexual abuse remain inclusive of the original definition. In the past, criminal statutes have defined and classified sexual abuse as misdemeanors or felonies, depending on the degree of penetration of body orifices or whether physical or psychological force was used.[15]

Environmental risk factors for child abuse include economic deprivation, poor housing, unemployment, and illness. These risk factors correlate closely with those patients likely to seek care in an ED.[13] A working knowledge of child sexual abuse enables the emergency physician to provide valuable assistance in a child's recovery from a traumatic, devastating event. It is critical that the emergency physician remain cognizant that sexual abuse affects patients of all socioeconomic levels. When available, organized response teams consisting of nursing, social work, and law enforcement professionals who have knowledge and expertise in pediatric sexual abuse may be utilized. Pediatric Forensic Assessment Teams (FACT) or Sexual Assault Nurse Examiners (SANE) help to maximize the efficiency of a busy ED and contribute to expanded, effective management of these very sensitive cases.[16,17] Though the short-term benefit of such programs in the ED is evident, outcome data is needed to define the actual long-term success of these programs.[18]

Presentation

Families often present to the ED immediately following a child's disclosure of sexual abuse or immediately following direct parental observation or discovery of abuse.[19] Sometimes a parent or caretaker simply will bring a child to the ED because of "suspicious" behavior and/or concern that someone has sexually abused their child. Regardless of the presentation, it is critical for the emergency physician to involve the appropriate social service, child protective, or law enforcement agency. A sexual abuse evaluation rarely is overlooked in the child who directly discloses abuse. In these cases, reports are made to appropriate agencies, a physical evaluation is performed, and forensic evidence is collected when indicated. It is important, however, that the emergency physician be familiar with non-specific complaints and other presentations of sexual abuse that may not involve any form of disclosure by the child.[20,21] In the sexual abuse assessment, there are a number of behavioral, complaint, and exam indicators that may suggest sexual abuse.[11,21-24] (*See Tables 1 and 2.*) Though the behavioral indicators occasionally are correlated with sexual abuse, none independently are diagnostic of sexual abuse. A great number of physical exam findings have been correlated with sexual abuse; however, only a small number of physical exam findings independently are diagnostic of sexual abuse.[19] Child sexual abuse often occurs in the context of other family problems such as substance abuse and family violence.[13]

Often, the parental, social service, or law enforcement expectation is that the emergency physician definitively confirms or rules out sexual abuse. Emergency physicians should not give in to this demand for an immediate, definitive diagnosis. It is more appropriate to emphasize that there are very few findings that definitively diagnose sexual abuse; that normal or nonspecific findings do not exclude a diagnosis of abuse; and

Emergency Medicine Reports™ (ISSN 0746-2506) is published biweekly by American Health Consultants, 3525 Piedmont Road, N.E., Six Piedmont Center, Suite 400, Atlanta, GA 30305. Telephone: (800) 688-2421 or (404) 262-7436.

Vice President/Group Publisher: Brenda Mooney
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Marketing Manager: Schandale Kornegay
GST Registration No.: R128870672

Periodical postage paid at Atlanta, GA. **POSTMASTER:** Send address changes to ***Emergency Medicine Reports***, P.O. Box 740059, Atlanta, GA 30374.

Back issues: $28. Missing issues will be fulfilled by customer service free of charge when contacted within one month of the missing issue's date.

Multiple copy prices: One to nine additional copies, $323 each; 10 to 20 additional copies, $287 each.

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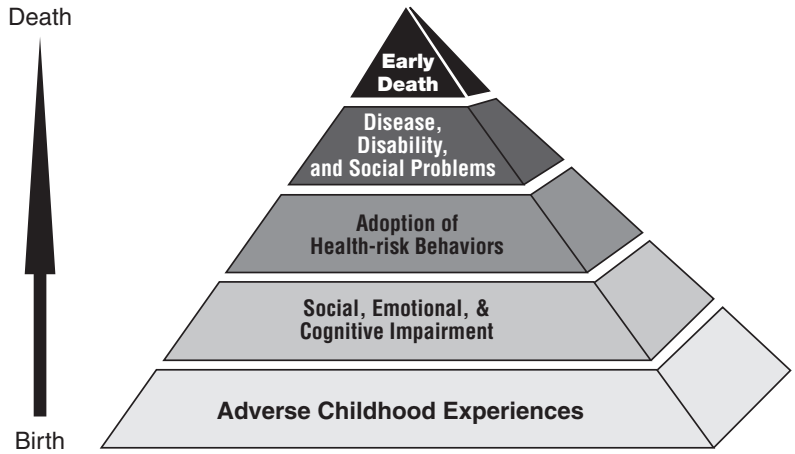
Figure 1. Potential Influences of Child Abuse Throughout Lifespan



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that suspicious findings may have other causes in addition to sexual abuse.[12,13,21]

History and Interview

The history of sexual abuse may be very difficult to obtain from a child. An understanding of the child's developmental and emotional state is critical. A full medical history and detailed review of systems should be obtained. If sexual abuse is the leading diagnostic consideration, it is recommended that the child be interviewed as few times as possible. A forensic specialist trained to interview children is most desirable. Anyone not trained in forensic interviewing should limit detailed questioning of the child.

For the purpose of the medical evaluation, it is appropriate for the emergency physician to ask open-ended, non-leading questions and to make reassuring, supportive statements. Generally, questions that begin with the words "Is, Are, Were, Do, Did" have the potential for being considered leading questions. It is important to quote the child directly when recording responses.[25,26] (*See Table 3.*) Nods and other gestures of reassurance should be provided for the child. Express to the child that what he/she says is believed to be true. Avoid showing disgust, shock, or disbelief regarding details of the child's disclosure. Children are more likely to change statements and give incorrect information with repeated questioning or other negatively interpreted gestures from the interviewer. The child who has been interviewed multiple times may interpret this as disbelief and start to embellish facts in an attempt to please interviewers.[27,28] Whenever possible, the child should be interviewed alone and never in the presence of the alleged perpetrator. It is important that caregivers not be interviewed regarding sexual abuse events in the presence of the child to avoid influencing changes in the child's disclosure.[27,28] Caregivers also should be questioned privately regarding family history of sexual abuse and prior incidences of abuse in the child.[28]

Sexual Abuse Examination

Many children who present to the ED with a disclosure of sexual abuse present several days or weeks after the event. In these cases, it is most appropriate to make a report to the appropriate child protection agency, establish that it is safe for the child to go home, and refer the child to a regional center specializing in child sexual abuse. In cases of disclosures or presentations as the result of an acute event, the emergency physician should be knowledgeable and prepared to perform a sexual abuse examination. A general physical examination of the child always should be performed prior to examination of the perineum, genitalia, and anus. It is important to convey to the child that all aspects of the physical examination are of interest to the examiner.

The examination of the genitalia should be done as gently as possible. A person not suspected as the perpetrator and trusted by the child represents an acceptable additional presence with the child during the examination. The examination area should be comfortable and child-friendly. It is important that the physical examination of a child not result in additional trauma.[29] Proceed in a slow, calm manner and allow time for the child to ask questions and understand what is happening. Conscious sedation or general anesthesia should be considered in the excessively uncooperative, traumatized patient, particularly if there is a high suspicion for physical evidence, anogenital trauma, or persistent bleeding. Skilled examiners who take the time to talk the child through the examination, however, rarely need to use conscious sedation. If the presentation is non-acute (disclosed events occurred prior to the previous 72 hours), then re-scheduling the exam for another time is acceptable.[19]

The physical assessment should start with simple observation. Note the child's general appearance and stage of development.[13] (*See Table 4.*) Examination of the perineum, hymen, and vagina in females and the penis, scrotum, and perineum in males should be followed by an anal examination in both. The majority of abused children have normal or non-specific physical examinations.[30,31] It is imperative to recognize that a normal genital and/or anal examination does not exclude sexual abuse. Because the examination of the abused child rarely differs from that of the nonabused child, it has been recommended that legal experts focus on the child's history as the primary evidence of abuse.[31] The physician's observation of the child's behavior, the history/disclosure, the review of systems for behavioral indicators of sexual abuse, and the physical exam indicators of sexual abuse become the critical aspects for identifying sexual abuse in the absence of conclusive physical exam findings.

Table 1. Behavioral Indicators of Sexual Abuse[21-24]

BEHAVIORS SUGGESTIVE OF SEXUAL ABUSE	
• Abrupt change in personality	• Excessive fear
• Age-inappropriate knowledge of sexual acts	• Problems at school
• Aggression	• Sexual behavior
• Appetite disturbances	• Sexual perpetration on others
• Clinging	• Self-injury
• Depression	• Sleep disturbances
• Eating disturbances	• Social problems with peers
• Low self-esteem	• Substance abuse
• Neurotic or conduct disorders	• Suicidal ideation
• Nightmares	• Suicide attempt
• Phobias	• Temper tantrums
	• Withdrawal

Table 2. Complaint/Exam Indicators of Sexual Abuse[21-24]

COMPLAINTS/FINDINGS SUGGESTIVE OF SEXUAL ABUSE	
• Abdominal pain	• Chronic pain
• Anogenital bleeding	• Dysuria
• Anogenital discharge	• Encopresis
• Anogenital itching	• Enuresis
• Anogenital pain	• Foreign bodies in vagina or rectum
• Anogenital trauma	• Pregnancy
• Bruises to hard palate	• Recurrent urinary tract infection
• Bruises to soft palate	• Sexually transmitted disease
• Chronic constipation	• Vulvovaginitis

Physical Examination Techniques

It is acceptable for pubertal adolescent females who have achieved menarche to receive speculum examinations. In circumstances of sexual abuse, however, it may not be well-tolerated by the adolescent who has never undergone a speculum examination. Speculum examinations are not indicated in prepubertal females. Techniques for examination of children without a speculum provide adequate visualization of many structures. These techniques also can be used in pubertal females who cannot tolerate a speculum exam.[6,29]

Supine Frog Leg Position. This positioning can be performed with the child lying on an examination table or sitting comfortably in a caretaker's lap. The plantar surfaces of the feet can be placed together while the hips are abducted and externally rotated. A child facing the examiner in a caretaker's lap can tolerate abduction of the legs so the child's feet rest on the outer aspect of the caretaker's legs. The supine frog leg position and its variations allow adequate visualization of the perineum in females and males.[6,29]

Labial Separation. As the child relaxes in the supine frog leg position, gently separate the labia. *(See Figure 2.)* This does not require significant traction or tension on the perineum. Gentle separation provides visualization of the hymenal orifice.[29,32]

Labial Traction. With the child in the supine frog leg position, gently grasp the labia majora and apply gentle traction outward and downward. *(See Figure 3.)* This will help relax the pelvic musculature, allowing maximal visualization of the hymenal orifice. The internal vaginal canal also may be visualized with this technique.[6,29]

Supine Knee-Chest. This position can be accomplished by having the child pull his or her knees to the chest. This position allows visualization of anal structures without significantly moving the child.[6,29]

Prone Knee-Chest. The child lies on the table with the anterior chest and shoulders touching the table, the knees apart, and the buttocks in the air. The back should assume a significant lordosis. The hymen is then examined by using the thumbs to separate the labia in an upward and outward motion. *(See Figure 4.)* This alternative position can be used for better visualization of the hymen and vagina. This position facilitates visualization of posterior hymenal injuries in both prepubertal and pubertal females. This position also facilitates visualization of the vaginal canal. Vaginal foreign bodies and/or the cervix also can be visualized when a child is in this position. The prone knee-chest position is important for clarifying findings noted in the supine position.[6,29] Findings identified with the child in the supine position often disappear when the child is placed in the prone knee-chest position.[32] This simple maneuver potentially decreases the rate of false positive findings for sexual abuse.[33]

Saline, Swab, and Foley Catheter Techniques. In the prepubertal female, saline can be squirted gently over the hymen to facilitate movement so that the edges can be visualized. In contrast to the prepubertal hymen, the adolescent hymen is estrogenized, thickened, redundant, and elastic. Viewing the edges of an estrogenized hymen can be challenging. A moistened saline swab can be used to visualize the edges of the thick, elastic adolescent hymen without discomfort. If a moistened saline swab does not adequately reveal the edges of the adolescent estrogenized hymen, the Foley catheter technique can be used. The Foley catheter technique allows improved visualization of the adolescent estrogenized hymen, but it is not indicated in the prepubertal female. A 12- to 14-gauge Foley catheter can be inserted gently just past the vaginal opening, and the balloon can be inflated using normal saline or air. Following inflation of the balloon, the catheter is pulled gently to expose the estrogenized hymenal edges.[34] This technique generally is well-tolerated in adolescent females as well as in adult women.

Other Specialized Forensic Exam Techniques

Many techniques have been utilized to facilitate the anogenital examination of sexually abused children. Some are controversial and have been studied minimally in children.[35] Colposcopy is commonplace in centers where frequent sexual abuse examinations of children occur. Colposcopy can increase the accuracy of

Table 3. Interview Questions[25-26]

SEXUAL ABUSE DISCLOSED

- I understand that something has happened to you.
- Do you hurt anywhere?
- Where do you hurt?
- What happened?
- Who did this?

SEXUAL ABUSE SUSPECTED

- Do you have private places on your body?
- What do you call them?
- Have you been touched in those private places? (Assign child's terminology.)
- Have you been hurt in those private places? (Assign child's terminology.)

Table 4. Tanner Staging[13]

PUBIC HAIR

Stage 1: Preadolescent. No pubic hair, or hair in pubic region is fine, like that over other areas of the body.
Stage 2: Appearance of few, long, lightly pigmented hairs. Straight or curled hair develops at the base of the penis or along the labia.
Stage 3: Hair increases in density, becomes coarse and curled, and darkens.
Stage 4: Hair is of adult color and texture but covering a smaller area, with no spread to the medial thighs.
Stage 5: Adult-like pattern

BREAST DEVELOPMENT

Stage 1: Preadolescent
Stage 2: Breast bud stage
Stage 3: Further enlargement and elevation of breast areola
Stage 4: Projection of areola and papilla to form secondary mound above the level of the breast
Stage 5: Adult stage, projection of papilla only, areola even with breast

MALE GENITALIA

Stage 1: Preadolescent
Stage 2: Enlargement of scrotum and testes, without enlargement of penis; scrotum reddens and changes texture
Stage 3: Continued enlargement of scrotum and testes, now with lengthening of penis
Stage 4: Increase in size of penis and glans
Stage 5: Adult stage

descriptions and facilitate consultation between examiners.[36] A colposcope provides superior light and magnification. When attached to a camera or video recorder, it can be used for photography or videography of the examination. Most forensically significant examination findings, however, are visible without colposcopy.[35] A hand-held otoscope can be used to provide a small field of light and magnification, and is readily available in most exam rooms.[29] The lens of an otoscope provides a reasonable degree of magnification of suspicious areas; however, it is important not to contaminate the instrument. Wood's lamp illumination has been recommended for identifying seminal fluid, but substantial shortcomings of this method have been identified. Numerous substances other than seminal fluid illuminate with use of the Wood's lamp. Therefore, Wood's lamp illumination should be used only to identify suspicious areas or specimens for more definitive forensic testing.[35] Toluidine blue dye can be used to aid in the detection of perineal lacerations. The dye is absorbed only by the nuclei of damaged epithelial cells and can be useful for the identification of small lacerations that otherwise may be difficult to detect. This technique cannot distinguish accidental injury from intentional injury.[37]

Terminology and Anatomy

The diagnosis of pediatric sexual abuse is difficult for a number of reasons. The literature has produced evidence to suggest that many physicians are unable to recognize normal and abnormal female prepubertal anatomy.[38] In addition to a potential lack of physician awareness of age-adjusted genital anatomy, there are a number of conditions that can be confused with sexual abuse.[11,39] The ability to describe and accurately document abnormalities is dependent upon the use of correct terminology.[40] It is standard nomenclature to refer to location on the hymen, anus, or perineum using positions on the face of a clock.[39] The 12 o'clock position is anatomically the most superior, and the 6 o'clock position is the most inferior. Clock-face nomenclature designation is completely useless, however, if the position of the patient is not clearly indicated. For example, 6 o'clock in the supine position becomes 12 o'clock when the same patient is placed prone. The emergency physician performing abuse evaluations on females should be familiar with the following anatomy and descriptive terminology for accuracy and consistency:

- *Clitoris*—a small, cylindric, erectile body, situated in the anterior, superior portion of the vulva, covered by a sheath of skin (clitoral hood);
- *Labia majora*—rounded folds of skin forming the lateral boundaries of the vulva (external genitalia of the female);
- *Labia minora*—longitudinal, thin folds of tissue within the labia majora. In prepubertal children, the labia minora are not completely developed and do not connect inferiorly until puberty. This area is referred to as the posterior commissure in the prepubertal female and posterior fourchette in the pubertal or postpubertal female;
- *Fossa navicularis*—concavity of the lower part of the vestibule situated posterior (inferior) to the vaginal orifice and extending to the posterior commissure;
- *Hymen*—a membrane located at the junction of the vestibular floor and the vaginal canal that partially or completely (rare finding) covers the external vaginal orifice;
- *Vaginal vestibule*—the area external to the hymen that is bordered laterally by the labia minora, superiorly by the clitoris, and posteriorly by the posterior commissure or posterior fourchette. It encompasses the fossa navicularis;

Figure 2. Labial Separation

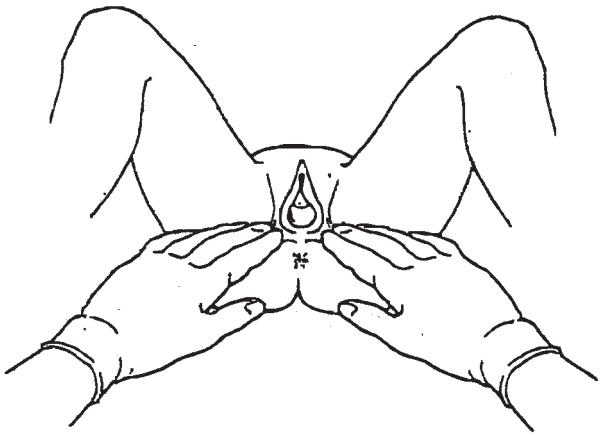


Figure 3. Labial Traction

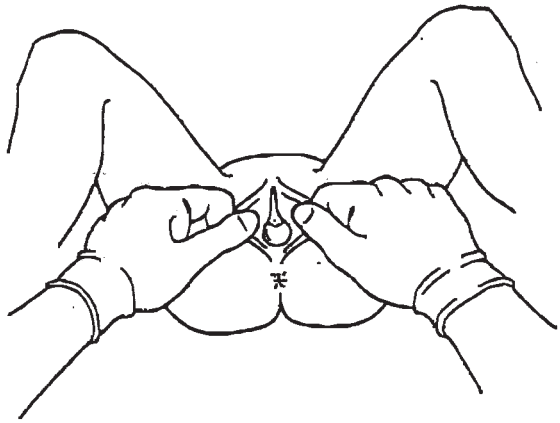
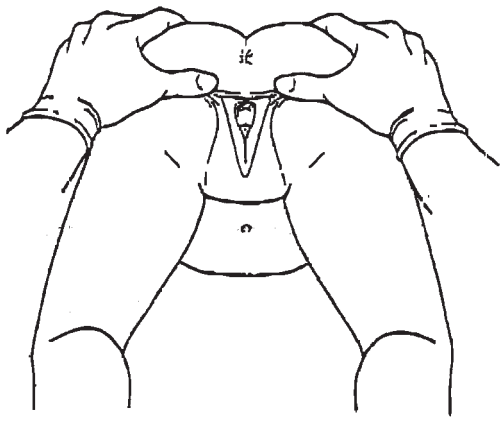


Figure 4. Prone Knee-Chest



Figures 2-4 reprinted with permission from: Nancy D. Kellogg, MD, University of Texas Health Science Center at San Antonio, 1998.

• *Vagina*—internal structure extending from the uterine cervix to the inner aspect of the hymen. It has two components, the vaginal vestibule and the vaginal canal; and
• *Urethral meatus*—external opening of the urethra from the bladder.[40]

Physical Examination Findings and Classification

Multiple research studies have been published describing the appearance of the genitalia of abused and nonabused children.[41-47] Many findings that previously were believed to be associated with sexual abuse subsequently have been determined to be present in a significant number of nonabused children.[39,46] Various classification systems for sexual abuse have been proposed.[28,33,48] Currently there is no single, agreed-upon, uniform system for classification of sexual abuse findings among child abuse specialists.[36] A simplified classification system for use by the emergency physician places findings into four categories. Normal findings represent findings commonly identified in children who never have been abused sexually.[28,33,48] (*See Table 5.*) Nonspecific findings represent findings occasionally seen in children who have been abused sexually but that also are seen in children who never have been abused sexually.[28,33,48] (*See Table 6.*) Specific or highly suspicious findings represent findings that commonly are seen in children who have been abused sexually but that occasionally are found in children who never have been abused sexually. Data related to highly suspicious findings are not sufficient to implicate sexual abuse as the only explanation.[28,33,48] (*See Table 7.*) Conclusive findings are those that have expert consensus on the definitive diagnosis of sexual abuse and constitute medical certainty for sexual abuse.[19,28,33,48] (*See Table 8.*) Unfortunately, no findings in the conclusive category can be identified by physical examination alone. When these findings are present, however, they make the diagnosis of sexual abuse a medical certainty, even in the absence of a positive history or disclosure of sexual abuse.

It has been proposed that clear evidence for penetrating trauma also be included as a category in diagnosing sexual abuse.[32] This category consists of injuries or conditions that have no explanation other than trauma to the anogenital tissues. They include acute laceration to the hymen; ecchymosis on the hymen; perianal lacerations extending (deep to) beyond the external anal sphincter; healed hymenal transections (which represent areas where the hymen has been torn through to the base so there is no hymenal tissue remaining between the vaginal wall and the fossa or vestibular wall); and absence of hymenal tissue (wide areas in the posterior/inferior half of the hymenal rim with an absence of hymenal tissue, extending to the base of the hymen). All findings must be confirmed in the knee-chest position.[33]

Evidence Collection

It generally is recommended that evidence collection on children be performed in the ED if the alleged abuse has occurred within the previous 72 hours or if there is bleeding or other evidence of acute injury. Protocols for evidence collection in pediatric sexual abuse should be established and followed. In these cases, a chain of evidence must be maintained. Collection methods and procedures vary by jurisdiction, but there are a few general principles that should be

Table 5. Findings Commonly Classified as Normal[28,33,48]

NORMAL FINDINGS	VARIANTS
• Periurethral bands	• Septate hymen
• Intravaginal ridges	• Failure of midline fusion
• Hymenal tags	• Groove in fossa
• Hymenal bumps	• Diastasis ani
• Linea vestibularis	• Perianal skin tags in the midline
• Hymenal cleft/notch in anterior half of rim	• Increased perianal pigmentation
• Urethral dilation (mild)	

Table 6. Findings Commonly Classified as Nonspecific[28,33,48]

NONSPECIFIC FINDINGS	
• Erythema of perineum	• Venous congestion
• Increased vascularity	• Venous pooling
• Labial adhesions	• Vaginal bleeding
• Vaginal discharge	• Vaginitis
• Posterior fourchette friability	• Large hymenal opening
• Thickened hymen	• Urethral dilation (moderate)
• Anal fissures	• Thickened perianal tissue
• Flattened anal folds	• Narrowed hymen
• Anal dilation	

followed. Specialized evidence recovery kits are available from law enforcement agencies. The kits usually contain necessary supplies and instructions for performing evidence recovery.[13] Recommendations for evidence collection in children if the abuse has occurred fewer than 72 hours previously is extrapolated from adult literature. In the only large study of evidence recovery kits in prepubertal children, it was concluded that general guidelines are not well suited for forensic evidence collection in prepubertal children and that swabbing the child's body for evidence is unnecessary after 24 hours. The study indicated that clothing and linens yield the majority of evidence in cases of prepubertal sexual abuse.[49]

Some centers have chosen to maintain a 72-hour rule, while others use 24 or 48 hours. Furthermore, some centers have a time rule that incorporates multiple modifiers, including the type of contact described, suspected material on exam to be sampled, and physical findings that suggest a recent act. Emergency physicians potentially could help collect more evidence for cases involving prepubertal children simply by reminding the police to search the crime scene for clothing, sheets, and towels. Pediatric FACT, SANE, or other established pediatric forensic response teams greatly assist the emergency physician and help the general flow of a busy ED when they are involved with these highly specialized cases.[16,17] The physician should establish that the child physically is safe from the alleged perpetrator if discharged home. If this is not the case, protective custody should be arranged for the child, or the child can be admitted to the hospital. In all other cases of alleged pediatric sexual abuse, it is acceptable for the emergency physician to refer the child to his or her primary care physician, a child abuse specialist, or a child advocacy center that performs these specialized exams on a regular basis.[15]

STD Testing and Prophylaxis

The yield of positive cultures is very low in asymptomatic, prepubertal, sexually abused children.[50,51] In most instances, cultures will be negative, and if positive, may not indicate new infection.[11] It is important that only "gold standard" culture techniques be used in children. Tests commonly used for adult screenings of STD (i.e., DNA probe) should not be used in children, due to reports of high false-positive rates.[11,52] Both historical and physical factors should be considered when deciding whether to obtain cultures and perform serologic tests for STDs in children. Historical criteria include the possibility of oral, genital, or rectal contact; a perpetrator known to have an STD; a sibling of the patient known to have an STD; abuse by multiple perpetrators; prior consensual sexual contact; or a history of genital discharge. Physical criteria include Tanner Stage 3 or greater; genital discharge or injury; or the presence of specific STD lesions.[11,35,50,51,53] Prophylaxis and treatment of pediatric STDs can be found in Table 9.[52,54]

Differential Diagnosis for Sexual Abuse

Most children with anogenital symptoms have some cause for their symptoms other than sexual abuse.[55] A variety of dermatologic, traumatic, infectious, gastrointestinal, urologic, and congenital conditions may be mistaken for physical findings caused

Table 7. Findings Commonly Classified as Suspicious/Concerning[28,33,48]

SUSPICIOUS/CONCERNING FINDINGS	
• Posterior hymenal notch	• Condylomal accuminata in a child younger than 2 years
• Acute abrasions	• *Trichomonas vaginalis*
• Acute lacerations	• Herpes simplex II
• Bruising	• *Chlamydia trachomatis*
• Scarring of posterior fourchette not involving hymen	• Hymenal tears
• Perianal skin tags outside the midline	• Vaginal tears
	• Irregularity of anal orifice

Table 8. Findings Classified as Conclusive/Independently Diagnostic[19,28]

CONCLUSIVE/INDEPENDENTLY DIAGNOSTIC FINDINGS
• Positive cultures for *Neisseria gonorrhoea**
• Positive serology for *Treponema pallidum**
• Positive culture for *Chlamydia trachomatis**
• Positive HIV serology*
• Sperm or seminal fluid recovered in discharge
• Acid phosphatase activity in discharge
• Pregnancy with no history of sexual activity

* Exclusion of transmission by congenital, transfusion, or needle-sharing means.

by sexual abuse. A pediatric presentation of anogenital erythema and/or edema frequently brings about the consideration of sexual abuse. Explanations or other causes for findings of anogenital erythema or edema include: excoriation, pruritis, fecal contamination, retained urine, restrictive clothing (such as tights), chemical irritants (such as bubble bath soaps), atopic dermatitis, diaper dermatitis, lichen sclerosus, scabies, nonspecific vaginitis, pinworms, perianal streptococcal cellulitis, inflammatory bowel disease, Kawasaki syndrome, and *Candida albicans* infection.[39,56-60]

The most common dermatologic syndrome mistaken for sexual abuse is lichen sclerosus. Lichen sclerosus manifests as subepidermal hemorrhage of the genital tissues, usually caused by minimal trauma to the area, such as wiping after using the toilet. Children occasionally may present with vesicular, blistering, or bullous lesions. The characteristic hourglass configuration of atrophic, hypopigmented skin around the genitalia and/or anus is consistent with the diagnosis, which is confirmed by biopsy.[39,57,58]

Anogenital bruising from accidental injury may be mistaken for sexual abuse. In general, these injuries result from straddle mechanisms, producing damage to external structures in a unilateral distribution, anterior or lateral to the hymen. The hymen usually is not traumatized in these instances, but periurethral or labial bruising is common. Hymenal and vaginal lacerations have been noted in young females who fall astride sharp objects. Although hymenal lacerations have been reported by accidental mechanisms, they occur infrequently. Therefore, hymenal damage should alert the clinician to an increased probability of sexual abuse.[61-63] Trauma that occurs in motor vehicle crashes has been reported to cause genital injury. In one report, an improperly placed lap belt was responsible for perineal tears and labial abrasions sustained in an automobile accident, but the hymen appeared uninjured.[64] Other conditions that can present with the complaint of anogenital bruising include lichen sclerosus, phytodermatitis, bleeding disorders, vascular nevi, and Mongolian spots.[39] The custom of female circumcision in African and Middle Eastern cultures may result in adhesions and scarring of the genitals.[63]

Infectious disorders from non-STD organisms also may produce findings similar to child abuse. Pinworms and *Candida albicans* cause erythema, edema, and excoriations. Perineal streptococcal cellulitis presents with bleeding, anal fissures, painful bowel movements, and profuse erythema.[39,65] Acute varicella (chicken pox) infection initially may appear in the genital area, prompting the physician to make the diagnosis of *H. simplex* infection. Only after the typical exanthem pattern is noted and/or viral culture results are available is the correct diagnosis made.[66]

Gastrointestinal and urologic conditions also have been misdiagnosed as sexual abuse. Crohn's disease may manifest with fistulas, rectal tumors, chronic constipation with anal fissuring, rectal prolapse, and megacolon.[67-71] Urologic conditions that may be mistaken for sexual abuse include urethral prolapse, urethral caruncle, and urethral hemangiomas. These conditions may present with complaints of pain and vaginal bleeding in children.[39,72,73] In the event of rectal or urethral prolapse, a number of etiologies other than sexual abuse have been reported. A thorough investigation of the history will aid in making the diagnosis.[74]

A number of congenital anomalies may masquerade as sexual abuse. A general guideline suggests that abnormalities of midline structures in the genital, perineal, and anal areas may represent congenital abnormality rather than sexual abuse. Failure of midline fusion across the posterior fourchette, congenital cleft superior to the urethra, and anomalies of the anal sphincter all have been diagnosed incorrectly as the sequelae of past sexual abuse.[39,75] Hemangiomas of the hymen, the vaginal wall, and the vulva also have been identified incorrectly as being the result of sexual abuse.[39,76] Other congenital abnormalities of the genitourinary tract that mimic sexual abuse include ectopic ureter and rectovaginal fistula.[74-76]

Conditions commonly presenting with anogenital bleeding or vaginal bleeding or discharge include: vaginal foreign bodies, atopic or seborrheic dermatitis, precocious puberty, hormone-producing tumors, vaginal polyps, vulvar hemangioma, and sarcoma botryoides.[39,60,65,67] Conditions that can present with non-bloody vaginal discharge include leukorrhea, vulvovaginitis, varicella, measles, scarlet fever, and typhoid.[39,66,67]

Other conditions confused with sexual abuse include phimosis/paraphimosis, hair tourniquet syndrome, hematocolpos, and mucocolpos. The diagnosis of sexual abuse should be based primarily on the history of an abusive event from the child.[31] A thorough history, therefore, is critical.[40,67,68] The emergency physician should be mindful that although physical symptoms in the anogenital region should raise concerns, the history is key to the diagnosis of sexual abuse.

Legal Issues and Reporting

Mandatory reporting of child maltreatment exists in all 50 states. In most states, the emergency physician is considered a mandated reporter. For mandated reporters, the law requires a penalty for failure to report and provides protection from liability if the report of suspected abuse turns out to be unfounded once an investigation is completed. The mechanisms for reporting sexual abuse to appropriate social service, child protection, or law enforcement agencies vary from state to state. It is important for emergency physicians to be familiar with these mechanisms in the scope of their given practice location.

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Table 9. Prophylaxis and Treatment for Sexually Transmitted Disease[52,54]

NEISSERIA GONORRHOEAE

Prophylaxis: Ceftriaxone 125 mg IM

Treatment:

• Child < 45 kg: Ceftriaxone 125 mg IM *or* spectinomycin 40 mg/kg (max 2 g) IM

• Child > 45 kg: Ceftriaxone 125 mg IM *or* cefixime 400 mg po x 1 *or* ciprofloxacin 500 mg po *or* ofloxacin 400 mg po x 1 *or* spectinomycin 2 g IM

• Adolescents: Ceftriaxone 125 mg IM x 1 *or* cefixime 400 mg po x 1 or ciprofloxacin 500 mg po x 1 *or* ofloxacin 400 mg po x 1 plus azithromycin 1 g po x 1 *or* doxycycline 100 mg po bid x 7 days

CHLAMYDIA

Prophylaxis: Child < 9 years: Erythromycin 50 mg/kg/d divided qid x 7 days (max dose 500 mg qid)

• Child > 9 years or > 100 lbs: Tetracycline 50 mg/kg/d divided qid x 7 days (max dose = 500 mg qid) *or* doxycycline 4 mg/kg/d divided bid x 7 days (max dose 100 mg bid) *or* azithromycin 1 g po

Treatment:

Infants < 6 months: Erythromycin 50 mg/kg/d divided qid 10-14 days

Child < 45 kg: Erythromycin 50 mg/kg/d divided qid x 10-14 days

Child > 45 kg but < 8 years of age: Azithromycin 1 g po x 1

Child ≥ to 8 years of age: Azithromycin 1 g po x 1 *or* doxycycline 100 mg po bid x 7 days

SYPHILLIS

Treatment: Benzathine penicillin 50,000 U/kg IM (max. 2.4 million U)

HERPES SIMPLEX VIRUS

Treatment: Children: Acyclovir 80 mg/kg/d divided qid x 7-10 days

• Adolescents: Acyclovir 400 mg po tid x 7-10 days *or* acyclovir 200 mg po 5 times per day for 7-10 days *or* famciclovir 250 mg po tid x 7-10 days *or* valacyclovir 1 g po bid x 7-10 days

TRICHOMONAS

Treatment: Children: Metronidazole 15 mg/kg/d (max 250 mg) divided tid x 7 days *or* metronidazole 40 mg/kg (max 2 g) po x 1

• Adolescents: Metronidazole 2 g po x 1 *or* metronidazole 500 mg po bid x 7 days

HUMAN PAPILLOMA VIRUS

Referral to dermatology should be considered. Treatment dependent on age of child and location/number of lesions.

Treatment: Podophyllin 10-25% topically followed in 1-4 hours by bathing every week x 4 weeks.

• Trichloroacetic acid (TCA) or bichloroacetic acid (BCA) 80-90% applied topically and repeated weekly if necessary.

• Imiquimod 5% cream applied at bedtime 3 times per week for up to 16 weeks.

• Podofilox 5% solution *or* gel atopically bid x 3 days followed by 4 days of no therapy.

• Laser or cryotherapy

BACTERIAL VAGINOSIS

Treatment: Children: Metronidazole 15 mg/kg/d divided tid x 7 days

• Adolescents: Metronidazole 500 mg po bid x 7 days

HEPATITIS B

Prophylaxis: Fully vaccinated patient should not be revaccinated. If not vaccinated: Hepatitis B immune globulin (0.06 mL/kg IM) within 14 days of exposure and Hep. B vaccine.

If vaccination status unclear, send hepatitis serology.

HIV

Consider consultation of infectious disease specialist. Indications for prophylaxis are unclear and/or controversial.

Prophylaxis: Option: Zidovudine (AZT) 200 mg po tid *or* 160-180 mg/m^2/dose tid x 4 weeks plus lamivudine 150 mg dose tid, 150 mg dose bid *or* 8 mg/kg/dose bid x 4 weeks.

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Physician CME Questions

43. Which of the following would represent a leading question when interviewing a child about possible sexual abuse?
    A. Can you tell me what happened?
    B. Did your stepfather do this to you?
    C. Where were you when this happened?
    D. What day did this happen?
    E. How many times did this happen?

44. A 6-year-old male is brought to the ED having disclosed inappropriate sexual contact with an adult, which occurred 10 days prior to presentation. The child has no physical complaints or findings on physical exam. The most appropriate next step would be:
    A. reporting to child protective services, referring to a center specializing in sexual abuse examinations of children, and establishing that it is safe for the child to go home.
    B. using an evidence recovery kit.
    C. a Wood's lamp examination for sperm.
    D. a Toluidine blue stain of perineum.
    E. taking anogenital cultures for *Chlamydia trachomatis.*

45. Of substantiated cases of child maltreatment in 1999, approximately what percentage were due to sexual abuse?
    A. 76%
    B. 46%
    C. 18%
    D. 9%
    E. 1%

46. Evidence collection (evidence recovery kit) is highly recommended in which of the following situations in cases of suspected pediatric sexual abuse?
   A. Acute event, occurring within the past 72 hours
   B. Acute event, occurring within the past 24 hours
   C. Acute anogenital bleeding
   D. Acute anogenital injury
   E. All of the above

47. The most appropriate treatment of chlamydia in a child who weighs fewer than 45 kg is:
   A. ceftriaxone 125 mg IM.
   B. spectinomycin 40 mg/kg IM (2 g maximum dose).
   C. metronidazole 15 mg/kg/day, divided tid for 7 days.
   D. erythromycin 50 mg/kg/day divided qid for 10-14 days.
   E. benzathine penicillin 50,000 U/kg IM (2.4 million, U maximum dose).

48. An acceptable technique(s) for examining a child for possible sexual abuse is/are:
   A. supine frog leg position.
   B. labial separation.
   C. supine knee-chest position.
   D. prone knee-chest position.
   E. All of the above

49. The concavity of the lower part of the vestibule situated posterior (inferior) to the vaginal orifice and extending to the posterior commissure is correctly termed the:
   A. posterior fourchette.
   B. urethra.
   C. vagina.
   D. fossa navicularis.
   E. hymen.

50. What is the most common dermatologic syndrome mistaken for sexual abuse?
   A. Lichen sclerosus
   B. *Streptococcal cellulitis*
   C. *Candida albicans*
   D. Herpes simplex
   E. Atopic dermatitis

In Future Issues: **Congestive Heart Failure**

Emergency Medicine Reports
CME Objectives

To help physicians:

- quickly recognize or increase index of suspicion for specific conditions;
- understand the epidemiology, etiology, pathophysiology, and clinical features of the entity discussed;
- be educated about how to correctly perform necessary diagnostic tests;
- take a meaningful patient history that will reveal the most important details about the particular medical problem discussed;
- apply state-of-the-art therapeutic techniques (including the implications of pharmaceutical therapy discussed) to patients with the particular medical problems discussed;
- understand the differential diagnosis of the entity discussed;
- understand both likely and rare complications that may occur;
- and provide patients with any necessary discharge instructions.

Emergency Medicine Reports
The Practical Journal for Emergency Physicians

Pediatric Sexual Abuse

Findings Commonly Classified as Normal

NORMAL FINDINGS	VARIANTS
• Periurethral bands	• Septate hymen
• Intravaginal ridges	• Failure of midline fusion
• Hymenal tags	• Groove in fossa
• Hymenal bumps	• Diastasis ani
• Linea vestibularis	• Perianal skin tags in the midline
• Hymenal cleft/notch in anterior half of rim	• Increased perianal pigmentation
• Urethral dilation (mild)	

Findings Commonly Classified as Suspicious/Concerning

SUSPICIOUS/CONCERNING FINDINGS	
• Posterior hymenal notch	• Condylomal accuminata in a child younger than 2 years
• Acute abrasions	• *Trichomonas vaginalis*
• Acute lacerations	• Herpes simplex II
• Bruising	• *Chlamydia trachomatis*
• Scarring of posterior fourchette not involving hymen	• Hymenal tears
• Perianal skin tags outside the midline	• Vaginal tears
	• Irregularity of anal orifice

Findings Commonly Classified as Nonspecific

NONSPECIFIC FINDINGS	
• Erythema of perineum	• Venous congestion
• Increased vascularity	• Venous pooling
• Labial adhesions	• Vaginal bleeding
• Vaginal discharge	• Vaginitis
• Posterior fourchette friability	• Large hymenal opening
• Thickened hymen	• Urethral dilation (moderate)
• Anal fissures	• Thickened perianal tissue
• Flattened anal folds	• Narrowed hymen
• Anal dilation	

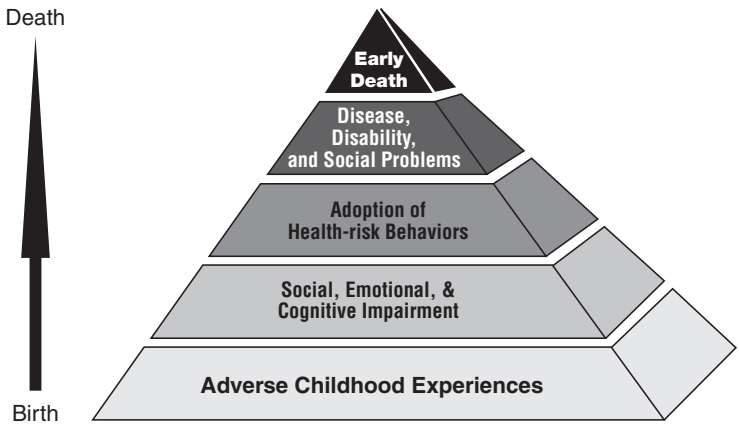
Findings that Are Conclusive/ Independently Diagnostic

CONCLUSIVE/INDEPENDENTLY DIAGNOSTIC FINDINGS

- Positive cultures for *Neisseria gonorrhoea**
- Positive serology for *Treponema pallidum**
- Positive culture for *Chlamydia trachomatis**
- Positive HIV serology*
- Sperm or seminal fluid recovered in discharge
- Acid phosphatase activity in discharge
- Pregnancy with no history of sexual activity

* Exclusion of transmission by congenital, transfusion, or needle-sharing means.

Potential Influences of Child Abuse Throughout Lifespan



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Behavioral Indicators of Sexual Abuse

BEHAVIORS SUGGESTIVE OF SEXUAL ABUSE	
• Abrupt change in personality	• Excessive fear
• Age-inappropriate knowledge of sexual acts	• Problems at school
• Aggression	• Sexual behavior
• Appetite disturbances	• Sexual perpetration on others
• Clinging	• Self-injury
• Depression	• Sleep disturbances
• Eating disturbances	• Social problems with peers
• Low self-esteem	• Substance abuse
• Neurotic or conduct disorders	• Suicidal ideation
• Nightmares	• Suicide attempt
• Phobias	• Temper tantrums
	• Withdrawal

Complaint/Exam Indicators of Sexual Abuse

COMPLAINTS/FINDINGS SUGGESTIVE OF SEXUAL ABUSE	
• Abdominal pain	• Chronic pain
• Anogenital bleeding	• Dysuria
• Anogenital discharge	• Encopresis
• Anogenital itching	• Enuresis
• Anogenital pain	• Foreign bodies in vagina or rectum
• Anogenital trauma	• Pregnancy
• Bruises to hard palate	• Recurrent urinary tract infection
• Bruises to soft palate	• Sexually transmitted disease
• Chronic constipation	• Vulvovaginitis

Prophylaxis and Treatment for Sexually Transmitted Disease

NEISSERIA GONORRHOEAE

Prophylaxis: Ceftriaxone 125 mg IM

Treatment:

- Child < 45 kg: Ceftriaxone 125 mg IM *or* spectinomycin 40 mg/kg (max 2 g) IM
- Child > 45 kg: Ceftriaxone 125 mg IM *or* cefixime 400 mg po x 1 *or* ciprofloxacin 500 mg po *or* ofloxacin 400 mg po x 1 *or* spectinomycin 2 g IM
- Adolescents: Ceftriaxone 125 mg IM x 1 *or* cefixime 400 mg po x 1 or ciprofloxacin 500 mg po x 1 *or* ofloxacin 400 mg po x 1 plus azithromycin 1 g po x 1 *or* doxycycline 100 mg po bid x 7 days

CHLAMYDIA

Prophylaxis: Child < 9 years: Erythromycin 50 mg/kg/d divided qid x 7 days (max dose 500 mg qid)

- Child > 9 years or > 100 lbs): Tetracycline 50 mg/kg/d divided qid x 7 days (max dose = 500 mg qid) *or* doxycycline 4 mg/kg/d divided bid x 7 days (max dose 100 mg bid) *or* azithromycin 1 g po

Treatment:

Infants < 6 months: Erythromycin 50 mg/kg/d divided qid 10-14 days

Child < 45 kg: Erythromycin 50 mg/kg/d divided qid x 10-14 days

Child > 45 kg but < 8 years of age: Azithromycin 1 g po x 1

Child ≥ to 8 years of age: Azithromycin 1 g po x 1 *or* doxycycline 100 mg po bid x 7 days

SYPHILLIS

Treatment: Benzathine penicillin 50,000 U/kg IM (max. 2.4 million U)

HERPES SIMPLEX VIRUS

Treatment: Children: Acyclovir 80 mg/kg/d divided qid x 7-10 days

- Adolescents: Acyclovir 400 mg po tid x 7-10 days *or* acyclovir 200 mg po 5 times per day for 7-10 days *or* famciclovir 250 mg po tid x 7-10 days *or* valacyclovir 1 g po bid x 7-10 days

TRICHOMONAS

Treatment: Children: Metronidazole 15 mg/kg/d (max 250 mg) divided tid x 7 days *or* metronidazole 40 mg/kg (max 2 g) po x 1

- Adolescents: Metronidazole 2 g po x 1 *or* metronidazole 500 mg po bid x 7 days

HUMAN PAPILLOMA VIRUS

Referral to dermatology should be considered. Treatment dependent on age of child and location/number of lesions.

Treatment: Podophyllin 10-25% topically followed in 1-4 hours by bathing every week x 4 weeks.

- Trichloroacetic acid (TCA) or bichloroacetic acid (BCA) 80-90% applied topically and repeated weekly if necessary.
- Imiquimod 5% cream applied at bedtime 3 times per week for up to 16 weeks.
- Podofilox 5% solution *or* gel atopically bid x 3 days followed by 4 days of no therapy.
- Laser or cryotherapy

BACTERIAL VAGINOSIS

Treatment: Children: Metronidazole 15 mg/kg/d divided tid x 7 days

- Adolescents: Metronidazole 500 mg po bid x 7 days

HEPATITIS B

Prophylaxis: Fully vaccinated patient should not be revaccinated. If not vaccinated: Hepatitis B immune globulin (0.06 mL/kg IM) within 14 days of exposure and Hep. B vaccine.

If vaccination status unclear, send hepatitis serology.

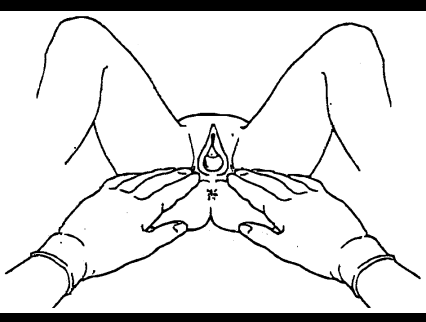
HIV

Consider consultation of infectious disease specialist. Indications for prophylaxis are unclear and/or controversial.

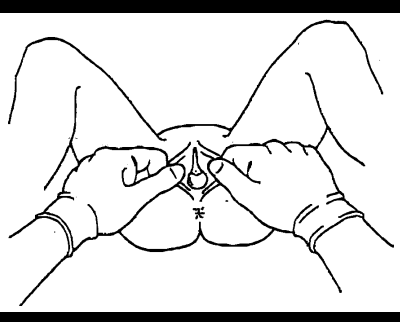
Prophylaxis: Option: Zidovudine (AZT) 200 mg po tid *or* 160-180 mg/m^2/dose tid x 4 weeks plus lamivudine 150 mg dose tid, 150 mg dose bid *or* 8 mg/kg/dose bid x 4 weeks.

Reprinted from: Leder MR, Leder MS. Emergency department evaluation and management of the sexually abused child or adolescent. *Pediatric Emergency Medicine Reports* 2000;5:67.

Labial Separation



Labial Traction



Tanner Staging

PUBIC HAIR

Stage 1: Preadolescent. No pubic hair, or hair in pubic region is fine, like that over other areas of the body.

Stage 2: Appearance of few, long, lightly pigmented hairs. Straight or curled hair develops at the base of the penis or along the labia.

Stage 3: Hair increases in density, becomes coarse and curled, and darkens.

Stage 4: Hair is of adult color and texture but covering a smaller area, with no spread to the medial thighs.

Stage 5: Adult-like pattern

BREAST DEVELOPMENT

Stage 1: Preadolescent

Stage 2: Breast bud stage

Stage 3: Further enlargement and elevation of breast areola

Stage 4: Projection of areola and papilla to form secondary mound above the level of the breast

Stage 5: Adult stage, projection of papilla only, areola even with breast

MALE GENITALIA

Stage 1: Preadolescent

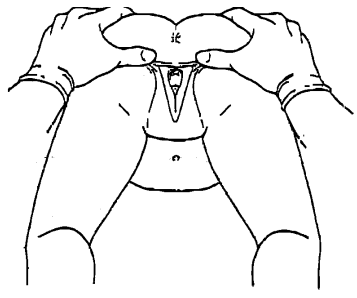
Stage 2: Enlargement of scrotum and testes, without enlargement of penis; scrotum reddens and changes texture

Stage 3: Continued enlargement of scrotum and testes, now with lengthening of penis

Stage 4: Increase in size of penis and glans

Stage 5: Adult stage

Prone Knee-Chest



Figures reprinted with permission from: Nancy D. Kellogg, MD, University of Texas Health Science Center at San Antonio, 1998.

Interview Questions

SEXUAL ABUSE DISCLOSED

- I understand that something has happened to you.
- Do you hurt anywhere?
- Where do you hurt?
- What happened?
- Who did this?

SEXUAL ABUSE SUSPECTED

- Do you have private places on your body?
- What do you call them?
- Have you been touched in those private places? (Assign child's terminology.)
- Have you been hurt in those private places? (Assign child's terminology.)

Supplement to Emergency Medicine Reports, March 11, 2002: "Evaluating Pediatric Sexual Abuse in the Emergency Department."

Authors: Pamela A. Ross, MD, Director, Pediatric Emergency Medicine, University of Virginia Health System, Charlottesville; William J. Brady, MD, FACEP, FAAEM, Associate Professor and Program Director, Emergency Medicine Residency, Department of Emergency Medicine, University of Virginia School of Medicine, Charlottesville.

BIOTERRORISM WATCH

Preparing for and responding to biological, chemical and nuclear disasters

Anthrax aftermath: Adverse drug reactions, vaccine controversy undercut CDC extended treatment offer

Some 8,000 people say thanks but no thanks

Despite the lingering possibility of late-onset anthrax infection, more than 8,000 people potentially exposed in the bioterrorism attacks of 2001 have turned down offers of additional antibiotics and immunization with the controversial vaccine, *Bioterrorism Watch* has learned.

Faced with insufficient data to truly assess the risk, the Centers for Disease Control and Prevention (CDC) in Atlanta offered the additional measures but fell short of actually recommending them.

Additional treatment offered as an 'option'

Operating on a thin margin of data about anthrax exposures, incubation periods, and subsequent infections, the CDC concluded it couldn't make a formal recommendation. The additional antibiotics and vaccine were made available as "options" to those exposed.

"The feeling was that this was the best thing we could do for people, and at least, leave it up to them to make a decision," says **Ian Williams**, PhD, medical epidemiologist in the CDC national center for infectious diseases. "We don't know what the answer is, but these are the options. We were really caught between a rock and a hard place on this one."

The 10,000 people potentially were exposed to anthrax in Connecticut, Florida, New Jersey, New York City, and Washington, DC.

They were all originally recommended to take at least 60 days of post-exposure antibiotic prophylaxis, but emerging data suggest that there has been a surprising lack of compliance.

In some preliminary surveys, fewer than half of those exposed were fully adhering to their original 60-day regimen. The CDC now has undertaken a telephone survey of all 10,000 people to identify adverse reactions and other reasons for the lack of adherence. **(See related story, p. 3.)**

The vaccine and additional antibiotic options were brought into play in part because the CDC knew it had large numbers of people who had not completed the original 60-day regimen. But the offer of additional care may have been undermined to some degree by prior adverse antibiotic reactions and fear of an anthrax vaccine that has been mired in controversy for years. Then again, many of those exposed may have felt they were no longer at risk and if their status changed, they would consult a physician.

Anthrax alive at 100 days

Though no known cases of anthrax have developed in any of the individuals who were prescribed the 60-day antibiotic course, the CDC also was aware of some disturbing data in animal studies. Traces of live anthrax spores have been detected in test animals' lungs up to 100 days following exposure, raising the theoretical possibility that the spores remaining still could

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cause disease. In that regard, one of the additional options offered to the exposed people was to take antibiotics for another 40 days (bringing total therapy time out to 100 days).

The other option was to take the additional drug regimen and also be vaccinated against anthrax. The latter option included three doses of anthrax vaccine over a four-week period, but antibiotics still had to be taken as the vaccine took effect.

The vaccine was not designed for post-exposure prophylaxis, but the theory is that it may provide additional protection by inducing an immune response to anthrax.

"People were unclear what the upper limit [for the onset of infection] was," Williams says. "That is what really drove both the vaccine and the antibiotic [offer]. We thought that 40 additional days to make 100 days looked sufficient based on our scant data. The vaccine was added because, is 100 days enough? I can't tell you absolutely for sure that it is enough."

Thousands took their chances

Most people were willing to take their chances that late onset anthrax will not occur.

Of the exposed cohort of some 10,000 people, 1,547 elected to receive more antibiotics after their 60-day regimen. Another 192 opted to be immunized with the anthrax vaccine and take additional antibiotics while the series of shots is given. Are the other 8,000-plus people at any real risk?

"Our feeling is that there shouldn't be any late cases of anthrax, based on what we know," Williams says.

"But that very well might be dose-dependent. We can't quantify the dose. If you go back and look at the animal studies that were done, they were actually done with probably lower doses than we have seen in the [U.S. Senate] Hart office building. But based on the data we can draw from animal models, it looks like there shouldn't be late onset cases," he explains.

If such an event occurred, the disease presumably still could be treated — provided the person seeks medical care. Still, making assumptions about anthrax can be tricky.

The CDC has been on a steep learning curve throughout the bioterrorism attack, with officials caught off guard by the ability of anthrax to disperse and spread during mail handling.

In addition, the ability to predict risk of infection in an exposed individual remains elusive, said **Julie Gerberding**, MD, director of the CDC division of healthcare quality improvement.

"We know that the exposure dose probably varies depending on how close you are to the source when it's released and how long you are in the [area] of release," Gerberding reported at a recent CDC meeting on post-exposure prophylaxis for anthrax.

> *"This is not an experiment to help us later. We don't have a control group. All we are doing is using the best science we have, which suggests that this is best way to give protection to people."*

"[But] despite our capacity to think about populations, we cannot accurately identify individual exposure, and we cannot accurately quantify individual risk," she explained.

Faced with that conundrum, the CDC put the same options on the table for all 10,000 people potentially exposed.

"The risk was probably different in different places," Williams says. "If you look at Capitol Hill, the concentration of anthrax released was probably much higher than say, Connecticut, where a letter just went through a post office. But that's group risk. Individual risk is different. [We] can't tell you exactly what your risk is. We'll give you the best available data, but you are going to have to make that decision."

Of the 190 people receiving anthrax vaccine, 80 had some political connection in Washington, DC, and 44 were postal workers in that city. Another 49 people in New Jersey were vaccinated; and the remainder were in New York City (12), Florida (four), and Connecticut (three). Of those who chose additional antibiotics only, 849 were in Washington, DC; 354 in New Jersey; 248 in New York City; 55 in Connecticut; and 41 in Florida.

A mixed message?

The CDC has drawn criticism for its approach, particularly for making a controversial vaccine available but leaving the immunization decision up to patients and their providers.

"It would have been much better if they had come out and said, 'Yes, we think in order to have as much protection as possible against the potential of developing disease, you should receive both

Side effects undermine anthrax drug adherence

More than half dropped drugs by 30 days

Amid the hype and horror of the 2001 anthrax attacks, it seemed a given that the people potentially exposed would be particularly diligent in completing their antibiotic regimens. But as time passed — and side effects continued or worsened for some — compliance fell off dramatically for many of the 10,000 people put on 60-day regimens for ciprofloxacin and doxycycline, according to preliminary data from the Centers for Disease Control and Prevention (CDC).

None of the people who started on antibiotics have developed anthrax, but the CDC wants some answers on the lack of adherence. To that end, the CDC is conducting a telephone survey project that will attempt to reach all 10,000 people for whom post-exposure antibiotic prophylaxis was recommended. The interviews began in late January and are expected to continue through March 2002. The people were potentially exposed to anthrax in Connecticut, Florida, New Jersey, New York City, and Washington, DC.

"We are making sure we get in touch with all of these people to evaluate how they did in terms of taking antibiotics," says **Ian Williams**, PhD, medical epidemiologist in the CDC national center for infectious diseases. "We have data showing adherence definitely wasn't as high as people, prior to this outbreak, would have thought it would be."

The CDC attempted a variety of methods to assess compliance prior to the phone survey, including tracking individuals who did not return to refill their medication. Other methods include giving a sample of those exposed questionnaires that were self-administered, given by a nurse, or by telephone, according to **Nancy Rosenstein**, MD, medical epidemiologist in the CDC national center for infectious diseases.

"In general, adherence has declined over the course of the [first] 30 days to as low as 45%," Rosenstein said at a recent CDC meeting on post-exposure prophylaxis for anthrax.

Some groups were more compliant than others. For example, employees who worked in the American Media Building in Boca Raton, FL, were closer to 70% compliant, she said. But only 45% compliance at 30 days was also found in a "high risk group" of mail handlers in New York City, she added.

"Adherence experts tell me that when we actually count pills, the self-reporting numbers probably overestimate real adherence by as much as 20%," Rosenstein said. "So the real estimates of adherence — taking the antibiotics every day — are obviously substantially lower."

In terms of self-reported adverse events, within two weeks of taking ciprofloxacin, 19% were reporting severe nausea, vomiting, abdominal pain, and diarrhea. At 30-day surveys, many people had switched to doxycycline, but self-reported adverse events increased to 45%.

Again, the predominant symptoms were severe nausea, vomiting, diarrhea, and abdominal pain. About 12% of the people reporting adverse events required additional follow-up with medical chart review and physician interviews, she said.

"I don't want to in any way minimize the impact of these symptoms on people's daily life, but when we actually investigated further, we were unable to identify anybody who actually required hospitalization or an emergency room visit for their adverse events," Rosenstein said.

Thus, based on Food and Drug Administration criteria, no serious adverse events have been linked to taking antibiotics for anthrax exposure. A more complete picture of the adherence problems should emerge from the CDC telephone survey of all recipients. Preliminary surveys have found that 6% to 12% of respondents reported at least missing some of their doses because of the side effects, she said. ■

antibiotic and vaccine,'" says **Phillip Brachman**, MD, a professor in the Rollins School of Public Health at Emory University in Atlanta.

The vaccine has been embroiled in a safety dispute since the military began a mandatory immunization policy several years ago, with some veterans saying it made them sick and others refusing to take it.

"A number of [the exposed people] undoubtedly read about the problems some of the military

folks claimed they had experienced after having the vaccine," Brachman says.

"They associated their problem with the vaccine. Remember, that those people in the military who have made those complaints are a very small number, considering the total number of doses given," he adds. "So there are very few voices creating a lot of concern."

Brachman did what remains the only clinical trail on the safety and efficacy of an anthrax vaccine precursor when he worked for the CDC in the 1950s.

In a study of goat's-wool workers — which was once an occupational risk group for anthrax in the United States — he found the vaccine safe and effective. He reported few side effects to vaccination and an efficacy rate of 92.5%.[1] The vaccine used in the study was a protective-antigen variety similar to the current vaccine. However, the manufacturing process has since changed and a different strain of anthrax is now used.

"There have been a few minor changes, and some people make a lot more out of it then it really should be," he says. "A different strain is being used to prepare the vaccine, but that should make no difference because the organism is not in the vaccine. It is the protein product from the organism."

Dearth of data

An Institute of Medicine committee that convened to look at the current anthrax vaccine cited a dearth of data in concluding: "The published studies have found transient local and systemic effects (primarily erythema, edema, or induration) of the anthrax vaccine.

"There have been no studies of the anthrax vaccine in which the long-term health outcomes have been systematically evaluated with active surveillance. . . . The committee concludes that in the peer-reviewed literature, there is inadequate/insufficient evidence to determine whether an association does or does not exist between anthrax vaccination and long-term adverse health outcomes. . . . To date, published studies have reported no significant adverse effects of the vaccine, but the literature is limited to a few short-term studies,"[2] the committee said.

For its part, the CDC would not have made the vaccine an option for those exposed if it had any doubts about its safety, Williams says.

"It seems to be a very safe, efficacious vaccine," he says. "[The] CDC reviewed the data with the military, which has the most experience with this."

Still, some people may have been confused because the CDC did not roll out the vaccine right after the exposures occurred. Thus, the response was somewhat tepid to a vaccine "add-on" option 60 days after the potential exposure. One problem is that the U.S. military, which controls the dispersal of anthrax vaccine, did not release any stocks in the immediate aftermath of the bioterror attacks, he says.

"One of the lessons we have learned is that if the vaccine had been available when this first started, I think the post-exposure prophylaxis would have been approached much differently," Williams says.

With the military now more amicable on the issue, if a bioterrorist strikes again with anthrax, the vaccine could play an important role from the onset, he emphasizes.

"If this should happen again, the vaccine might be used closer to day zero," Williams says. "After a series of doses over a month or so, most people will develop an antibody response, so it would obviate the need for additional antibiotics. It will be used in more of a true post-exposure fashion."

Those who have been recently vaccinated will be followed over time. Indeed, the CDC is discussing following the whole cohort of 10,000 people. It is an interesting group, having been potentially exposed to anthrax, taken prolonged antibiotic regimens, and in some cases, received a vaccine whose long-term safety is in some question.

Another curious fact — as with other post-exposure regimens for diseases — is that no one will ever know if the additional measures taken by 1,739 of these people actually prevent a late-onset anthrax infection.

"This is not an experiment to help us later," Brachman says. "We don't have a control group. All we are doing is using the best science we have, which suggests that this is best way to give protection to people."

References

1. Brachman PS, Gold H, Plotkin S, et al. Field evaluation of a human anthrax vaccine. *Am J Public Health* 1962; 52:632-645.

2. Committee on Health Effects Associated with Exposures during the Gulf War. *An Assessment of the Safety of the Anthrax Vaccine: A Letter Report*. Washington, DC: Institute of Medicine; March 30, 2000. ■