Diagnosis and Management of Uncomplicated *Chlamydia trachomatis* Infections in Adolescents and Adults: Summary of Evidence Reviewed for the 2010 Centers for Disease Control and Prevention Sexually Transmitted Diseases Treatment Guidelines

William M. Geisler

Departments of 1Medicine and 2Epidemiology, Division of Infectious Diseases, University of Alabama at Birmingham

In preparation for the 2010 Centers for Disease Control and Prevention (CDC) Sexually Transmitted Diseases (STD) Treatment Guidelines, the CDC convened an advisory group in April 2009 to examine recent abstracts and published literature addressing the diagnosis and management of STDs. This article summarizes the key questions, evidence, and recommendations for the diagnosis and management of uncomplicated *Chlamydia trachomatis* infection in adolescents and adults that were considered in development of the 2010 CDC STD Treatment Guidelines. The evidence reviewed primarily focused on specimen types used for nucleic acid amplification testing for chlamydia diagnosis, considerations in screening men for chlamydia and repeat testing after infected men receive treatment, and the natural history of chlamydia.

*Chlamydia trachomatis* infection is the most frequently reported bacterial sexually transmitted infection in the United States [1]. The number of *C. trachomatis* cases reported in the United States continues to increase, with >1.1 million cases reported in 2007 [2]; this increase is probably in part the result of increased chlamydia screening efforts, along with increased use of more sensitive diagnostic tests (ie, nucleic acid amplification tests [NAATs]). Younger age and prior chlamydial infection are 2 of the strongest risk factors for chlamydia. The prevalence of chlamydia is highest in persons ≤25 years of age [2]. Because the majority of chlamydial infections are asymptomatic, detection of infection often relies on screening. The Centers for Disease Control and Prevention (CDC) recommends annual chlamydia screening in all sexually active women ≤25 years of age and older women with risk factors (eg, those who have a new sex partner or multiple sex partners) [3]. The benefits of chlamydia screening in women have been demonstrated in areas where screening programs have reduced both chlamydial prevalence [4, 5] and rates of pelvic inflammatory disease (PID) [6, 7].

The approach to the diagnosis and management of uncomplicated *C. trachomatis* infection in adolescents and adults includes (1) routine chlamydia screening as recommended by the CDC, using NAATs; (2) treatment with CDC-recommended therapy to reduce complications and prevent transmission to others; (3) treatment of sexual partners to prevent reinfection of patients and complications in patients and partners; (4) risk-reduction counseling; (5) repeated chlamydia testing a few months after treatment to identify recurrent infection; and (6) a test of cure in pregnant women at a minimum of 3 weeks after treatment to identify treatment failure and/or...
early recurrence so that repeat treatment can be provided promptly with the hope of limiting maternal and neonatal morbidity.

After publication of the 2006 CDC Sexually Transmitted Diseases (STD) Treatment Guidelines [3], unanswered questions and topics requiring further study on the diagnosis and management of uncomplicated genital chlamydial infection remained. In preparation for the 2010 CDC STD Treatment Guidelines, the CDC convened an advisory group in April 2009 to review evidence and make recommendations on the diagnosis and management of C. trachomatis infection in adolescents and adults. This article summarizes the key questions and evidence related to diagnosis and management of uncomplicated C. trachomatis infection that were considered in the development of the 2010 CDC STD Treatment Guidelines. The review and recommendations focused on key questions with new evidence or those covering topics of higher priority.

SUBJECTS AND METHODS

Three searches of the literature from 1 October 2004 through 5 November 2008 were conducted with the MEDLINE computerized database of the US National Library of Medicine and were limited to reports that were in humans aged ≥13 years, written in English, and with tag terms in titles/abstracts. The subject heading chlamydia and subheadings for each search were combined and exploded with the limitations applied. Search 1 focused on C. trachomatis diagnosis and yielded 690 citations (the subheadings were diagnosis, test, testing, screening, and repeat). Search 2 focused on management of genital chlamydial infection and yielded 447 citations (the subheadings were treatment, therapy, antibiotic, resistance, failure, persistence, eradication, cure, partner, and behavior). Search 3 focused on chlamydia epidemiology and natural history and yielded 567 citations (the subheadings were risk factor, prevalence, incidence, clearance, persistence, resolution, and natural history). Data from the following 2 CDC consultation meetings taking place since the previous CDC STD Treatment Guidelines meeting in 2005 were also reviewed: the Male Chlamydia Screening Consultation (March 2006) and the Chlamydia Immunology and Control Expert Advisory Meeting (April 2008). In addition, we reviewed select articles that were previously reviewed for the 2002 and 2006 CDC STD Treatment Guidelines.

Articles solely discussing Chlamydia species other than C. trachomatis were excluded. Citations were then selected and reviewed for key questions that could be addressed with new evidence or were deemed of high priority. Articles were summarized in a table of evidence with respect to study design, methodology, results, and conclusions, and the quality of evidence was rated as good, moderate, or insufficient. The quality of the evidence and discussions with expert consultants were then used to address key questions and to formulate recommendations for the upcoming 2010 CDC STD Treatment Guidelines. Below are the key questions addressed at the meeting, the summary of evidence, and recommendations for the guidelines. Other key question topics initially considered but not addressed at the meeting because of lack of new evidence that would contribute to recommendations included (1) expedited partner therapy, (2) treatment regimens for pregnant women with chlamydial infection, (3) new antibiotic regimens for chlamydia treatment, and (4) timing of repeat chlamydia testing in women.

RESULTS

Performance of Nucleic Acid Amplification Tests for Detection of C. trachomatis at Extragénital Sites in Men and Women and Use in Clinical Practice

Chlamydia culture has been the diagnostic test traditionally used for detection of C. trachomatis at rectal and oropharyngeal sites. However, chlamydia culture performed on specimens from these extragenital sites has low sensitivity, which is concerning because most patients with rectal or oropharyngeal chlamydia are asymptomatic and, therefore, might receive treatment only if the chlamydia test at these extragenital sites has positive results. Men who have sex with men (MSM) may not have insertive penile sex and, therefore, would have chlamydia diagnosed only at an exposed oropharyngeal or rectal site. Furthermore, chlamydia culture requires specialized laboratory expertise in cell culture and is now not widely available in the United States. Therefore, although not currently cleared by the Food and Drug Administration for extragenital sites, NAATs are an attractive alternative to culture for testing at these sites because (1) they have been shown to be more sensitive than culture on genital specimens and this probably is the case for rectal and oropharyngeal specimens and (2) most laboratories performing chlamydia testing on genital specimens are using NAATs and could validate these assays for testing at extragenital sites.

Two studies evaluated the performance of C. trachomatis NAATs on extragenital specimens. Schachter et al evaluated the performance of the transcription-mediated amplification assay APTIMA Combo 2 (AC2; Gen-Probe) and the strand-displacement amplification assay (SDA) ProbeTec (Becton Dickinson), compared with culture of oropharyngeal and rectal swab specimens collected from MSM presenting to an STD clinic in San Francisco [8]. Participants were considered chlamydia infected at a site if the culture result was positive, if both NAAT results were positive, or if a single positive NAAT result was confirmed by another NAAT targeting alternative sequences. They demonstrated higher chlamydia prevalence in the oropharynx and rectum with NAATs compared with culture (0.8% vs 0.4% and 6.1% vs 1.6%, respectively). Test sensitivity for oropharyngeal specimens was 44% for culture, 67% for SDA, and 100% for AC2, and for rectal specimens it was 27% for culture, 63% for SDA, and 93% for
AC2. Specificity was >99.3% for both NAATs at both extragenital sites. NAATs performed better than culture regardless of symptoms.

Bachmann et al evaluated the performance of the AC2, SDA, and Amplicor polymerase chain reaction (PCR; Roche), compared with culture, in rectal swab specimens collected from MSM and women [9]). Participants were considered chlamydia infected on the basis of 2 rotating standards: the first standard required at least 2 of 3 C. trachomatis comparator test results to be positive for classification as a true-positive, and the second, more stringent standard required all 3 comparator test results to be positive for a true-positive. In this study, a single positive NAAT result was not considered a true-positive, because there was no alternative NAAT with a different target sequence performed to confirm a true-versus false-positive test. Test sensitivity for the first standard for rectal specimens was 36% for culture, 100% for AC2, 92% for SDA, and 81% for PCR. Test specificity for rectal specimens was 99.7% for culture, 96% for AC2, 96% for SDA, and 99% for PCR.

There were several published reports, primarily in MSM populations, in which NAATs were validated for chlamydia testing at extragenital sites [10–15], and some provide epidemiological, clinical, and behavioral data to improve our knowledge of associations of these factors with extragenital chlamydia. One study used NAATs to study recurrent rectal chlamydia in MSM attending Melbourne Sexual Health Centre clinics and found that the frequency of recurrent chlamydia was high (18%), especially in human immunodeficiency virus (HIV)-positive versus HIV-negative MSM or those who HIV status was unknown (41% vs 10%) [10].

A limitation of current studies evaluating NAATs on oropharyngeal specimens is the very low prevalence of oropharyngeal chlamydia. It is uncertain whether C. trachomatis causes clinically significant disease of the oropharynx and whether it is transmissible from this site. Thus, although sparse data suggest that NAATs are the tests of choice for detecting C. trachomatis in oropharyngeal specimens [8] and there are limited clinical data validating their use at the oropharyngeal site [11, 14], it is unclear whether oropharyngeal chlamydia screening by NAATs is justified in heterosexual populations or lower-risk MSM. Further studies on the clinical and epidemiological significance of oropharyngeal chlamydia are needed.

In summary, there is strong evidence that NAATs perform better than culture for C. trachomatis detection in rectal specimens, but there is limited evidence that they perform better on oropharyngeal specimens. Although NAATs are not cleared by the Food and Drug Administration for C. trachomatis detection in these extragenital specimens, based on the evidence reviewed a strong recommendation was made for the 2010 CDC STD Treatment Guidelines to add text stating that NAATs perform better than culture for detecting C. trachomatis in rectal and oropharyngeal swab specimens and that some clinical providers are using laboratories that have validated NAATs for use with these specimens.

**Patient-Collected Vaginal Swab Specimens for Genital C. trachomatis Detection in Women**

The use of vaginal swab specimens for chlamydia testing has the advantages of being minimally invasive, can be self-collected with ease, and can be easily transported to a laboratory. Two studies evaluated the performance of C. trachomatis NAATs on patient-collected vaginal swab (PVS) specimens, compared with alternative specimens (first-catch urine [FCU] and/or endocervical swab [CS] specimens). Schachter et al evaluated the performance of the APTIMA CT (APT; Gen-Probe) and AC2 assays on PVS and clinician-collected vaginal swab (CVS) specimens [16]. PVS, CVS, CS, and FCU specimens were tested using the APT and AC2 assays; SDA was also performed on FCU and CS samples. Chlamydia positivity was established if 2 of the SDA and/or AC2 test results were positive for FCU or CS samples. Apparent false-positive vaginal specimens were confirmed as chlamydia positive if results of both the APT and AC2 (which have different targets) were positive. For the APT assay, the sensitivity was 98% versus 97% for PVS versus CVS, and the specificity, 96% versus 95%; the AC2 had similar sensitivity and specificity for vaginal specimens. Skidmore et al evaluated the performance of PCR and SDA with mailed PVS and FCU specimens and a polymer conjugate-enhance enzyme immunoassay with PVS specimens [17]. An algorithm with these 3 assays was used to establish chlamydia positivity. The sensitivity of the NAATs was 97% for PVS and 91%–93% for FCU specimens, and the specificity was >99.5% for both specimen types. The sensitivity of the enzyme immunoassay for PVS specimens was 38%–74%. Two other studies reviewed found a high rate of agreement in C. trachomatis detection by NAAT for PV versus FCU or CS specimens [18, 19].

Several studies that evaluated PVS acceptability found that PVS was a highly acceptable and easy specimen collection strategy [19–22]. Gaydos et al used a novel strategy for chlamydia screening by PVS, which involved a Web site through which participants could request a PVS kit and obtain a questionnaire (via phone, email/Internet, or at a community center) [22]. PVS specimens were tested by PCR, SDA, and AC2, and the questionnaire addressed acceptability of the PVS and Internet strategy. Of kit users, 76% preferred a self-collection method (54% PVS, 13% PVS or FCU, and 9% FCU), and 91% found PVS to be easy or very easy. Those who did not request a kit were more likely to prefer pelvic examination collection, and if they preferred self-collection, they tended to prefer providing FCU specimens and picking up the test kit at a pharmacy.

In summary, there is strong evidence that PVS specimens are excellent specimens for C. trachomatis NAAT, and patients find this screening strategy highly acceptable. There was a strong recommendation to add PVS specimens as recommended specimens.
for *C. trachomatis* NAATs in the 2010 CDC STD Treatment Guidelines.

**Liquid-based Cytology Specimens for Detection of Genital *C. trachomatis***

The ability to perform chlamydia testing on Pap test specimens may reduce the number of cervical swab specimens collected and may make it easier to test for chlamydia at the time of Pap test screening. Studies by Hopwood et al [23] and Koumans et al [24] used ligase chain reaction (LCx; Abbott Laboratories) on Thin-Prep (Cytyc [23] [24]) and conventional CS specimens and found a high concordance of *C. trachomatis* positivity with both specimens. Hopwood et al also compared ligase chain reaction performance on these specimens with CS testing by culture and alternative NAATs and found high sensitivity (93%–99%) and specificity (95.5%–99%) [23]. Chernesky et al evaluated the performance of APT and AC2 with SurePath (TriPath Care Technologies), with the *Chlamydia*-infected reference considered positive if both NAAT results were positive on a conventional CS specimen [25]. Each assay performed well with SurePath, with sensitivities of 85.2% for AC2 and 89.1% for APT, specificities of 99.5% and 98.7%, respectively, positive predictive values of 93.2% and 85.7%, and negative predictive values of 98.7% and 99.1%; sensitivity of the assays varied across the 6 study sites. Use of a cervical broom rather than a cervical spatula or cytobrush by Koumans et al [24] and Chernesky et al [25] may have lowered *C. trachomatis* detection in Pap test samples if less cellular material was collected. Collectively, these studies suggest that liquid-based cytology specimens may be suitable for *C. trachomatis* NAATs.

In summary, there is moderate evidence supporting liquid-based cytology specimens as acceptable for *C. trachomatis* NAATs; however, the sensitivity appears to be lower than that of NAATs for CS specimens. Consideration should be given to adding them as acceptable specimens for *C. trachomatis* NAATs in the 2010 CDC STD Treatment Guidelines, but with a mention that they may have lower sensitivities than NAATs with CS specimens.

**Routine Chlamydia Screening for Men**

Although the CDC recommends routine chlamydia screening annually in sexually active women <26 years of age and for older women with risk factors, there is no recommendation for routine screening in men [3]. Chlamydia complications in men are believed to be rare, and the primary benefits of screening men would be to prevent adverse outcomes in their female partners and to improve chlamydia control efforts. Chlamydial infections may increase rates of transmission or acquisition of HIV infection, and therefore, HIV prevention through identification and treatment of chlamydia would be another benefit. In 28–29 March 2006, the CDC convened the Male Chlamydia Screening Consultation meeting, during which expert consultants reviewed evidence and made recommendations relating to chlamydia screening in men.

A meeting report, posted by the CDC on 22 May 2007, summarized the evidence and recommendations [26], and consultants compiled their evidence reviews and recommendations into manuscripts that were published in a supplement of *Sexually Transmitted Diseases* in November 2008.

For consideration of chlamydia screening recommendations in men for the upcoming 2010 CDC STD Treatment Guidelines, the CDC’s Male Chlamydia Screening Consultation Meeting Report [26] was reviewed. Conclusions from the report include (1) programs that screen males for chlamydia should include chlamydia education; (2) programs should screen women <26 years of age for chlamydia as a primary focus, and screening men should be considered a secondary focus to prevent chlamydial infection and sequelae among women; and (3) programs that are currently screening men or planning to screen men for chlamydia should select appropriate populations to screen, usually those for whom a high chlamydia prevalence is suspected or has been demonstrated. Expert consultants strongly recommended chlamydia screening for men in the following populations: patients in STD clinics, men enrolled in National Job Training Programs, men <30 years of age in the military, men <30 years of age and entering jail, and men whose partners receive a diagnosis of chlamydia. Expert consultants also recommended screening males entering juvenile detention facilities.

Four articles relevant to the 2010 CDC STD Treatment Guidelines were published in the November 2008 *Sexually Transmitted Diseases* supplement relating to material reviewed at the CDC Male Chlamydia Screening Consultation. To determine estimates of chlamydia among men in the United States, Satterwhite et al reviewed national chlamydia morbidity data and prevalence data collected from general population (National Health and Nutrition Examination Survey, AddHealth, National Job Training Program data) and specific populations (MSM Prevalence Monitoring Project and juvenile and adult correctional facilities) [27]. In 2005, there were 232,781 chlamydia cases reported in men (161 cases/100,000 men), an increase compared with 2001 data (112 cases/100,000). General population chlamydia prevalence in men ranged from 3.2% to 8.1% (the 8.1% was from the National Job Training Program and juvenile and adult correctional facilities) [27]. In 2005, there were 232,781 chlamydia cases reported in men (161 cases/100,000 men), an increase compared with 2001 data (112 cases/100,000). General population chlamydia prevalence in men ranged from 3.2% to 8.1% (the 8.1% was from the National Job Training Program) and was significantly higher in African American men. Specific population chlamydia prevalence ranged from 6% to 7.8%. Rietmeijer et al reviewed data on *C. trachomatis* positivity rates among asymptomatic men screened for chlamydia in non-STD clinic venues [28]. The median positivity rate was 5.1%, and the highest rates were in males juvenile (7.9%) or adult detention (6.8%), African American men (6.7%), males 15–19 years (6.1%) or 20–24 years (6.5%), and men screened in the southern United States (6.4%).

Gift et al reviewed studies on the cost-effectiveness of chlamydia screening in men; 25 articles met inclusion criteria [29]. They found that, from a cost-effectiveness standpoint, screening men from the general population was not preferred to screening
women from the general population, but some studies found combined male and female screening programs to be cost saving. Gift et al also performed a cost-effectiveness analysis on data derived from a multistate male chlamydia screening demonstration project, an associated longitudinal cohort, and a literature review [30]. They found that (1) a program targeting high-risk men was cost saving, compared with equivalent program money to expand screening of lower-risk women; (2) combining partner notification with chlamydia screening in men was more effective than screening alone; and (3) a chlamydia screening program for high-risk men was not always cost effective but averaged $10 520 per quality-adjusted life-year saved compared with expanded screening in women, which would make it a highly cost-effective preventive intervention.

In summary, published findings and a CDC consultation meeting report support the recommendation that routine chlamydia screening in young sexually active women remain the primary focus of chlamydia screening efforts. Chlamydia screening in men can be considered (1) in select venues with a high chlamydia prevalence (as noted above), (2) when resources permit and screening does not hinder chlamydia screening in women, and (3) when screening is accompanied by chlamydia education and partner management. There is insufficient evidence to recommend routine chlamydia screening in men in the general population. On the basis of the strong evidence that chlamydia prevalence among men is high in select venues, it was recommended to add text in the 2010 CDC STD Treatment Guidelines stating that chlamydia screening in men in these select venues should be performed when resources permit and screening does not hinder chlamydia screening efforts in women and is accompanied by chlamydia education and partner management. The text should acknowledge that the primary focus is chlamydia screening in women and that the goal of any screening efforts for men should be to decrease chlamydia and its adverse effects in women.

**Repeat Chlamydia Testing for Men to Detect Recurrent Chlamydia After Treatment**

As in women, recurrent chlamydial infections are common in men after treatment for chlamydia. It is important to identify recurrent chlamydia in men, because it contributes to reinfection of their partners and puts their partners at risk again for chlamydia complications. Several studies were published since the data review for the 2006 CDC STD Treatment Guidelines that provided meaningful contributions to the literature on recurrent chlamydia in men. In a prospective study, Dunne et al evaluated recurrent chlamydia at 1- and 4-month follow-up visits in 272 men with chlamydial infection at various venues in 3 US cities as part of a male chlamydia screening demonstration project [31]. Recurrent chlamydia was detected in 13% and was predicted by history of an STD and the venue (highest in adolescent primary care and juvenile and adult detention clinics). The incidence of recurrent chlamydia was 45.4 infections/100 person-years, and the median time to recurrent infection was 52 days. Of men with 2 follow-up visits, most men (76%) had their recurrent infection detected at the first visit. Two retrospective studies, one evaluating STD clinic attendees [32] and the other involving persons from a genitourinary medicine clinic [33], reported recurrent chlamydia in 10% and 16% of men, respectively, within 6–12 months of follow-up. Fung et al reviewed data from 12 studies on recurrent chlamydia in men diagnosed by NAAT that were identified through a PubMed search of the period 1995–2006 and abstract review [34]. They found that the median probability of recurrent chlamydia among men was 11.3% and that the probability was higher in studies with passively collected, compared with actively collected, follow-up data (17.4% vs 10.9%). Recurrent chlamydia was associated with prior STD and younger age but was inconsistently associated across studies with risky sexual behavior (eg, inconsistent condom use, numbers of partners, and new partner).

None of the studies evaluating recurrent chlamydia in men evaluated the impact of recurrent chlamydia in men on recurrent chlamydia and complications in female partners or chlamydia transmission to new partners. However, the consistent finding across studies of a high rate of recurrent chlamydia in men has identified a specific patient population for which chlamydia testing should be performed if resources are available and testing does not hinder chlamydia screening in women.

In summary, there is strong evidence that recurrent chlamydia in men within a few months after treatment is common (usually occurring ≥10% of men); however, there is insufficient evidence concerning the benefit to women when men undergo repeat screening for chlamydia. It was strongly recommended to add text in the upcoming 2010 CDC STD Treatment Guidelines stating that repeat chlamydia screening in men should be performed ~3 months after treatment.

**Natural History of Genital Chlamydial Infection and Relevance for Chlamydia Screening and Treatment Strategies**

An understanding of the duration of untreated C. trachomatis infection and factors that influence chlamydia clearance could have major implications on chlamydia screening and treatment decisions [35]. However, chlamydia natural history studies in humans are challenging, because (1) the precise duration of infection is usually not known because the time of chlamydia acquisition is not known, and more importantly, (2) withholding treatment in persons who receive a diagnosis of chlamydia is unethical. Most chlamydia natural history studies have capitalized on evaluating chlamydia outcomes in the interval between screening and returning for treatment of genital chlamydial infection or on retrospectively performing C. trachomatis testing on stored specimens.
Overall, chlamydia natural history studies in humans demonstrate that clearance of genital C. trachomatis infection increases over time. Studies with shorter follow-up (within weeks or months) have reported clearance rates of 11%–44% demonstrated by NAAT [36–42], compared with 1-year follow-up reporting clearance rates of 45%–54% [43, 44]. Molano et al demonstrated a 94% C. trachomatis clearance rate in women after 4 years of follow-up [43]. Older age and prior chlamydia were associated with C. trachomatis clearance in at least one study, although the association with age was not consistent across studies and few studies had data on prior chlamydia. There were no consistent associations of sex or race with C. trachomatis clearance. A study by Sheffield et al demonstrated that neither bacterial vaginosis clinical findings nor treatment were associated with C. trachomatis clearance [40].

One important consequence of untreated chlamydia is the development of complications. Geisler et al found that 2 (2%) of 115 women developed PID within 7–25 days from the time that they underwent chlamydia screening to the time that they returned for treatment, and 1 (7%) of 14 men developed epididymitis in a 55-day interval between chlamydia screening and his return for treatment [36]. Similarly, 2 other studies have reported PID rates of 3%–4% among women returning within weeks of a positive chlamydia test result to receive treatment [45, 46]. In contrast, Morré et al reported that no cases of PID were diagnosed in 30 women with asymptomatic chlamydia who were followed up for as long as 1 year without receiving antichlamydial antibiotics [44].

In summary, chlamydia natural history studies have demonstrated that C. trachomatis clearance increases over time, and a small (but not insignificant) proportion of persons with chlamydial infection may develop complications in the interval between screening and returning for treatment. We still need a better understanding of the factors that influence C. trachomatis infection duration. Future chlamydia natural history studies will need to incorporate a study design that can more precisely define the timing of C. trachomatis acquisition. Such studies may provide better guidance for chlamydia screening and treatment strategies.

Currently, insufficient evidence is available on correlates of C. trachomatis clearance to recommend any specific changes in chlamydia screening or treatment strategies. Because of the limited evidence that a small proportion of persons with chlamydial infection develop complications in the interval between screening and treatment, it was recommended that consideration be given to adding text in the 2010 CDC STD Treatment Guidelines emphasizing the importance of prompt treatment of persons with chlamydial infection and decreasing the interval between chlamydia screening and treatment to limit complications.

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**Notes**

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