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Findings from a Scoping Review: Presumptive Treatment for Chlamydia Trachomatis (CT) and Neisseria Gonorrhoeae (GC) in the USA, 2006–2021

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Abstract

Chlamydia trachomatis (CT) and *Neisseria gonorrhoeae* (GC) are the two most common reported sexually transmitted infections in the USA. Current recommendations are to presumptively treat CT and/or GC in persons with symptoms or known contact. This review characterizes the literature around studies with presumptive treatment, including identifying rates of presumptive treatment and over- and under-treatment rates. Of the 18 articles that met our inclusion criteria, six pertained to outpatient settings. In the outpatient setting, presumptive treatment rates, for both asymptomatic and symptomic patients, varied from 12% - 100%, and the percent positive of those presumptively treated ranged from 25% - 46%. Three studies also reported data on positive results in patients not presumptively treated, which ranged from 2% - 9%. Two studies reported median follow-up time for untreated, which was roughly nine days. The remaining 12 articles pertained to the emergency setting where presumptive treatment rates, for both asymptomatic and symptomic patients, varied from 16% - 91%, the percent positive following presumptive treatment ranged from 14% - 59%. Positive results without presumptive treatment ranged from 4% - 52%. Two studies reported the percent positive without any treatment (6% and 32% respectively) and one reported follow-up time for untreated infections (median: 4.8 days). Rates of presumptive treatment, as well as rates of over- or under- treatment vary widely across studies and within care settings. Given large variability in presumptive treatment, the focus on urban settings, and minimal focus on social determinants of health, additional studies are needed to guide treatment practices for CT and GC in outpatient and emergency settings.

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Keywords

Chlamydia; Gonorrhea; Sexually transmitted diseases; Sexually transmitted infections; presumptive treatment

Introduction

Infections caused by *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (GC) are the two most common notifiable conditions in the United States of America (USA), encompassing an estimated 1.5 million cases of CT and over 677,000 cases of GC in 2020.(1) Additionally, there are concerning trends related to the steady increase in sexually transmitted infection (STI) cases over the past five years. With the exception of CT from 2019–2020, there has been a steady rise in STIs in the USA from 2016 – 2020, even with the disruptions related to a global pandemic. GC alone was up an estimated 10% in 2020 over 2019.(1) This represents a large public health concern given the long-term consequences of undiagnosed STIs. Effective and timely treatment of these infections is critical to avoid future complications related to ongoing infection, including pelvic inflammatory disease, infertility, and urethral strictures.

CT, which is largely asymptomatic, relies on screening tests for diagnosis and treatment.(2) Among women, gonococcal infections are commonly asymptomatic or might not produce recognizable symptoms until complications (e.g., pelvic inflammatory disease) have occurred.(3) Currently, Nucleic Acid Amplification Tests (NAAT) are commonly used for the diagnosis of chlamydia and gonorrhea, and testing results can take several days to return. Because testing results are not available at the time of the clinic visit, many patients can be lost to follow up if not treated during the clinic visit, increasing the potential for CT and GC to remain untreated. Accordingly, the CDC Sexually Transmitted Diseases Treatment Guidelines include recommendations to presumptively treat CT and/or GC in persons with symptoms or known contact.(3) In the absence of point-of-care testing (the first POC chlamydia and gonorrhea test was approved by FDA on March 30, 2021, and is not yet broadly used in USA), treatment decisions are dependent on individual clinician discretion, leaving the potential for variability of presumptive treatment across care settings and health systems.(2) The approach is also not without risk, including increasing the potential for antibiotic resistance, increased healthcare costs, and adverse events (e.g., allergic reactions.)(4) However, under-diagnosis and under-treatment of these conditions remains a large concern for public health.

Understanding current patterns in presumptive treatment is important for better directing interventions and studies to guide prescribing practices. Accordingly, a scoping review was undertaken. The goal of a scoping review is to examine emerging evidence in an attempt to identify areas for further investigation or to clarify/inform clinical practice.(5,6) Scoping reviews are a relatively new approach to evidence synthesis and are a suitable substitute when the characteristics of a concept need reported (compared to systematic reviews which primarily examine appropriateness or effectiveness of concepts).(5) Scoping reviews are still methodologically sysematized, including processes identifying a research question,

identifying the relevant articles, study selection, data extraction, and summarizing. This study deployed the methodology as framed by Arksey, et. al.(6)

The primary aim of this scoping review is to characterize the literature around presumptive treatment for CT and GC infections. The research question we sought to characterize was to determine the extent presumptive treatment of CT and GC has been undertaken, how well subpopulations and geographic areas are represented, as well as the rates and outcomes of treatment. To characterize treatment, we assess three rates related to treatment of CT and GC in the USA: (1) rates of presumptive treatment; (2) the rates of over treatment (treating when disease not present), and (3) the rates of under treatment (failing to treat when disease is present). Additionally, we evaluate demographics, setting, geography, and presence of social risk factors.

Methods

Information Sources and Search Strategy

We conducted a systematic search of the following databases from January 1, 2006 until November 5, 2021: Medline (Ovid), EMBASE (Embase.com), CINAHL (EBSCO), and Web of Science (Clarivate). 2006 was chosen as this was the first year CDC recommended CT and GC treatment for asymptomatic persons meeting certain criteria.(7) A manual review of the references of the included studies was also conducted. Potentially relevant gray literature was gathered through targeted searches of conference abstracts in EMBASE.

The database search strategies were developed by a health sciences librarian (RH). Known, relevant articles collected by the authors were analyzed to select keywords and subject headings. Final search terms incorporated subject headings and keywords associated with chlamydia, gonorrhea, and treatment or therapy. This broad search had a high recall of articles, including irrelevant articles. To carefully narrow the results in line with the eligibility criteria, search filters were applied to remove studies not set in the USA, studies on infections in neonates, animal studies, randomized controlled trials, case reports, and pharmacokinetics, pharmacodynamics, and genomic studies. The results were also limited to English language articles. The full search strategies for all information sources are provided in the Appendix.

Eligibility Criteria, Screening, and Extraction

Study inclusion criteria stipulated publications reporting on adolescent and adult populations (14 and older) with presumptive health care services for CT and/or GC with reported treatment and positivity rates. Additionally, the healthcare setting was required to be within the USA. Initial title and abstract review were conducted independently by two researchers (KA, NV) utilizing the Covidence™ systematic review platform. Articles were not adjudicated, relying on sole discretion of the reviewer.

Full text review and data extraction from included studies was completed by author KA. Extracted data elements were recorded in Excel, utilizing a predefined template, and included publication details (title, journal, date); study details (setting, population demographics, design). The primary outcomes extracted were treatment and positivity rates.

Given the variability in reporting, reported study data was used to calculate the following variables (as applicable): percent treated presumptively, percent not treated presumptively, percent positive with presumptive treatment, percent negative with presumptive treatment, and percent positive without treatment. Where possible, median time to follow-up on patients positive, but not treated presumptively was recorded, as well as the percent left untreated. For the purposes of this analyses, percent positive and percent negative refer to result following laboratory testing. Secondary outcomes related to demographics, social factors, clincal setting, and location were also extracted. Studies were analyzed by clinical setting given the heterogeneity between providing emergency care and primary care. Upon review, this also became a natural division as all but one of the studies fell into one category. The exception, was a paper examining urgent care settings(8). For the purpose of this study, that manuscript was classified as emergency care.

Results

Selection of Sources of Evidence

The search strategy retrieved 5,508 non-duplicative articles for title and abstract screening. After title and abstract review, 71 articles were initially determined to meet criteria for full review. However, after full text review, another 53 studies were excluded. Exclusion reasons included unavailable full text, no presumptive outcomes data reported or being commentary/narrative in nature, and one identified as a duplicate. The remaining 18 articles were included in data extraction. The PRISMA flow diagram is shown as Figure 1.

Characteristics of included studies

The majority of the studies consisted of retrospective studies (94.4%) with data extracted from the electronic health record, either via chart review (76.5%) or programmatic data extraction (23%). Analysis methods primarily included frequencies and Chi-square though one-third did include logistic regressions (33.3%).(9–14) Studies primarily took place at academic medical sites. However, four studies did represent data exclusively from clinics primarily providing services related to sexually transmitted disease (22.2%).(11,14–16) All of the studies also required testing for CT and GC as part of the inclusion criteria. Only two studies (11.1%)(14,16) reported testing results by collection site.

Four studies (22.2%) included sufficient analysis detail to consider symptomatic vs. asymptomatic (e.g., partner expsosure) rates of treatment.(9,15–17) However, three analyses did not represent unique persons making a direct comparison difficult. One study did report 1.8% as an overlap of both exposure and symptoms(9), leaving 2.2% of treated individuals as exposure only. One study(16) examined this topic specifically, finding a large increase in the number of asymptomatic patients treated over the past two decades. The same study also noted a high number of uninfected patients receiving treatment.

Six of the 18 articles (33.3%) were classified as pertaining to outpatient settings and the remaining 12 (66.7%) were from emergency department or urgent care settings. Given the difference in clinical workflow and healthcare seeking behaviors between emergency and non-emergency care settings, the results are reported separately.

Synthesis of Results

Table 1 shows the presumptive treatment data for the outpatient subgroup (n=6). One study had stated inclusion criteria of presumptive treatment, thus having a treatment rate of 100%. In the outpatient setting, the average rate of presumptive treatment across all studies was 42.96% (31.6% when excluding the study with a treatment rate of 100%). However, the presumptive treatment rates varied from 12.01% - 88.45% (excluding the one study with 100% treatment), and the percent positive of those presumptively treated ranged from 25.42% - 46.11%. The average positivity rate following presumptive treatment, across all studies, was 34.0%. Three studies (50%)(9,12,14) reported data on positive results without presumptive treatment, which ranged from 3.13% to 15.62%. Two studies (33.3%) included results related to no treatment (lost to follow-up), which were 3.18% and 22.0% respectively.(9,12) Two studies (33.3%) reported median follow-up time for those patients not treated presumptively. The median times from clinic encounter to treatment were 8.1(9) and 9.9 days(12) respectively.

The outpatient articles pertained only to adult populations, with no adolescents included. Four (67%) of the studies contained data from single-site organizations. All studies utilized data derived from electronic health records. Three of the six articles (50%)(11,14,16) focused primarily on men and the other three (50%) included both male and female patients. Four studies (66.7%) included sexual orientation as a variable of interest. Articles in the outpatient setting did not include analysis related to treatment of pregnant patients and only one study (16.6%) included social risk factor variables (e.g., homelessness, lack of insurance, etc.).(9) Studies in this subgroup represented data from California, Florida, Oregon, and Seattle. The clinic settings were primarily urban academic medical centers, with one study (16.6%) representing state-wide public health clinics. Reported race data (not shown) varied by study inclusion criteria and geographic setting but focused primarily on White and Black/African American populations. Ethnicity data was inconsistently reported. Cohort sizes for outpatient studies ranged from 1,209 – 63,889 (median: 9,012; mean: 21,066.2)

Table 2 presents the presumptive treatment data for the emergency department/urgent care subgroup (n=12). The average rate of presumptive treatment across all studies was 41.58%. However, the presumptive treatment rates varied from 15.66% - 91.16%. One study did not report positivity following treatment. For the remaining studies, the percent positive following presumptive treatment ranged from 4.55% to 59.24%. For those not treated presumptively, positive rates ranged from 4.28% to 29.52%. The average positivity rate, across all studies, following presumptive treatment was 28.07%. Two studies reported the percent positive without any treatment (loss to follow-up), which were 6.8% and 32.33% respectively. One study (0.08%) reported the median time between ED encounter and antibiotic treatment (4.8 days).

Eight (66.7%) of these 12 studies utilized data from single-site organizations. One article represented data from a multi-site urgent care network. All studies utilized data derived from an electronic health record. Five of the 12 studies (41.66%) focused exclusively on female patients and one (0.08%) focused on male subjects. Four studies (33.33%) had a female inclusion rate greater than 75% of the cohort. Articles examining the emergency setting

had two studies (1.66%) which included pregnancy as a variable of interest. Three studies (25.0%) included adolescents, either as the sole focus or as part of the cohort. No studies included sexual orientation. One study (0.08%) included insurance status as a variable and one (0.08%) included employment status, no other social risk factors are represented. Studies in this subgroup represented data from California, Illinois, Iowa, Massachusetts, Maryland, Michigan, Ohio, North Carolina, and Washington DC. Clinical settings were primarily large, urban, academic medical centers with one study (0.08%) representing urgent care centers in a small, urban area. Race and ethnicity variables were inconsistently reported and are not included in this review. Cohort sizes for emergency department studies ranged from 145 – 10,452 (median: 601; mean: 1556.3)

Qualitative Analysis

An informal thematic analysis was undertaken related to the conclusions and policy recommendations of the studies included in this review. A little more than half (55.5%) (8,14–16,18–23) of the studies suggest that clinicians may be over treating patients for CT and GC, especially in light of antimicrobial resistance. These studies suggest advancements in point-of-care testing would allow for identification of cases in a more timely manner. Additionally, studies suggest better targeted guidelines, such as varying guidelines based on empirical evidence for specific subpopulations, may be more appropriate for accurate treatment.

The remaining studies (44.5%) were either neutral as to presumptive treatment recommendations(10,11,13) or argued for increased awareness and implementation of presumptive treatment.(9,12,17,24,25)

Discussion

This scoping review sought to characterize the literature surrounding presumptive treatment of CT and GC within private healthcare settings in the USA. Interestingly, the average presumptive treatment rates across healthcare settings were roughly the same (outpatient, 42.96%; ED 41.58%). However, this masks the heterogeneity found across the studies and care settings, which is important for demonstrating the true variability uncovered. The individual articles included in this review showed highly variable rates of presumptive treatment. While there was significant hetergenity across studies in location and cohorts, there was significant variation across the studies examined, which was not explainable by healthcare setting. While some of the variability is due to how cases were selected in each study, many articles reported data on positive and negative results, allowing for calculation of treatment rates as well as CT/GC positivity/negativity across treatment categories. There was no detectable difference between years in either care setting, suggesting one reason for variability in prescribing guidelines adherence may be variability among health system and prescribers' practices. Moreover, presumptive treatment varied across geographical areas, without identifiable pattern, which suggests there are no relationship of geography with presumptive treatment. Patients seeking care with symptoms of GC and CT may receive a diagnostic test but not treatment. Yet a precise estimate of treatment cannot be determined due to heterogeneity in study design.

Rates of over- and under-treatment were also examined. While overtreatment was examined, it is important to note that overtreatment in this instance does not denote incorrect treatment. The treatment given may have been applicable to other symptoms or conditions present that are not represented clearly in the literature examined. In the outpatient setting, one study utilized presumptive treatment as inclusion criteria, limiting usefulness for under-treatment analyses. However, the remaining studies demonstrate wide variability on under-treatment. Of particular interest, is the lack of reported data on final treatment (e.g., median time to treatment, loss to follow-up) for those not presumptively treated at the time of the visit. From many studies, it was difficult to assess whether treatment was ultimately received - but not reported - or whether the infections remain untreated. Additionally, there is a lack of literature related to treatment of asymptomic/exposed individuals compared to symptomatic individuals. This gap in knowledge leaves unanswered clinical and policy questions, such as the extent to which individuals, especially vulnerable populations, may go untreated and may subsequently cause secondary infections as well as experience poor outcomes or identifying correct strategies of antibiotic stewardship in a time of antimicrobial resistance. (26)

Interestingly, the inclusion of men and women as subjects varied between clinical settings. More outpatient studies focused on males, while emergency department studies were over representative of female populations. This is consistent with past findings on testing behaviors of men and women, which found that men were more likely to seek STI testing at sexual health clinics.(27) The same study found increasing utilization of emergency care for STI testing. Emergency department use may be related to the prevalence of females seeking urgent care, particularly related to concerns around gynecological health and pregnancy. However, this was not explicitely studied and may warrant future investigations. Additionally, within the emergency department setting, there is an opportunity to examine rates of treatment for men to establish whether missed treatment opportunities exist in this setting. Additionally, there were limited analyses - and none in the emergency setting - that included male sexual orientation as a variable. Given the broader move in biomedical and public health studies to examine gender, sex, and sexual orientation (GSSO) in medical records(28–30) and examine health care for LGBTQ+ minority populations, additional studies that accurately reflect GSSO identities is warranted.

Also of interest is the lack of mention of extragenital testing in this group of articles. Only two studies reported positivity and treatment by laboratory collection site. Previous work suggests this may be related to lack of collection at this sites(25) but may also be an artifact of electronic data collection. As mentioned above, the literature is also sparse as it relates to LGBTQ+ minority populations, and specifically gender diverse individuals. There is a need for increased conversations related to increased testing of all applicable anatomical sites.

Many studies focused on large, urban medical centers, which may not be representative of many areas of the USA. One in five Americans live in areas defined as rural and those areas often suffer from minimized access to healthcare as well as social determinants that present differently from their urban counterparts, including increased stigma around STIs. (31,32) Rural populations, particularly adolescents, remain understudied despite significant increases in sexually transmitted infections. Moreover, most studies were single center that

limited participants to those seeking care at a single hospital or clinic. All studies relied exclusively on data available from the electronic health records. Future research should examine STI treatment in larger, population-based studies perhaps with the inclusion of alternate data sources, such as claims or health information exchanges, which aggregate clinical data from multiple data sources. Access to alternative data sources would ensure a more comprehensive view of filled prescriptions and potentially identify care received outside of the health system. Understanding the full spectrum of care received is critical to fully characterize current treatment practices.

As highlighted by the previous paragraphs, an important distinction discovered in this review was the heterogeneity of the outcomes of these studies. However, there is homegeniety among the inclusion criteria, namely requiring laboratory testing to be included, and the study aims/objectives. There was also considerable homogeneity among the populations studied, recruiting adolescents and adults, with most being from metropolitan areas. However, there were meaningful differences in inclusion criteria that are of note.

Although there has been increased attention to social determinants of health and social risk factors in recent years, those variables were largely unrepresented in the literature found in this review. Previoius studies have demonstrated connections between social determinants and the increase in health disparities across multiple population subgroups, specifically regarding STIs.(33) While intervention and treatment remain the primary focus, examining the interplay between social/environmental factors and disease transmission will be critical to closing disparity gaps.(34) Accordingly, we included an analysis of these characteristics as part of this review. Only one study in the outpatient setting included homelessness and poverty, despite the increased risk for health inequities in this population. The emergency department subgroup includes two studies that included references to social variables. One included employment and the other insurance status. There are numerous social factors that play a role in the overall health status of an individual(35) and future studies should seek to examine those factors which may play a role in under- or over-treatment for CT and GC.

This study is not without limitations. While systematic methods were utilized for the search, the full guidelines for systematic review were not followed given the scoping nature of this review. Accordingly, there are studies or elements within studies that may have been missed during data extraction. Additionally, full text review and data extraction was handled by one author so interrater reliability cannot be established. However, this study does benefit from systematized processes as outlined above. All authors did participate in discussions related to the creation of the search criteria and, importantly, with discussion of the results. Even with the limitations, this study identified large variability in the primary and secondary outcomes which gives confidence that the review accurately characterizes the current state of the literature in this space.

The variability identified in this scoping review suggests that more work is needed to address inconsistencies in presumptive treatment practices for CT and GC infections as well as to assist in identification of best practices across care settings. This is of critical importance, as CT and GC infections are rising and there is a growing public health and long-term clinical burden concern. The lack of point-of-care diagnostic tests for these

conditions requires reliance on clinical presentation and clinician judgment. This could lead to discrepancies in application of prescribing guidelines, causing over- or under-treatment and exacerbation of health inequities. Future studies should address the gaps identified through this review to address questions more adequately around the policy for, and implementation of, presumptive treatment guidelines for CT and GC across healthcare settings. Moreover, future research should examine organizational factors associated with presumptive treatment to potentially identify the drivers for those prescribers and health systems that adhere to recommended guidelines for CT and GC treatment. Also, with the first point of care (POC) chlamydia and gonorrhea test was approved by FDA on March 30, 2021, it is expected that POC tests will be more broadly used in USA and will need to be assessed for real-world effectiveness as well as treatment practice implications. With the changing landscape of laboratory testing, the troubling rise in STIs, and variability of treatment practices, assessments of presumptive treatment for chlamydia and gonorrhea will continue to be an important area of focus.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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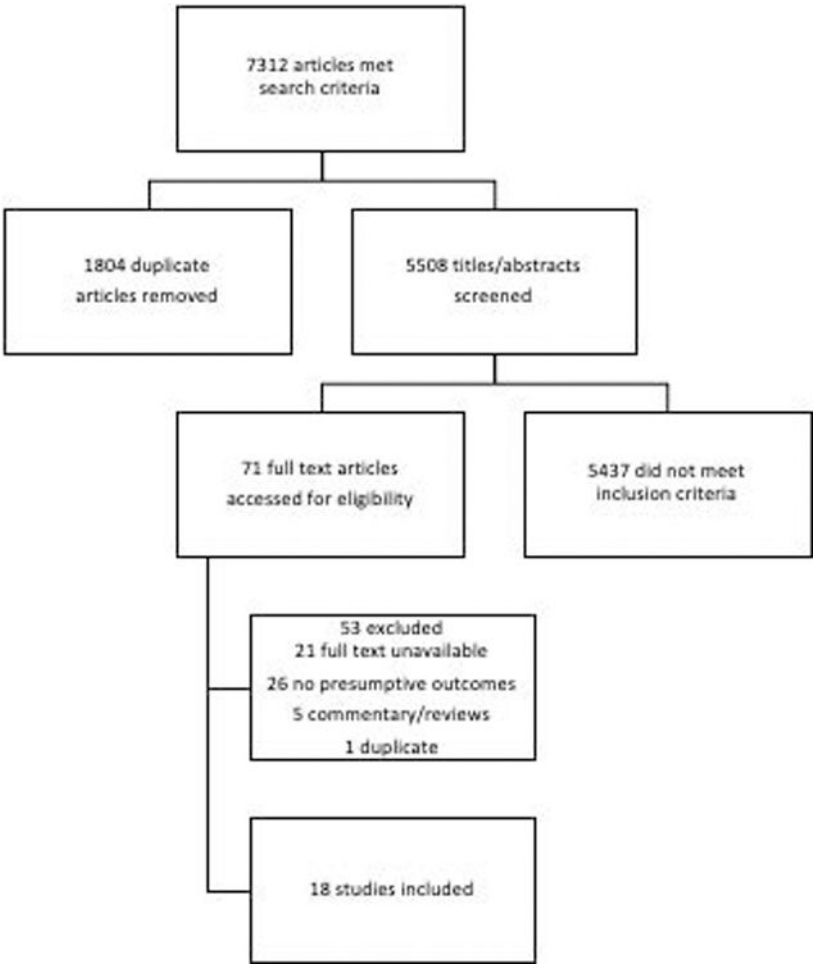

Figure 1.
PRISMA Diagram

Table 1.

Included Studies on CT and GC Treatment in the Outpatient Setting

	Faricy et. al.(9)	Andric et. al.(15)	Shover et. al.(14)	Pugsley, et. al.(12)	Anker et. al.(11)	Rowlinson et. al.(16)
Study Demographics						
Location	OR	FL	CA	VA	CA, FL	WA
Data Year(s)	2007	2008	2015	2016	2013–2017	1994–2018
Size	1222	1209	9141	63889	42050	8886
Female	485 (39.7%)	542 (44.83%)	0 (0.0%)	18,202 (28.49%)	168 (0.40%)	6220 (7.0%)
Presumptive Treatment						
Presumptively Treated	295 (24.14%)	1209 (100%)	1677 (18.35%)	9443 (14.78%)	5051 (12.01%)	7860 (88.45%)
Positive among presumptive treatment[†]	75 (25.42%)	387 (32.01%)	527 (31.43%)	3843 (40.70%)	2329 (46.11%)	2288 (28.35%)
No Presumptive Treatment						
No Presumptive Treatment	927 (75.86%)	--	7464 (88.65%)	54446 (85.22%)	36999 (87.99%)	1026 (11.55%)
Positive, no treatment	29 (3.13%)	--	657 (8.80%)	1232 (15.62%)	--	--
Untreated, no follow-up	7 (3.18%)	--	--	397 (22.7%)	--	--

[†]Positive among presumptive treatment is defined as those patients who received treatment at the time of encounter and were subsequently confirmed to be positive by laboratory testing.

Table 2.

Included Studies on CT and GC Treatment in the Emergency Department & Urgent Care Settings

	Hack et. al. (24)	Krivochensiter et. al.(17)	Schechter-Perkins et. al.(36)	Breslin et. al.(10)	Wilson et. al.(18)	Holley et. al.(20)	Huppert et. al.(21)	Sheele et. al.(23)	Garlock et. al.(13)	Wilson et. al.(19)	Burkins et. al.(22)	Glasgow* et. al.(8)
Study Demographics												
Location	NC	MI	MA	DC	MI	MD	OH	OH	OH	CA	IL	IA
Data Year(s)	2009	2008–2011	2010–2011	2012	2012	2012	2011–2012	2013–2014	2016	2015–2016	2013–2017	2018
Size	145	382†	500†	1223	639	522	1877	562	490	1162	10452	722
Female	145 (100%)	382 (100%)	247 (49.4%)	1028 (84.06%)	557 (87.17%)	522 (100%)	1492 (100%)	562 (100%)	375 (76.53%)	1112 (95.7%)	8675 (83.0%)	487 (67.45%)
Presumptive Treatment												
Presumptively Treated	41 (28.28%)	116 (30.37%)	269 (53.8%)	615 (50.29%)	278 (43.51%)	101 (19.35%)	1711 (91.16%)	88 (15.66%)	278 (56.73%)	512 (44.06%)	2334 (22.33%)	314 (43.49%)
Positive among presumptive treatment††	11 (26.83%)	--	--	192 (31.22%)	65 (23.38%)	14 (13.86%)	816 (47.69%)	4 (4.55%)	73 (26.26%)	129 (25.20%)	525 (22.49%)	186 (59.24%)
No Presumptive Treatment												
No Presumptive Treatment	104 (71.72%)	266 (69.63%)	232 (46.4%)	608 (50.29%)	361 (56.49%)	421 (80.65%)	166 (8.84%)	474 (84.34%)	212 (43.27%)	650 (55.94%)	8118 (77.67%)	408 (56.51%)
Positive, no treatment	7 (6.73%)	108 (40.6%)	--	92 (15.13%)	28 (7.76%)	18 (4.28%)	49 (29.52%)	--	11 (5.19%)	58 (8.92%)	456 (5.62%)	44 (10.78%)
Untreated, no follow-up	--	--	75 (32.33%)	--	--	--	--	--	--	--	31 (6.8%)	--

† Utilized only positive cases in the analysis.

* Study that included urgent care facilities.

†† Positive among presumptive treatment is defined as those patients who received treatment at the time of encounter and were subsequently confirmed to be positive by laboratory testing.