Is the Routine Pelvic Examination Needed With the Advent of Urine-Based Screening for Sexually Transmitted Diseases?

Mary-Ann B. Shafer, MD; Robert H. Pantell, MD; Julius Schachter, PhD

Objective: To determine the most cost-effective method of screening for chlamydia and gonorrhea to prevent pelvic inflammatory disease (PID) in asymptomatic sexually active adolescent females.

Design: Cost-effectiveness decision analysis comparing pelvic examination with cervical screening (the current national standard) with a model of urine screening with ligase chain reaction testing for *Chlamydia trachomatis* and *Neisseria gonorrhoeae*.

Methods: Four strategies using decision analysis were compared for a potential cohort of 100,000 asymptomatic sexually active young women: (1) pelvic examination screening in 100%; (2) urine screening in 100%; (3) actual predicted pelvic examination screening in 70%; and (4) actual predicted urine screening in 90%. Assumptions and costs were generated from published sources.

Main Outcome Measures: Cases of PID prevented per year and cost to prevent a case of PID.

Results: A total of 1750 cases of PID would be predicted to occur per year with no screening. Strategy 1 would prevent the most cases of PID (1283) at a mean cost of $10,230. Strategy 2 would prevent 1215 cases of PID at a mean cost of $5,093. The marginal cost to prevent an additional case of PID by strategy 1 is $101,454. Strategy 3 would prevent 898 cases of PID and 1093 cases of PID would be prevented with urine screening in strategy 4.

Conclusion: Urine-based ligase chain reaction screening is the most cost-effective strategy to detect chlamydial and gonococcal genital infection in asymptomatic sexually active adolescent females and, owing to ease of implementation, the most likely to prevent the greatest number of cases of PID.

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Sexually transmitted diseases (STDs) continue to be epidemic among sexually active adolescents, especially females. Of the 12 million STD cases occurring annually in the United States, 25% are identified in adolescents.1 Although gonorrheal rates have been declining for all ages in recent years, the rate among 15- to 19-year-old females (840 per 100,000) remains 6 times that of the United States as a whole.2 The actual gonorrheal rate among sexually active adolescent females is higher, as reporting is incomplete and only 52% of high school females reported sexual activity in 1995.3 It is estimated that chlamydia is the most common bacterial STD, with 4 million cases occurring annually in the United States.4 Although the precise incidence of chlamydial infection is unknown owing to lack of routine testing in adolescents, in 1995 the rate was estimated to be 6% among females younger than 19 years attending family planning clinics.2 However, these rates also may not reflect the actual rates of infection among adolescents, owing to the lack of uniform testing among sexually active youth.

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Clearly, the national health emergency of STDs among adolescents must be addressed in more systematic and creative ways. Current prevention efforts attempt to focus on primary prevention by assisting youth to delay the onset of sexual activity and, once active, to consistently use condoms and limit the number of sexual partners.5-6 Secondary prevention efforts focus on the identification and treatment of
asymptomatic infections is pivotal in controlling this epidemic.

The goals of performing these screening tests include detecting asymptomatic STDs and treating them with antibiotics to reduce the likelihood of PID, with its principal consequences of infertility and tubal pregnancy. A Papanicolaou test is performed to identify dysplasia and carcinoma in situ with appropriate intervention available to prevent the progression to carcinoma of the cervix. While a pelvic examination can also be used to diagnose pregnancy and may reveal other asymptomatic infections, this is not the goal of a pelvic examination, nor is it recommended by published preventive guidelines. Therefore it will not be considered in our analysis.

STRATEGIES AND ASSUMPTIONS

We evaluated the cost-effectiveness of 4 clinical strategies to prevent 1 case of PID among a cohort of 100,000 sexually active adolescent females. Each strategy employed either a urine-based LCR test or endocervical sampling for LCR to detect chlamydial and gonococcal infection. Because cervical cancer is rare in adolescents (0.2 per 100,000), we address these costs separately and focus our analysis on the costs of various strategies to prevent PID.

Strategy 1 reflects 100% compliance with current recommendations for a cohort of 100,000 sexually active and asymptomatic adolescents to receive pelvic examinations and be screened during health supervision visits with endocervical chlamydial and gonococcal screening tests and a Papanicolaou smear.

Strategy 2 assumes that, following a routine physical examination at a health supervision visit, a pelvic examination would not be performed but that urine-based screening LCR for chlamydial and gonococcal infection is completed on all 100,000 sexually active adolescent females (100% compliance).

Strategy 3 acknowledges studies showing the reluctance of adolescent females to have gynecologic examinations and assumes an actual predicted screening rate of 70% of the targeted patients actually having a pelvic examination completed with endocervical sampling. Studies show actual rates to be less than 50%.

Strategy 4 assumes less than perfect compliance in obtaining urine samples, resulting in a 90% actual predicted rate of urine-based screening LCR for chlamydial and gonococcal infection.

Although many physicians are still using a variety of nonculture, non–nucleic acid amplification (enzyme immunoassays) or direct nucleic acid detection tests (nonamplified DNA testing techniques), we decided to exclude these tests because they are far less sensitive and are being rapidly replaced in the clinical setting by the more sensitive nucleic acid amplification tests for chlamydial and gonococcal infection.

Calculations for each strategy result in a different rate of specified outcomes. The outcomes depend on the anticipated rates of underlying asymptomatic infection, the expected rate of PID following chlamydial or gonococcal infection, the rate of serious sequelae following PID (infertility, ectopic pregnancy), and the reduction in disease progression that would be expected assuming appropriate antibiotic treatment of gonorrhea or chlamydia. The assumptions used in our analyses are summarized in Table 1.
Table 1. Rates for asymptomatic chlamydial and gonococcal infection were chosen to reflect a population of adolescent females attending family planning or general youth clinics where universal screening for chlamydia is recommended for the target population. Assuming more cases of chlamydial endocervical infection are asymptomatic and remain undetected as compared with gonococcal infections, we assigned a lower rate of gonococcal infection progressing to silent PID as compared with chlamydial infection. We also assumed that treatment of gonococcal infections is more effective at preventing PID because there is potentially a proportion of asymptomatic chlamydial infections that progress to "silent" PID prior to detection and treatment.

COSTS

We have relied on costs, not charges, for the analyses. The costs we use for this analysis are displayed in Table 2. We did not include the cost of the adolescent health supervision examination, which would be the same for all strategies. The costs, therefore, represent the marginal cost of opting for 1 of the 4 potential strategies. Costs for ambulatory services are from a single system of fully allocated costs in a large, metropolitan, nonprofit health system. As many costs, such as those for medications, change rapidly, a relative weighting system is used. Costs include overhead costs (such as building maintenance, administration, and insurance) as well as the actual cost to the health system for the patient care item or service. For simplicity, we calculated only the cost of a single follow-up visit for treatment of young women identified as positive for chlamydial or gonococcal infection. No follow-up visits for test of cure were included. We also did not include costs of follow-up of inadequate or equivocal Papanicolaou smears (requiring another pelvic examination to repeat the Papanicolaou test), which would increase the costs for strategy 1.

Although the purpose of this analysis is to identify the most cost-effective approach to prevent a case of PID, it is useful to compare these costs with the cost of treating a case of PID, the most common result of undetected chlamydial and gonococcal infections in women. Using methods similar to those of Washington and Katz, we identified all hospitalized adolescents with PID (International Classification of Diseases, Ninth Revision [ICD-9] codes 614-615.9) from the latest available (1993) data from the California Office of Statewide Health Planning and Development. Charges were deflated by aggregate cost-to-charge ratios to obtain costs. There were 1338 hospitalizations with a mean length of stay of 3.6 days and a mean cost of hospital care of $7726; the 1990 data reported a mean length of stay of 4.8 days at a cost of $7267. We inflated the professional service fees reported by Washington and Katz by using the medical consumer price index from 1990 to 1996, calculated this to be $2977, and similarly adjusted their calculated complication costs. The outpatient cost for PID by this same method, inflated by the medical consumer price index, would be $293. In 1990, 13% of patients with PID were hospitalized. Assuming this rate of hospitalization, we calculated the cost for each case of PID to be $3066. A lower rate of hospitalization (7%; Kaiser Permanente Medical Group, Northern California, oral communication, 1996) would result in a PID cost of $2482.

SENSITIVITY ANALYSES

To test whether the results of our cost-effectiveness analyses were dependent on the accuracy of the probability and cost estimates that we used, we conducted several sensitivity analyses. We varied test accuracy over a wide range that we considered plausible, eg, urine LCR sensitivity from 70% to 95%. We also changed costs over a wide range to see if these alterations would affect our findings. Finally, we varied the underlying assumptions for the rate of asymptomatic infection.

RESULTS

We have estimated that approximately 1750 cases of PID would occur annually in a cohort of 100 000 sexually active and asymptomatic adolescent females (Table 3). Strategy 1 (100% pelvic examinations) has the potential for the greatest reduction in disease, with an estimated reduction of 1283 cases compared with a potential reduction of 1215 cases by strategy 2 (100% urine screening). The advantage of direct endocervical sampling, in terms of prevention of disease, is diminished because we know that not all sexually active adolescents will agree to and receive pelvic examinations. Strategy 3 illustrates that 898 cases would be prevented if we were successful in obtaining pelvic examinations and endocervical samples in 70% of young women. Strategy 4 would result in 1093 cases of PID being prevented when a 90% urine sampling compliance rate is reached.

When we consider costs of preventing PID, the urine test strategy is the clear winner. The cost of preventing a case of PID is $5984 for strategy 2 compared with $11 044 for strategy 1. The magnitude of this difference is not sensitive to the actual costs of the LCR tests, which currently range from approximately $7 to $40. Doubling the costs of both the LCR tests increases the cost to prevent a case of PID by strategy 2 to $8412, compared with $13 376 for strategy 1. In essence the added cost of performing a pelvic examination, even if the Papanicolaou smears were eliminated, is significantly higher than that of a urine screen. If mass screening reduces the cost of LCR tests by half, strategy 2 prevents a case of PID for $3474 while strategy 1 costs $8697 to prevent each case of PID. By assuming a higher sensitivity by endocervical sampling, we detected more STD cases and prevented 68 more PID cases than urine-based screening (by having 95% vs 90% sensitivity). However, the additional cost to prevent each case of PID is calculated to be $102 043.

Although strategy 2 is less costly, it can be argued that strategy 1 prevents additional cases of PID. This advantage is conferred principally because of the assumption that endocervical samplings are actually more sensitive; in fact, it may be that urine LCR detects more cases of infection than singular endocervical sampling since urine represents indirect sampling of the endocervix via a "perineal wash" as well as a "direct" sampling of the urethra. To address this issue, we performed a sensitivity analysis in which

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we varied the sensitivities of both urine and endocervical LCR. Obviously if the sensitivities of the tests by site (urine vs endocervical) are similar, the number of cases detected would be identical while the costs would differ. If the sensitivity of urine LCR is better than endocervical LCR, then we prevent more cases at a lower cost, an easy choice. If urine LCR sensitivity is 70%, a much lower rate than reported, the cost to prevent a case of PID using urine-based screening is still less expensive at $6482 compared with $11 044 for screening by endocervical sampling via pelvic examination.

We also varied the rate of STD infection in this population, which did not alter our findings. For example, assuming a gonorrheal rate of 1% instead of 2% would lead to strategy 3 costing $4996 to prevent a case of PID while strategy 1 would cost $10 087. Similarly, a chlamydial rate of 3% instead of 6% results in a cost to prevent a case of PID with strategy 3 of $8193 and with strategy 1 of $16 938.

Finally, it is possible to vary actual screening rates achievable in a population. While we chose 70% as an achievable rate for screening, which was derived in part from the literature,33,36 no such data exist on obtaining urine samples. Assuming a 90% rate of success in obtaining urine samples, 1093 cases of PID would be prevented compared with 898 cases prevented by the achievable pelvic examination screening rate (70%).

Professional societies and the US Preventive Services Task Force currently recommend annual pelvic examinations in sexually active adolescent females, with endocervical screening for chlamydia and gonorrhea and a Pap-panicolaou smear,12,14-18 unless sexual activity since the last chlamydial test has been limited to a single mutually monogamous partner.3 New urine-based nucleic acid amplification tests prompted our consideration of changing our current screening strategy from endocervical sampling to a urine-based screening model for asymptomatic sexually active adolescent females.

We selected 4 plausible models for evaluation. We ignored some newer suggested strategies, such as self-obtained vaginal swabs, because of their inherent invasive nature and limited data regarding performance overall and in adolescents specifically. Our first strategy, obtaining pelvic examinations on 100% of a population, is highly unlikely to be achieved but serves as a reference point. Our second strategy calls for using urine samples as the primary method of screening for chlamydia and gonorrhea on all sexually active female teenagers being seen for annual health supervision visits.

Our analysis indicates that strategy 1 of testing endocervical specimens for chlamydia and gonorrhea by LCR would prevent the largest number of cases of PID (1283). However, the urine screening strategy would prevent nearly as many (1215) at a substantially lower cost. The cost to prevent a case of PID with endocervical screening is more than twice as high as urine screening ($11 044

### Table 1. Assumptions in Analyses*

<table>
<thead>
<tr>
<th>Assumption</th>
<th>References</th>
</tr>
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<tbody>
<tr>
<td>Assumes 95% sensitivity of cervical LCR for chlamydia and gonorrhea</td>
<td>16, 23</td>
</tr>
<tr>
<td>Assumes 90% sensitivity of urine LCR for chlamydia and gonorrhea</td>
<td>12, 14-18</td>
</tr>
<tr>
<td>Assumes 25% of chlamydia cases develop PID</td>
<td>24-26</td>
</tr>
<tr>
<td>Assumes 12.5% of gonorrhea cases develop PID</td>
<td>27, 28</td>
</tr>
<tr>
<td>Assumes treating chlamydia prevents 75% of PID</td>
<td>29, 30</td>
</tr>
<tr>
<td>Assumes treating gonorrhea prevents 90% of PID</td>
<td>29, 30</td>
</tr>
<tr>
<td>Assumes only 70% of adolescents would keep appointment for a pelvic examination</td>
<td>21, 22</td>
</tr>
<tr>
<td>Assumes 6% rate of asymptomatic chlamydia</td>
<td>2, 4, 14, 15, 31</td>
</tr>
<tr>
<td>Assumes 2% rate of asymptomatic gonorrhea</td>
<td>2, 23, 31</td>
</tr>
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</table>

*LCR indicates ligase chain reaction; PID, pelvic inflammatory disease.

### Table 2. Costs

<table>
<thead>
<tr>
<th>Item</th>
<th>Cost, $</th>
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<tbody>
<tr>
<td>Pelvic examination</td>
<td>48</td>
</tr>
<tr>
<td>Papanicolaou smear</td>
<td>33</td>
</tr>
<tr>
<td>Chlamydial ligase chain reaction</td>
<td>20</td>
</tr>
<tr>
<td>Gonococcal ligase chain reaction</td>
<td>20</td>
</tr>
<tr>
<td>Visit for acute gonococcal or chlamydial infection</td>
<td>92</td>
</tr>
<tr>
<td>Single intramuscular dose of ceftriaxone, 1 g</td>
<td>38</td>
</tr>
<tr>
<td>Single oral dose of azithromycin, 1 g</td>
<td>24</td>
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</table>

### Table 3. Prevention Strategies for PID in 100 000 Asymptomatic Sexually Active Adolescent Females*

<table>
<thead>
<tr>
<th>Strategies</th>
<th>No. of Cases Detected</th>
<th>No. of Cases Prevented, $</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pelvic examination (all)†</td>
<td>2000</td>
<td>1900</td>
</tr>
<tr>
<td>Chlamydial ligase chain reaction</td>
<td>2000</td>
<td>1800</td>
</tr>
<tr>
<td>Gonococcal ligase chain reaction</td>
<td>2000</td>
<td>1330</td>
</tr>
<tr>
<td>Urine screening (all)‡</td>
<td>2000</td>
<td>1620</td>
</tr>
<tr>
<td>Pelvic examination (actual) with 70% compliance</td>
<td>2000</td>
<td>1620</td>
</tr>
<tr>
<td>Urine screening (actual) with 90% compliance</td>
<td>2000</td>
<td>1620</td>
</tr>
<tr>
<td>No screening done</td>
<td>2000</td>
<td>1620</td>
</tr>
</tbody>
</table>

*PID indicates pelvic inflammatory disease.
†95% sensitivity of cervical ligase chain reaction.
‡90% sensitivity of urine ligase chain reaction.
The potential financial benefit of urine-based screening of adolescent females is enormous. There are an estimated 5 million sexually active 15- to 19-year-olds in the United States. Although it is clear not all sexually active teenagers are screened for STDs, the cost of universal screening by urine sampling would be $202 500 000 cheaper than the current recommendations for universal pelvic examination screening.

In this analysis we focused principally on direct costs. However, there are considerable indirect and intangible costs that accompany PID, including lost time from school and work, pain, anxiety, the profound sense of loss due to infertility, and so on. Thus, the $3000 treatment cost cited per case of PID is clearly an underestimate when one considers the subsequent physiologic sequelae and psychological morbidity. Furthermore, widespread implementation of urine LCR testing might be expected to reduce the cost of the screening test and a prevention cost of less than $3500, as shown in our sensitivity analysis, may be achievable.

Urine-based screening may provide other advantages beyond cost savings in our attempts to maximize screening in adolescents for STDs. For example, the anxiety over possible pain and embarrassment associated with having to undergo a pelvic examination would be eliminated. The current policy that requires a pelvic examination to screen for cancer by Papanicolaou smear in all asymptomatic young women and judiciously limits the number of pelvic examinations in adolescents to those with actual indications may increase the number of young women actually tested for chlamydia and gonorrhea.

Furthermore, the increased number of adolescents likely to receive screening when urine techniques are applied has the potential to identify infected adolescents in need of pelvic examinations to identify comorbid conditions. In addition, urine-based testing minimizes the dependence on physicians’ limited time, skill, and willingness to perform a pelvic examination on an adolescent to screen for chlamydia and gonorrhea. The “physician-limiting factor” is reflected in one study that showed that almost 40% of pediatricians surveyed never perform pelvic examinations on their sexually active adolescent patients. In a second study only half of the at-risk sexually active teenagers were screened for STDs in primary care settings during a routine health supervision examination within the previous 2 years. Again, making the transition to urine-based testing will likely increase screening, detection, and subsequent treatment for chlamydia and gonorrhea. Data are lacking on the potentially large populations of sexually active adolescents who never enter the health care system for preventive reproductive care because of fear of the pelvic examination.

Potential limitations of the urine screening approach include missing clinical conditions that might be detected with pelvic examination, such as other STDs, pregnancy, cervical dysmorphology, and other gynecologic abnormalities. Examples of other STDs that may be missed include genital herpes, for which there is no recommendations for routine screening in asymptomatic patients. Even if genital lesions (which are almost universally symptomatic on the perineum) would be identified only by an external or internal examination, it is not currently recommended to treat asymptomatic herpes infections in healthy young women. External warts can be identified on an external examination and the need for a pelvic examination can be explored at that juncture. Screening for asymptomatic human papillomavirus infection by nuclear antigen testing is not recommended since there is also no recommendation for treatment of this “viral shedding.” Similarly, trichomonas may be missed; however, it would likely be missed during a pelvic examination as well because there is also no recommendation to screen asymptomatic women by wet mount or culture for trichomonas infection. Although pregnancy can be detected on pelvic examination after 6 weeks, the preferred strategy is by history and urine human chorionic gonadotropin testing.

An in-depth analysis of the cost-effectiveness of routine Papanicolaou smears in sexually active females younger than 18 years is beyond the scope of this article; however, a brief discussion is appropriate. In general, “premalignant” lesions occur most frequently among younger women, carcinoma in situ occurs most frequently in women in their mid 30s, and invasive disease has its greatest prevalence in women in their mid 40s. One of the largest studies to evaluate cervical screening in adolescents evaluated the Papanicolaou smears of almost 200 000 15- to 19-year-olds. Of these, 1.8% had grades 1 and 2 cervical intraepithelial neoplasia (mild-moderate dysplasia) and less than 0.1% had grade 3 cervical intraepithelial neoplasia or severe dysplasia or carcinoma in situ. There were no invasive carcinomas reported and therefore no deaths reported. From the data published by the California State Cancer Registry from 1988 to 1993, the annual rate of cervical cancer among 15- to 19-year-old women was determined to be only 0.2 per 100 000 population; the annual rate for in situ disease for this same age group was 18.7 per 100 000, or less than 0.02%. In other
words, 500,000 pelvic examinations with Papanicolaou smears (and an additional number requiring repeated examinations and Papanicolaou smears due to inadequate sampling) would have to be performed to identify a single case of cervical cancer in the adolescent female. Given the later onset and slow progression of cervical cancer, its plateauing in incidence from age 35 years and onward,18 and the likelihood that some women with cervical cancer will have had symptoms from reproductive conditions warranting a pelvic examination (pregnancy, symptoms of STDS, and so on) during their teenage years, the likelihood of missing cervical cancer in this adolescent age group is extraordinarily low. Missing other major gynecologic abnormalities among this group of healthy asymptomatic young women is unlikely as is supported by our recent work.31 Of 330 young women reviewed, 7% had chlamydia or gonorrhea and 9% were pregnant, conditions that can be easily diagnosed by urine-based tests. In addition, only 1.4% had either grade 1 cervical intraepithelial neoplasia or a low-grade squamous intraepithelial lesion, the highest-grade lesions found.

If one supports the argument that Papanicolaou smears may not be necessary during the first few years of sexual activity in the adolescent, then the cost of the Papanicolaou smear can be removed from the analysis of strategy 1. In this scenario, the cost to prevent a case of PID in strategy 1 is reduced to $7658, which remains 50% more costly than strategy 2. We believe that deferring routine Papanicolaou smears among healthy asymptomatic women until after age 18 years or 2 to 3 years after initiation of sexual activity would not have a significant effect on the morbidity in this young population based on the currently available data. The question of the ideal time to begin Papanicolaou smear screening in the young sexually active woman needs to be addressed in a prospectively controlled fashion. However, maintaining the current universal policy of Papanicolaou smear screening of all sexually active adolescent and young adult women is very costly. Using the California State Cancer Registry data and costs in our analysis, we estimate the cost to detect each case of cervical cancer in teenagers to be more than $40 million. Deferring routine pelvic examinations in healthy, asymptomatic, and nonpregnant sexually active adolescent females and using the urine-based screening strategy does not preclude inspection of the external genitalia for signs of other gynecologic disorders and STDS, nor does it prevent the performance of a pelvic examination when indicated by other symptoms or signs. In addition, it has been suggested that swab samples from the vagina may be helpful in identifying vaginal18 and cervical infections in asymptomatic women when indicated (self-collected vaginal swabs).35 However, the facility with which the urine tests can be applied will most likely lead to the detection of more STDS. Teenagers identified to have STDS by urine testing could then be screened for additional STDS, including cytopathologic changes associated with human papillomavirus infection by Papanicolaou smears if warranted. Empirical studies would be required to determine whether this would increase the detection of important precancerous lesions in a more focused approach and whether early identification of such lesions in adolescence makes a difference in preventing morbidity of cancer later. In addition, adolescent females identified as being pregnant or having other gynecologic disorders could then receive traditional reproductive evaluations, including a pelvic examination as indicated.

In summary, the use of urine screening for chlamydia and gonorrhea in all sexually active adolescent women younger than 18 years is the most cost-effective approach to prevent PID. Using urine-based screening and delaying Papanicolaou smears until after age 18 years have potential benefits for the adolescent. The practical ease in obtaining the specimens may potentially increase the detection rate for asymptomatic STDS and improve adolescents' compliance with preventive health care visits while having only a minimal, if any, effect on the risk of delayed identification of rare cervical cancer in this young population.

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Corresponding author: Mary-Ann B. Shafer, MD, Division of Adolescent Medicine, Box 0503, University of California, San Francisco, San Francisco, CA 94143-0503 (e-mail: shaf@itsa.ucsf.edu).

REFERENCES


1999 Certifying Examinations of the American Board of Pediatrics: Adolescent Medicine Subspecialty Examination*

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