Research article

Improving HIV post-exposure prophylaxis rates after pediatric acute sexual assault

Samantha Schilling\textsuperscript{a,\*}, Stephanie A. Deutsch\textsuperscript{a}, Rebecca Gieseker\textsuperscript{c}, Jennifer Molnar\textsuperscript{b}, Jane M. Lavelle\textsuperscript{b,\*}, Philip V. Scribano\textsuperscript{b,c,a}

\textsuperscript{a} Division of General Pediatrics, TH: Children's Hospital of Philadelphia, Philadelphia, PA, United States
\textsuperscript{b} Division of Emergency Medicine, The Children's Hospital of Philadelphia, Philadelphia, PA, United States
\textsuperscript{c} PolicyLab, The Children's Hospital of Philadelphia, Philadelphia, PA, United States
\textsuperscript{d} Department of Pediatrics, University of Pennsylvania School of Medicine, Philadelphia, PA, United States

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\textbf{A R T I C L E  \ I N F O} & \textbf{A B S T R A C T} \\
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\textbf{Keywords:} Sexual assault \quad HIV-PEP \quad Pathway \quad Order set

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\textbf{The purpose of our study was to increase the rate of children with appropriate HIV-PEP regimens among those diagnosed with sexual assault in The Children's Hospital of Philadelphia Emergency Department (ED). The outcome measure was the percent of patients receiving correct HIV-PEP.} & \textbf{We retrospectively reviewed 97 charts over 31 months to define the baseline rate of children receiving appropriate HIV-PEP regimens (pre QI-implementation period: 2/2012-8/2014). Among children in which HIV-PEP was indicated following sexual assault, 40\% received the recommended 28-day course. Root cause analysis indicated prescribing errors accounted for 87\% of patients not receiving appropriate HIV-PEP. Process drivers included standardizing care coordination follow-up calls to elicit specific information about HIV-PEP, ED educational initiatives targeted at HIV-PEP prescribing, revision of the clinical pathway to specify indicated duration of HIV-PEP, and revision of the order set to auto-populate the number of days for the HIV-PEP prescription. During the QI-implementation period (9/2014-4/2015), the rate of appropriate HIV-PEP increased to 64\% (median 60\%) and the average number of days between incorrect HIV-PEP regimens was 24.5. Post QI-implementation (5/2015-3/2016), the rate of appropriate HIV-PEP increased to 84\% (median 100\%) and the average number of days between incorrect HIV-PEP regimens increased to 78.4. A multifaceted quality improvement process improved the rate of receipt of appropriate HIV-PEP regimens for pediatric victims of sexual assault. Decision support tools are instrumental in sustaining ideal care delivery, but require ongoing evaluation and improvement in order to remain optimally effective.} \\
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1. Background

The sexual assault of children in the United States is common. A national survey of youth and caretakers suggested that 4.6 children per 1000, or 320,400 children were sexually abused or assaulted in 1999 (Finkelhor, Hammer, & Sedlack, 2008). National surveys of adults suggest that between 9 and 32\% of women and 5–10\% of men report that they were victims of sexual abuse or assault during their childhood (Briere & Elliott, 2003; Finkelhor & Dziuba-Leatherman, 1994; Kilpatrick et al., 2000; Ruggiero et al., 2004; Vogeltanz et al., 1999; Wonderlich, Wilsnack, Wilsnack, & Harris, 1996). When the sexual assault is identified acutely, typically

\textsuperscript{\*} Correspondence to: Division of General Pediatrics and Adolescent Medicine, UNC School of Medicine, 231 MacNider Hall, Chapel Hill, NC 27599, United States.

E-mail addresses: Samantha.Schilling@med.unc.edu (S. Schilling), Deutschb@email.chop.edu (S.A. Deutsch), R.Gieseker@uchicago.edu (R. Gieseker), Molnar@email.chop.edu (J. Molnar), Lavellej@email.chop.edu (J.M. Lavelle), ScribanoP@email.chop.edu (P.V. Scribano).

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within a 72-h timeframe, or when the sexual exposure results in traumatic injury to the child, urgent medical evaluation is indicated (Kaufman, 2008; Kellogg, 2005). Protocols guiding the care of acute sexual assault victims include a comprehensive physical examination, possible forensic evidence collection, and possible testing and prophylactic treatment for sexually transmitted infections (STIs) and pregnancy (Kaufman, 2008; Kellogg, 2005; Pickering, Baker, & Kimberlin, 2012; Workowski & Berman, 2011).

HIV infection has been reported in children whose only known risk factor was sexual assault, rendering the prompt evaluation and prophylactic treatment of acute victims deemed to be high risk for HIV critical to preventing transmission (Ellis, Ahmad, & Molyneux, 2005; Lindgren et al., 1998; Speight et al., 2006). Although in general, the frequency of transmission of HIV from sexual assault is low, specific circumstances such as bleeding (which often accompanies trauma) increase risk (Adams et al., 2016; Smith et al., 2016). Children, in particular, might be at higher risk of HIV acquisition because the sexual abuse of children is frequently associated with multiple episodes of assault and might result in mucosal trauma (Adams et al., 2016). HIV post-exposure prophylaxis (HIV-PEP) may therefore be initiated depending on the nature of the alleged assault, the timeframe of the assault, and the HIV risk profile of the assailant (Smith et al., 2016).

HIV-PEP has been associated with a reduced risk of HIV acquisition following occupational exposures (Cardo et al., 1997). Less is known about its efficacy in preventing acquisition following acute sexual assault. Nonetheless, if possible exposure to HIV has occurred during an acute (within 72 h) sexual assault, current treatment protocols for evaluation of pediatric victims recommend prompt initiation of HIV-PEP for a 28-day duration to prevent infection (Adams et al., 2016; Havens & AIDS, 2003; Smith et al., 2016). Available data from animal studies indicate that PEP is most effective when initiated as soon as possible after HIV exposure; it is unlikely to be effective when instituted > 72 h after exposure (Otten et al., 2000).

Although safety data are insufficient in sexually assaulted children prescribed HIV-PEP, risk for serious adverse reactions is thought to be minimal because of the short period (28 days) recommended and because HIV treatment is well tolerated by children who have not been sexually assaulted (with and without HIV infection) (Smith et al., 2016). In considering whether to prescribe HIV-PEP, health care providers should consider whether the child can be treated promptly after the sexual exposure (within 72 h), the likelihood that the assailant is infected with HIV, and the likelihood of high compliance with the prescribed medication regimen (Havens & AIDS, 2003; Smith et al., 2016). Acute care delivery for sexual assault victims frequently occurs in the emergency department (ED). Previous authors have found that ED care of these victims is often suboptimal and rates of STI testing and prophylaxis in this setting are widely variable (Merchant et al., 2008; Rovi & Shimoni, 2001; Schilling et al., 2015; Straight & Heaton, 2007). Inappropriate testing and prophylactic prescribing practices may place a child at risk for significant adverse outcomes related to undetected or undertreated infections. For patients specifically at risk of HIV transmission following acute sexual assault, the more immediate the prophylaxis is initiated, the lower the likelihood of HIV acquisition (Adams et al., 2016; Otten et al., 2000). Therefore, appropriate and accurate management of HIV-PEP following acute sexual assault is paramount, and failure of children to receive this standard of care warrants quality improvement evaluation and intervention. The aim of our project was to increase the rate of children who receive correct HIV-PEP regimens among those diagnosed with acute sexual assault at our ED. Standardized Squire guidelines were used for quality improvement project planning and manuscript preparation (Davidoff, Batalden, Stevens, Ogrinc, & Mooney, 2008).

2. Methods

2.1. Setting and patient population

The setting for our project was the ED of the Children’s Hospital of Philadelphia. This is a single site ED of a large, urban, tertiary pediatric care center that has an annual census of over 90,000 patient visits. Approximately 100 children annually are evaluated for suspected acute sexual assault where evidence collection and acute care management is warranted. Given the complexities of caring for acute sexual assault victims, in 2008 our hospital developed the Sexual Assault Response Team (SART) composed of nurses and nurse practitioners skilled at performing acute sexual assault examinations and forensic evidence collection in the ED setting. A clinical pathway for sexual assault ED evaluations with an associated order set linked to the patient electronic medical record was developed in 2010 by a multi-disciplinary team led by pediatric emergency medicine subspecialists, and included child abuse pediatricians, HIV specialists, ED nurses, and ED social workers (Lavelle, Christian, Frioux, & Scribano, 2008). The SART pathway, intended for use when a child presents to the ED within 72 h of a suspected sexual assault, guides clinical decision-making around the history and physical examination, forensic evidence collection, and STI and pregnancy testing and treatment.

Pathway recommendations for HIV-PEP included indications for use and sample regimens. For children in whom HIV-PEP was indicated, the clinical pathway recommended providing the patient with a 4-day starter pack of HIV-PEP medication in the ED prior to discharge. A protocol was established which included follow-up care coordination by the child abuse team within 2-3 days of discharge. Included in this care coordination was review of medical and photographic documentation at the ED visit, and a telephone call to the child’s caregiver to discuss medication management and need for follow-up in a specialty clinic for pediatric victims of sexual abuse.

2.2. Improvement team

In 2012 a multidisciplinary quality improvement (QI) team convened, consisting of ED and child abuse physicians, ED nurses, ED nurse practitioners, ED social workers, and ED child life specialists to review the medical management of acute sexual assault patients presenting to our ED. The team was developed to review cases on a monthly basis and discuss strategies to improve care. A case
reviewed at a team meeting in the fall of 2014 identified an important area for improvement: review of the procedures involved in the provision of HIV-PEP after acute sexual assault.

2.3. Assessment of the problem

Since 2012, demographic and clinical information for all children undergoing SART evaluation and treatment has been prospectively collected and managed using Research Electronic Data Capture (REDCap), a secure, web-based application designed to support data capture for research studies (Harlis et al., 2009). To define the baseline rate of children receiving correct HIV-PEP regimens, we queried the database for all children who were prescribed HIV-PEP from February 2012 to August 2014 inclusive (31 months) and retrospectively reviewed the 97 identified charts (pre-QI implementation period). Correct HIV-PEP was defined as being prescribed a 28-day course with a recommended 2- or 3-drug regimen, and obtaining the full course from the pharmacy. We did not consider whether or not the decision to prescribe HIV-PEP was appropriate, rather we focused on whether the child received the HIV-PEP once the decision was made to prescribe it. Although difficulties in adherence to prescribed HIV-PEP following sexual assault is a well recognized problem, improving patient adherence was not the goal of our QI initiative and we did not measure patient compliance with completion of the prescribed 28-day regimen (Chacko, Ford, Shaitt, & Siddiqui, 2012; Ford et al., 2014). We documented whether or not families reported that the child was or was not taking the medication as prescribed 2–4 days following discharge from the ED visit, and if not, the reason for non-adherence. However, data were not routinely collected regarding completion of the 28-day course. Our project focused on whether or not the patient received the appropriate course of HIV-PEP, not whether the patient completed the course. We excluded families who were offered but declined HIV-PEP.

Cases that did not receive correct HIV-PEP were categorized as: duration error (fewer than 28 days prescribed), no prescription provided, prescription provided for incomplete/incorrect regimen, caregiver discontinuation of medication prior to 28 days, insurance problem, and/or pharmacy supply problem. Each incorrect case could have 1, or more than 1 of these 6 failure factors. Next we conducted a root cause analysis by constructing a Pareto chart to highlight the largest contributor to failures among this set of 6 factors (Tague, 2005). Finally, after identifying the highest contributor to error, we employed the “5 Whys,” a technique used in the Analyze phase of the Six Sigma DMAIC (Define, Measure, Analyze, Improve, Control) methodology (“Determining the Root Cause: 5 Why’s,”). To employ this technique, members of the SART QI team were queried in an iterative fashion until the team reached consensus around identification of reasons for the major contributors to error.

2.4. Ethical considerations

According to the policy activities that constitute research at our institution, this work met criteria for operational improvement activities exempt from institutional review board review.
3. Results

3.1. Baseline measurement

Our outcome of interest was the percent of children diagnosed with sexual assault receiving correct HIV PEP regimens. At baseline, among the 97 children identified, 40% (n = 39) received the correct 28-day HIV-PEP course. In some cases, multiple problems were identified. Among the 58 children who did not receive the correct medication regimen, 69 problems were identified and categorized as follows: 68% (n = 47) prescription duration error, 12% (n = 8) no prescription provided, 7% (n = 5) prescription provided for incorrect/incomplete regimen, 7% (n = 5) caregiver discontinuation of medication prior to 28-days, 3% (n = 2) insurance problem, and 3% (n = 2) pharmacy supply problem. From the Pareto chart, when combining the 3 prescription categories (prescription duration error: 68%, no prescription provided: 12%, prescription for incorrect regimen: 7%), we found prescriber error accounted for 87% of the failures to provide correct HIV-PEP regimens (Fig. 1).

After identifying that incorrect prescriptions were the highest contributor to error, our QI team employed the '5 Whys' exploratory technique (Fig. 2). Querying members of the SART QI team illustrated a reliance on the sexual assault clinical pathway among medical providers, and a key leverage point was identified: lack of clarity regarding HIV-PEP duration in our current clinical decision.
support aids on the clinical pathway. Because of this, a critical review of the pathway schematics and order-set was undertaken. Although pathway schematics for the most common HIV-PEP regimens prescribed included specific information on age and weight-based formulations and dosing, recommended total duration of treatment for HIV-PEP was absent in both the SART clinical pathway and the electronic medical record-linked order set (Figs. 3 and 4). Since medical providers relied heavily on these two clinical decision tools when caring for acute sexual assault patients, we hypothesized that the absence of this key information was the primary cause of the observed failures.

3.2. Interventions

From September 2014 to April 2015 inclusive (8 months), 6 interventions targeting key process drivers identified during the root cause analysis were implemented (QI implementation period). The first intervention involved standardizing the telephone follow-up assessment process by the child abuse team that occurred 2–3 days following ED discharge to include a script to elicit specific information about HIV-PEP. The standardized script for follow-up calls was implemented in September 2014 and included specific questions about the duration of therapy indicated on the prescription, successful filling of the prescription by the pharmacy, retrieval of the prescription from the pharmacy, and any unanticipated/early discontinuation of the medication by the patient or caregiver. Child abuse pediatricians using the standardized script were asked to document their telephone conversations, including answers to these key items, in the child’s electronic medical record. Identification of any barriers to successful acquisition of the correct 28-day course of HIV-PEP were identified and addressed during these care coordination calls.

The next 3 interventions were educational initiatives within the ED regarding HIV-PEP prescribing. A screen saver reminding providers to order the 28-day supply of HIV-PEP when indicated for acute sexual assault victims was implemented onto ED clinicians computers in October 2014. The screen saver appeared for 3 months in a rotation of 5 screen savers providing reminders to clinicians about specific ED management issues. During November 2014, HIV-PEP prescribing recommendations were highlighted as a “safety tip” during ED clinician rounds at the beginning of change of shift for ED staff. In addition, in March 2015, an HIV-PEP email “pearl,” or key practice recommendation, was sent to SART practitioners reinforcing the appropriate 28-day duration for HIV-PEP prescriptions.

Two final interventions focused on clinical decision support tools, including the pathway and order set. Both the revision of schematics on the SART clinical pathway to specify the indicated duration of therapy for HIV-PEP, and revision of the associated order set to auto-populate the number of days for the HIV-PEP prescription printed at discharge, were implemented in April 2015 (Figs. 3 and 4).

3.3. Results of interventions

To assess the impact of our interventions, a G- statistical process control chart was constructed to track the number of days between incorrect HIV-PEP regimens (failures) based on the assumption that our data followed a geometric distribution (Provost & Murray, 2011). Alpha of 0.01 was used, and the average, upper, and lower control limits were graphically displayed.
A: Order Set Pre Intervention

HIV Prophylaxis

- For Age 2-12 years who are less than 30 kg OR children who CANNOT swallow whole tabs/caps
  - Lamivudine 10 mg/mL Oral Solution 4 mg/kg/Dose
  - Zidovudine 10 mg/mL Oral Syrup 240 mg/m2/Dose
  - Raltegravir 25 mg Oral Chew (10 to <14kg) 75 mg
  - Raltegravir 25 mg Oral Chew (14 to <20kg) 100 mg
  - Raltegravir 25 mg Oral Chew (20 to <28kg) 150 mg
  - Raltegravir 25 mg Oral Chew (28 to <40kg) 200 mg
  - Raltegravir 25 mg Oral Chew (> I = 40kg) 300 mg
  - Lopinavir/Ritonavir (Kaletra) 400-100 mg/mL Oral Solution 300 mg/m2/Dose

B: Order Set Post Intervention

HIV Prophylaxis - IF HIV PEP IS STARTED IN THE ED, REMEMBER TO PRESCRIBE A 28 DAY COURSE OF PEP

- For Age 2-12 years who are less than 30 kg OR children who CANNOT swallow whole tabs/caps
  - Lamivudine 10 mg/mL Oral Solution
  - Zidovudine 10 mg/mL Oral Syrup
  - Raltegravir 25 mg Oral Chew (10 to <14kg)
  - Raltegravir 25 mg Oral Chew (14 to <20kg)
  - Raltegravir 25 mg Oral Chew (20 to <28kg)
  - Raltegravir 25 mg Oral Chew (28 to <40kg)
  - Raltegravir 25 mg Oral Chew (> I = 40kg)
  - Lopinavir/Ritonavir (Kaletra) 400-100 mg/mL Oral Solution

Fig. 4. (A) Order Set Pre Intervention. (B) Order Set Post Intervention. © 2016 Epic Systems Corporation. Used with permission. Panel A shows a screen shot of the pre intervention order set linked to the Suspected Sexual Assault Clinical Pathway and the patient electronic medical record. Panel B shows a screen shot of the post intervention order set, including a duration of therapy prompt and auto-population of the duration of therapy on the prescription generated from this order set.

The outcome measure was the percent of patients receiving correct HIV-PEP regimens (defined as a 28-day course with a recommended 2- or 3- drug regimen). During the QI implementation period, effectiveness of the standardized phone-call script and educational initiatives were assessed from September 2014 to March 2015 inclusive (7 months). Following implementation of the standardized script, but prior to the pathway and order set revisions, 14 of 22 (64%) children received the correct 28-day regimen of HIV-PEP (median 60%). Half (n = 4) of the errors were due to no prescription provided, 25% (n = 2) were due to pharmacy supply, and 25% (n = 2) were due to caregiver unanticipated/early discontinuation of HIV-PEP. From May 2015 to March 2016 inclusive (11 months) following the clinical pathway and order set revisions (the post-QI implementation period), 42 of 50 children (84%) received correct HIV-PEP regimens (median 100%). For 7 of these 8 patients, caregiver discontinuation of medications accounted for the errors and inadequate pharmacy supply accounted for 1 error. Sustained effect in correct HIV-PEP prescriptions was demonstrated for the 11 months following completion of intervention implementation (Fig. 5).
Prior to implementation of the quality improvement interventions, the average number of days between incorrect HIV PEP regimens was 14.51 (Fig. 6). During the quality improvement intervention period 9/2014–4/2015 inclusive (8 months), the average number of days between incorrect HIV PEP regimens increased to 24.5, and post-intervention the average number of days between failures increased to 78.4. The process has been error free since 12/2015 and was tracked to the end of 3/2016, indicating that the time between errors may in fact be longer. The g-chart indicates that the quality improvement interventions were effective at significantly reducing the frequency of failures in the process of HIV-PEP prescribing (Fig. 6).

4. Discussion

The aim of this quality improvement project was to increase the percentage of patients who received correct 28-day HIV-PEP regimens after being evaluated and treated for acute sexual assault at a single large, urban, pediatric ED. We accomplished our aim and reduced errors in HIV-PEP prescriptions for this population. A major contributor to the increased rate of appropriate treatment was revision of key clinical decision support aids to automatically include the dosages, duration, type, and number of indicated medications. This finding is not unexpected, as the goals of clinical pathways are to standardize care, improve outcomes, and reduce variability (Newman et al., 2003; Norton, Pusic, Talia, Headlee, & Carleton, 2007; Schilling et al., 2015; Todd, Bertuch, & Dolan, 2002). However, because of the reliance on clinical pathways to guide real-time care, pathways must contain accurate and relevant information to ensure that high quality care is delivered, and must be periodically re-evaluated to ensure the care delivered is reflective of the intended high quality.

As illustrated by this project, issues related to the presentation of data on a clinical pathway itself may have unintended consequences and ultimately prove problematic in achieving the desired goals of patient care. In this case, the initial protocol developed in 2010 indicated that a 4-day starter pack be provided to the child during the ED encounter. While it was recognized as a “starter pack”, there was no explicit prompt on the pathway to ensure prescriptions were provided at discharge for the remaining HIV-PEP treatment course. As part of the care coordination, a follow up assessment was to be made 2–4 days later by the child abuse team to evaluate treatment adherence, potential medication side effects, mental health needs, and follow up appointment scheduling. However, following initial publication of the pathway, and the recognition of these prescribing errors through this QI project, a modification was made on the pathway and order set to explicitly state, in addition to providing a 4-day starter pack, a prescription for the remaining 24 days should also be provided to the patient. Regular and systematic scrutiny of existing clinical pathways is paramount to delivery of effective, high quality care.

Because these improvements involved system changes to heavily relied upon clinical decision support work aids, we expect these improvements to be sustainable; to date the data support the longevity of our improvements. Employment of the g-statistical process control chart, compared to other QI methodology, most effectively aids this ongoing surveillance of the success of our QI efforts. G-charts specifically track the number of normally occurring events (in our study, correct HIV-PEP prescriptions) between rarely occurring incidents (incorrect HIV-PEP), based on the assumption of a geometric distribution of data and variable time interval between events (Provost & Murray, 2011). Unlike conventional statistical process control charts (for example, p or c charts), which when utilized to track rare or infrequent events often result in subgroups being plotted too infrequently for real-time control of these
problems, g-chart analysis based on inverse sampling detects process changes or verifies improvements faster (Benneyan, 2001a, 2001b; Schrem et al., 2016). Relevant increases or decreases of the incidence of rare events (i.e., incorrect HIV-PEP) are easily detectable; a decrease in time interval between HIV-PEP prescribing errors will serve as an “alarm bell” indicating additional QI interventions, or a secondary root cause analysis, may be necessary to sustain our initial improvements. G-charts have been effectively employed in other healthcare research involving occurrence of rare outcomes, including cancer surveillance, monitoring of catheter-associated, surgical site, cardiac bypass and cesarean-related infections, contaminated needle sticks, osteomyelitis treatment failures and medication errors (Benneyan, 2001a, 2001b; Brady et al., 2014; Dyrkorn, Kristoffersen, & Walberg, 2012).

Our quality improvement project addressed a critical patient outcome: facilitating appropriate initiation and management of HIV-PEP when indicated in children following acute sexual assault. While the ultimate goal of HIV-PEP is to prevent the acquisition of HIV by children who have been acutely sexually assaulted, this very rare outcome was beyond the scope of our project. Regardless, when a child in whom HIV-PEP is indicated fails to receive this appropriate treatment, a potential serious adverse event may result i.e. the child may acquire HIV. If appropriate prophylaxis is prescribed, this outcome can more assuredly be avoided. Additionally, completing part, but not all, of a course of HIV-PEP (such as a 4 day starter pack only) has the potential to lead to HIV resistance within the community. Finally, families of children who have been sexually assaulted are often in crisis by virtue of this victimization. When there are prescribing errors, or pharmacies are unable to fill the necessary preventative medications, families experience additional stress and loss of control in an already challenging situation. By achieving our project aims, we were successful in increasing the quality of care provided to this high-risk pediatric patient population.

Our project was conducted at a single center in which particular problems were identified. While these specific problems may not exist at other institutions, our approach to identify and evaluate the problems, and to develop and test interventions to improve medical care for child victims of sexual assault, is generalizable. Our study results also demonstrate internal validity, by virtue of our project consistency with the accepted methodological standards by Squire for quality improvement research (Davidoff et al., 2008). Many centers have clinical pathways with associated order sets in place, and our work therefore offers an important lesson; clinical decision support tools such as clinical pathways and order sets require continuous evaluation, revision, and improvement in order to be effective and remain a valuable tool for the delivery of high quality clinical care.
5. Conclusions

Utilizing a QI approach to implement standardized follow-up practices, embed educational initiatives within ED workflow, and improve the clinical decision support aids utilized in prescribing HIV-PEP measurably reduces the rate of errors associated with medications indicated following acute sexual assault among pediatric patients.

Contributors' statement

Samantha Schilling: Dr. Schilling contributed to conceptualization, design, and analysis, drafted the initial manuscript, and approved the final manuscript as submitted.

Stephanie A. Deutsch, Rebecca Gieseker, Jennifer Molnar, Jane M. Lavelle, Philip V. Scribano: Dr. Deutsch, Ms. Gieseker, Ms. Molnar, Dr. Lavelle, and Dr. Scribano contributed to conceptualization, design, and analysis, reviewed and revised the manuscript, and approved the final manuscript as submitted.

All authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work.

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Competing interest

The authors have no competing interests to disclose.

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