Uncomplicated Chlamydia in Adults and Adolescents

CHLAMYDIA: AZITHROMYCIN, DOXYCYCLINE, AND ANOGENITAL CHLAMYDIA (CT)

CITATION	STUDY DESIGN	STUDY POP/ SETTING	EXPOSURE/ INTERVENTION	OUTCOME MEASURES	REPORTED FINDINGS	DESIGN ANALYSIS QUALITY/BIASES	SUBJECTIVE QUALITY RATING
1. Thorpe EM Kr. Stamm WE, et al	Clinical trial (randomized, unblinded)	N = 597. Outpatient settings: STD clinics, hospital-based GYN clinics, private practice offices, college-student and adolescent health centers. Eligibility criteria: +Ag detection test and: symptoms (clinical MPC or urethritis), sexual contact of partner with proven chlamydia, or concomitant GC	Azithromycin (Az) 1 g (4 – 250 mg tabs) po x 1 in clinic vs doxycycline 100 mg po q 12 h x 7 days. Randomized 2:1 azithro: doxy.	Clinical response at 1 wk and 2 wks (cure, improvement, or failure); bacteriologic response (negative EIA or DFA = cure; positive EIA or DFA = failure)	Az regimen was as effective as doxy. Bacteriologic efficacy: 1 wk cure– Az = 92%; doxy = 89%. 2 wk cure – Az = 97%; doxy = 99%. Relapse vs re-infection between wks 1 and 2: Az = 2; doxy = 1. Clinical response 1 wk:- cured Az = 61%; doxy = 60%%; failed Az = 1%; doxy = 1%. 2 wks: cured: Az = 86%; doxy = 83%; failed Az = 1%; doxy = 3% Adverse events (all mild or moderate): Az=41%; doxy = 37%	Good generalizability to real world setting: good number and diversity of study sites. Limitations: Outcome assessments not blinded. Only 2 wks of f/u. 14% loss to f/u after 2 wks. Use of EIA/DFA as outcome measure.	I
2. Brihmer C, Mardh PA, et al	Randomized, double-blind clinical trial	N=146 (but ultimately only 120 actually eligible and evaluated), women >18 yrs with cx-verified CT infection of the cervix (pts with hx/o GI disorders excluded) - Sweden. Some identified via screening, others referred from STD clinics b/o symptoms or infected partners	Az 1 g po x 1 vs lymecycline 300 bid x 10 d. Randomly assigned by computer-generated code	Microbiological: +Cervical CT cx – days 18, 50. Clinical: complete resolution, improvement (or failure) at check up 2 (days 15-35) and check-up 3 (days 40-65). Adverse events at check-ups 2 or 3.	Micro: 0 +cx in both Az and lymecycline groups. Clinical efficacy: No difference at check-up 2 or 3. Check-up 2: Az-22/23 satisfactory (18 cured, 4 improved, 1 failed) (96%) (CI= 87.3-100); lymecycline 28/28 (100%) satisfactory (22 cured, 6 improved). Check-up 3: Az-16/17 satisfactory (15 cured, 1 improved); 1 relapsed after previous cure (94%) (CI= 83-100); lymecycline- 26/27 satisfactory (25 cured, 1 improved, 1 relapsed after previous cure) (96%) (CI= 90-100%). Adverse events: Fewer in Az (8.3%) than lymecycline (21.6%) (p=.04).	Method of blinding not noted, 9% loss to f/u not included in analysis, clinical efficacy based on small numbers of symptomatic patients (51 total)	II

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3. Charoenwatanachokchai A, et al	Case series, non-comparative	N=100 men, aged 17-35 with NGU. 18 had CT. NB: 34 excluded from analysis (22 didn't return for f/u, 8 unprotected sex, 4 changed abx early).	Azithro 1 g.	Clinical cure (absence of presenting symptoms/signs); microscopic cure (decrease in urethral PMN to <5HPF at f/u); microbiological cure (eradication of CT and/or U. urealyticum at f/u – i.e., cx-) at visit 2 (14 days after Az).	Excellent microbiologic efficacy, but questionable clinical efficacy: 18/18 men with CT had organism eradicated but 7/18 CT+ (2 with concomitant U. urealyticum) had persistent urethritis at visit 2. Of the 5 who received subsequent doxy, 3 resolved by visit 3. 2/?10 with CT who were seen on visit 4 had relapse.	Very small #s with CT. Large proportion excluded for analysis (eg, b/o unprotected sex, abx changes). No comparison group. Results difficult to follow.	III
4. Tan HH, Chan RKW	Open-label, non-randomized, clinical trial to compare efficacy of Azithro and doxy.	53 male pts with NGU (≥5 WBC/HPF and neg GC cx and G stain) and 63 female sex workers with +CT EIA (86% asymptomatic) seen at STD clinic in Singapore. Only women with + cx evaluated.	Alternating assignment of pts to 1 of 2 arms: doxy 100 bid x 7 d vs Azithro 1 g po.	Clinical cure rate (males only) (normal urethral smear <5 WBC/hpf); microbiological cure (males= neg EIA if initial EIA was+; females = neg repeat cx).	Azithro and doxy cure rates were similar. Clinical efficacy (men only): Wk 2 – Azithro- 19/22 (86%); doxy – 20/22 ((91%). Wk 4 – Azithro - 12/15 (80%); doxy – 13/17 (77%). Micro efficacy – men: wk 2: All EIAs neg in azithro (0 of 13 initial +) and doxy (0 of 12 initial +) groups.	Questionable validity; results difficult to follow. Microbiologic cure rate in women is unclear: never actually stated in paper – despite the fact that clinical cure rate also not analyzed for women because only 86% were asymptomatic. High rates of loss to f/u (e.g., men - wk 2: 18% - azithro; 15% doxy).	III
5. Charoenwatanachokchai A, et al	Open, single-armed, non-comparative study of efficacy and safety of azithro 1 g.	N=36 women, aged 18-45 in Thailand STD clinic with CT cervicitis	All given azithro 1 g.	Negative CT cx at visit 2 (14 d) and visit 4 (28 d).	100% eradication at all visits	Very small sample size, single armed study, 14 excluded from analyses (usually b/o failure to use condoms).	III

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6. Bachmann LH	Prospective study to evaluate compliance with doxycyline regimen.	N=221 men and women with indications for CT treatment at 2 STD clinics.	Doxycyline 100 mg po bid x 7 d and evaluation of compliance via self-report and MEMS caps	Medication compliance as measured by MEMS caps and self-report, CT PCR at f/u visit.	Despite poor compliance, relatively few pts failed therapy. 5 (2%) PCR+ at f/u. 4/4 +PCR pts had ≥2 24 hr intervals between doses in 8 days. 0/58 evaluable chlamydia+ pts who took 10-14 doses within 8 days of treatment failed therapy. 3/12 (25%) of pts who took only 6-9 doses failed; 1/8 pts who took only 1-5 doses failed.	Strength: use of PCR, MEMS to evaluate compliance, excellent generalizability.	I
7. McCormack W	Multi-center, double-blind, randomized, placebo-controlled trial to compare efficacy of trovafloxacin and doxycyline for Rx of CT urethritis and cervicitis	N=970 (403 men, 567 women; 511 microbiologically evaluable; 360 clinically evaluable) with urethritis or uncomplicated cervicitis and +noncx CT test	Trova 200 qd x 5 d vs doxy 100 bid x 7 d.	Primary efficacy endpoint = bacteriologic response at visit 4 (day 35): neg CT cx. Clinical response at visit 4: cure, improvement, or failure.	Trova and doxy equivalent in females, but trova less efficacious in men. CT eradication rates in women trova = 95%, doxy = 97%; men trova = 89%, doxy = 99% (p=.003). Cure rates – women – trova = 92%, doxy = 89%; men – trova = 86%, doxy = 100% (p=.049)	STRENGTHS: LARGE SAMPLE SIZE, DOUBLE BLIND, PLACEBO-CONTROLLED; LIMITATION: USE OF CX AS OUTCOME MEASURE	I
8. McCormack WM, Martin DH, et al.	Multi-center randomized, double-blind clinical trial to compare efficacy of grepafloxacin and doxycyline in Rx of CT endocervical infection	N=451 women attending 17 STD clinics in the US who had clinical MPC, recent +CT cx, +noncx CT test, or contact with male partner who had +CT cx. Only those with + CT cx evaluated (154/451)	Randomized to either grepafloxacin 400 mg qd x 7 d vs doxycycline 100 mg bid x 7 d.	Microbiologic cure: neg CT cx at 21-28 d; clinical success: cure or improvement.	Similar microbiologic and clinical efficacy for grepafloxacin and doxy. Microbiologic cure rate at 21-28 d: Grepafloxacin = 78/81 (96%); doxy = 72/73 (99%). Cure rate at 21-28 d: Grep = 54/81 (75%); doxy = 45/73 (79%). Adverse effects similar (47%, 46% grepa and doxy, respectively – except 15% taste perversion for grepa vs 0.4% for doxy.)		I

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9. Phillips I, et al	Randomized, double-blind multicenter study to evaluate 3 antibiotic regimens.	N=725 men with NGU in Europe (30% CT, 6% CT + U. urealyticum)	1) Sparfloxacin 200 mg/d x 1 -> 100 mg/d x 2; vs 2) Spar 200 mg/d x 1 -> 100/d x 6; vs 3) Doxy 200 mg/d x 7	Overall clinical efficacy (combining clinical and bacteriologic response and # PMNs/field) on visit 2 (days 9 – 12) and visit 3 (d 21-25).	7 d spar regimen is useful for NGU. Success in v2 and v3 – spar 3 d = 59%; doxy = 62%; spar 3 d = 51%. Non-success in v2 and v3: spar 3 d = 22%% doxy = 17%; spar 7 d = 24%.	Outcome measure somewhat unclear	II
10. Lau C and Qureshi AK	Meta-Analysis	Randomized clinical trials reported Jan 1975-Aug 2001 with: males and nonpregnant females >15yo, Rx with oral doxycycline and azithromycin, microbial cure eval at f/u.	azithro 1 g once versus doxy 100mg bid x 7d	pooled: treatment efficacy difference, risk difference for adverse events.	12 trials met inclusion criteria, with 1543 pt eval for cure and 2171 for adverse events. Cure rates: 97% azithro vs 98% doxy. Adverse events in 25% vs 23%. After pooling data, efficacy difference for cure (0.01; 95%CI 0.01-0.02) and risk difference for adverse effects (0.01; 95%CI 0.02-0.04) not significantly different. No evidence of publication bias and no bias by diagnostic assay, f/u time, attrition rate, sex, publication date, study design (open/blind) or study sponsor.	Most studies used CT culture or EIA. Most f/u periods 2wk or 4wk post-therapy. Good study design and analytical approach. Strong evidence for azithro and doxy being equally efficacious and tolerated.	I
11. Drummond, et al.	Retrospective study of azithromycin for rectal CT in asx MSM	Asx MSM (age 20-64) diagnosed w/ rectal CT by NAAT in 2009 at a Sexual Health Centre in Sydney who received azithro and had repeat CT test (n=85)	Azithro 1 g Review of behavioral data.	CT positivity by NAAT (PCR) at time of retesting (21-372 days). Classification of poss reinfection vs. persisting CT.	11 (13%) had repeat pos CT. 6/11 were prob reinfections vs. 5/11 poss treatment failures, suggesting azithro efficacy of 94%.	Limited by retrospective design. Not an RCT and no comparator drug. Rec TOC at clinic was 6 wks, but wide range of timing of repeat CT testing (45% test >12 wks). High risk population. Limited to asx CT. 12% HIV infected. LGV typing not done	II

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12. Elgalib, et al.	Retrospective study of doxycycline for rectal CT in asx MSM	Asx MSM (age IQR 26-38yo) diagnosed w/ rectal CT by NAAT Sep 2006- Sep 2009 at a GUM clinic in London who received doxy and had repeat CT test (n=165)	Doxy 100 mg bid x 7d	CT positivity by NAAT (SDA or TMA) at time of retesting (IQR 34-88 days)	2 of 165 had repeat pos CT, one pt with repeat pos CT only took 3d of doxy and the other pt had repeat testing at 240d. Data suggested doxy efficacy 98.8%.	Limited by retrospective design. Majority with rectal CT during study period were excluded.. Not an RCT; no comparator drug. Rec TOC at clinic was 4 wks. Only IQR reported for f/u interval; some pts had f/u >7 wks. High risk population. Limited to asx CT. 17% HIV pos. LGV excluded.	II
13. Steedman, et al.	Retrospective study of azithromycin for rectal CT in asx MSM	Asx MSM (age 16-83yo)diagnosed w/ rectal CT by NAAT in June 2005-May 2006 at a GUM clinic in Edinburg who received azithro and had repeat CT test (n=68)	Azithro 1 g	CT positivity by NAAT (PCR) at time of retesting (rec test $\geq$3 wks post-rx, but testing interval not provided).	9 of 68 (13%) had repeat pos CT, suggesting 87% azithro effiacy. However, 3 (33%) of repeat CT pos were tested $\leq$21 days post-rx (poss false pos NAAT) and 8 (88%) of repeat pos were sexually active between rx and retesting.	Limited by retrospective design. Not an RCT and no comparator drug. Rec TOC at clinic was $\geq$3 wks, but time interval to repeat CT test not reported. High risk population. Limited to asx CT. 17% HIV infected. LGV excluded.	II
14. Hathorn, et al.	Prospective observational study of azithromycin and doxy for rectal CT in women and MSM	MSM and women (age unknown) diagnosed w/ rectal CT by NAAT at Univ Clinic in Bham UK, treated and had repeat CT test. Rx differed by phase: Phase 1 (Jan-June 2010) azithro rx, repeat test in 42 of 89 Phase 2 – (Oct 2010-Mar 2011) doxy, repeat test in 40 of 78	Phase1 - Azithro 1 g Phase 2 – Doxy 100mg bid x 7d	CT positivity by NAAT (TMA) at time of retesting (rec test at 6 wks, but repeat testing interval not provided).	Phase 1 azithro – 11/42 (26%) pos TOC; adj for poss reinfection 9/42 (21%) pos TOC Phase 2 doxy – 2/40 (5%) pos TOC; adj for poss reinfection 0/40 (0%) pos TOC	Not an RCT. Rec TOC at clinic was 6 wks, but time interval to repeat CT test not reported.. 3% HIV infected. All women and most men asx. LGV excluded. High lost to f/u rate (only about 50% had TOC). Almost as many subjects got azithro in phase II but were not analyzed.	I

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15. Schwebke, et al.	Multi-center,, double-blind RCT phase IIb of azithro vs. doxy regimens (+/- trich rx) for sx NGU	Men (age median 27 +/- 7yr) w/ sx NGU dx at STD clinics in 4 US cities.. Of 305 pts w/ NGU in MITT group (randomized and took 1+ doses), 111 were CT+.	Randomized to either azithro 1g + doxy placebo +/- tinidazole vs. doxy 100 mg bid x 7d + doxy placebo +/- tinidazole	Repeat micro and clinical eval at Day 15-19 and Day 35-45. Cumulative micro cure of CT by urine NAAT (TMA) and clinical cure of NGU by sx/exam/Gr stain with clinical cure criteria that varied by f/u visit.	Cumulative microbiologic cure rate for CT higher for doxy (55/58, 95%) than azithro (41/53, 77%) (p=0.01). Rates of clinical cure of NGU did not differ by rx regimen at first f/u visit (doxy 75% vs azithro 69%) or final visit (doxy 49% vs. azithro 44%).	Micro eval by NAAT at Day 15-19 may be confounded by false-pos NAAT. Limited to sx men with urethritis on Gr Stain. No asx men and no women. High risk population. Most (98%) were Afr Am. Higher lost-to-f/u in azithro group.Lost-to-f/u counted as treatment failure in clinical cure eval.	I
16. Manhart, et al.	Multi-center,, double-blind, parallel group RCT of azithro vs. doxy for NGU with sx or signs	Men (mean age 34y, SD 10y) w/ sx or signs of NGU Jan 2007-July 2011 at STD clinic in Seattle. Of 422 pts w/ NGU in MITT group (randomized and took 1+ doses), 101 were CT+.	Randomized to either azithro 1g + placebo doxy vs. doxy 100 mg bid x 7d + placebo azithro	Repeat micro and clinical eval at 3 wk (allowed 2-5wk). Micro cure of CT by urine NAAT (TMA) and clinical cure of NGU by Gr stain <5PMNs and no discharge on exam.	Microbiologic cure rate for CT not significantly different for doxy (45/50, 90%) than azithro (44/51, 86%) (p=0.56). Rates of clinical cure of NGU did not differ by rx regimen (76% doxy vs 80% azithro).	Micro eval by NAAT at Day 3wk may be confounded by false-pos NAAT and unclear what % return as early as 2wk, though micro cure did not differ in 2-3wk vs 3-5 wk. Limited to men with sx or sign of urethritis. No asx men w/o signs of urethritis and no women. High risk population.	I
17. Takahashi, et al.	Prospective study of azithro for NGU w/ or w/o sx	Men (20+ yo criteria) w/ sx NGU (sx + 5+ cells/hpf in urine sediment) or asx NGU (pathogen detected) Sep-Dec 2004 at clinics in Sapporo Japan. Of 55 pts w/ NGU (42sx, 13 asx) who had repeat CT testing, 27 were CT+ (16sx, 11 asx)	Azithro 1g	Micro cure of CT by urine NAAT (PCR) at f/u visit (time interval between treatment and follow-up not known). Clinical cure of sx NGU by urine sediment w/ <5PMNs/hpf and no sx.	Microbiologic cure rate for CT was 13/16 (81%) in sx NGU vs. 11/11 100% in asx NGU. Clinical cure of sx NGU due to CT was12/16 (75%).	Not an RCT; no comparator drug. F/u interval planned or range not given; repeat CT + all had testing at $\leq$14 days, which is confounded by possibility of false pos NAAT. No demographic or behavior data provided.	III

DECISION ANALYSIS RE: COST EFFECTIVENESS

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18. Magid D, et al	Decision analysis which compares health outcomes, costs, and cost-effectiveness of doxycyline vs azithro for treatment of uncomplicated cervical chlamydial infections.	2 hypothetical cohorts of 100,0000 nonpregnant US women of child-bearing age with laboratory-confirmed, uncomplicated cervical chlamydial infection.	Doxycycline 100 bid x 7 d vs Azithro 1 g. Authors made assumptions re: probability estimates of outcomes from literature and survey of experts and estimated levels of compliance, cost estimates (via Blue Cross and Blue Shield), and health outcomes. Used incremental cost- effectiveness ratios to compare 2 interventions. Varied rates of sequelae, abx effectiveness, etc over a range of values and used univariate and multivariate sensitivity analysis to calculate effect of these changes on health outcomes, costs, and cost-effectiveness for all model variables.	Health outcomes and costs.	Azithro more cost effective than doxy. Azithro superior to doxy for preventing major and minor complications; this was insensitive to variation of cost estimates and sensitive only to variation in effectiveness of doxy. When doxy strategy was maximally enhanced relative to azithro, azithro still resulted in fewer complications but was more costly (unless abx cost-differential < $9.80).	Azithro may be even more cost effective – as assumptions of model may have underestimated advantages of this strategy.	I
19. Petitta A, et al	Decision analysis to determine economic impact of 3 methods of treating CT in the ER.	Hypothetical ER pts	Prescription for doxy x 7 d (doxy –Rx) vs prepacked 7 d supply of doxy (doxy-ED); vs single dose azithro.	Primary economic outcome: total of all associated short and long-term costs; primary health outcome: number of CT infection relapses	For every 1000 pts, doxy-ER and azithro resulted in 21.6 and 36.2 fewer relapses than doxy scripts. Total costs decreased for doxy-ER and azithro by $18,879 and $24,039 respectively. Moreover, azithro resulted in total cost decrease of $5,160 compared to doxy-ER.	Reasonable design	I
20. Genc M, Mardh P-A	Decision analysis to assess cost effectiveness of screening and treating asymptomatic female CT carriers.	1,000 asymptomatic women attending youth, family planning and gyn clinics in Sweden.	Screening with culture, EIA, and DNA amplification compared with no screening; also compared azithro 1 g vs doxy x 7 d.	Incremental cost per cured woman (direct and indirect costs of infection based on assumptions from literature re: se/sp of tests, abx efficacy).	PCR/LCR always most cost effective, although cost effectiveness of EIA rose as prevalence increased. Azithro increased cost effectiveness of all testing modalities.	?Generalizability to U.S. based on cost of medical care in Sweden.	II

CHLAMYDIA RESISTANCE

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21. Somani J, et al	Case report	3 patients with resistant CT isolates	N/A	N/A	3 patients with urogenital CT isolates resistant to doxy, azithro, and ofloxacin (minimum chlamydicidal concentration) >4.0. Two of these patients failed treatment.	N/A	N/A

GENITAL CT AND OTHER ANTIMICROBIALS

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22. Mikamo H, et al	Prospective clinical trial	N=86 women, aged 18-57 years, with dx of C. trachomatis uterine cervicitis based on "clinical symptoms" and PCR+ CT. PID patients excluded.	Levofloxacin 300 mg tid x 5, 7, or 14 days.	Short term efficacy (eradication): -PCR at 1 wk post-therapy; long term efficacy (recurrence): - PCR at 4-6 wks post-therapy.	7 and 14 d therapy superior to 5 d: Eradication rates: 44% (5 d), 88% (7 d), 89% (14 d). Recurrence rate: 50% (5d), 0% (7 and 14 d).	Small sample size without sufficient power to detect significant differences in 3 rx arms. No discussion of loss to f/u. PCR at 1 week may lead to some misclassification of patients with positive tests as treatment failures.	III
23. Martin DH, et al	Open, non-comparative phase II study to determine efficacy and safety of trovafloxacin for CT infections.	N=130 outpatients with urethral or endocervical discharge and +Df monoclonal Ab stain or Kodak Surecell test; asymptomatic men or women with +CT cx or + nonculture CT test within 4 wks of enrollment.	Trova: 200 mg qd x 7 d, 200 mg qd x 5 d, 100 mg qd x 7 d, and 50 mg q d x 7 d.	Bacteriologic eradication rates (neg cx at all posttreatment visits – 1, 2, 4 wks - vs persistence = CT isolated from $\geq$1 posttreatment cx). Clinical response assessed for those symptomatic at entry (complete resolution, vs improvement, vs failure).	Males/females, respectively: 200 x 7 d = 9/9, 10/11; 200 x 5 d = 9/9, 9/9; 100 x 7 d = 5/6, 7/8; 50 x 7 d = 10/11, 10/10. Well tolerated – although increased bili noted in 3 patients.	Phase II trial (small numbers). To be considered evaluable for efficacy, pts had to comply with 2/3 f/u visits and instructions to abstain from sex.	II

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24. Mikamo H, Sato Y, et al	Clinical trial (?non-randomized), unblinded to evaluate efficacy of erythromycin and clarithromycin.	N=96, School of Medicine Ob Gyn dept, Japan, women, aged 17-56 yrs with clinical evidence of cervicitis, and C. trachomatis on PCR (PID excluded).	5, 7, 14 days of either Erythro (E) 600 tid x 5, 7, 14 d vs Clarithro (CL) 400 bid.	Neg PCR after completion of Rx at 1 wk and 4-6 wks.	7 and 14 days of CL equally effective and both more effective than E. Eradication – E: 5 d=1/8, 7 d = 8/15, 14 d = 13/18. CL: 5 d = 5/10, 7 d = 26/26, 14 d = 19/19. Recurrence – E: 5 d = 1/1, 7 d = 3/8, 14 d = 2/13. CL: 5 d = 3/5, 7 d = 0/26, 14 d = 0/19.	Small sample size, ?randomization, no blinding of either intervention or outcome assessment. No documentation of criteria for cervicitis dx or recurrence. Strength: 4-6 wk f/u.	III
25. Ross JDC, et al	?Descriptive study vs non-controlled case series (audit)	N=116, men and women with + CT cx seen in GU Dept, Edinburgh Royal Infirmary from 9/1/94 – 12/31/94.	Their standard 7 day Rx (men = tetra 250 qid; women = erythro 500 bid)	+ cx on test of cure f/u at 2 wks.	3/97 (3%) pts who returned for test of cure were + (hx suggested 2 reinfections and 1 failure)	2 wk f/u short. 16% of original sample lost to f/u but not included in analysis as potential failures.	III limited use for assessment of treatment efficacy.
26. Peipert JF, Sweet RL, et al	Open-label, phase III, uncontrolled multicenter study to evaluate safety and efficacy of iv and po ofloxacin monotherapy.	N=70 women with clinical and laparoscopic evidence of acute PID; 12 had CT alone, 1 had CT and GC. Only 51 evaluated for clinical efficacy (see below).	Ofloxacin 400 mg iv q 12 h -> switched to po when able for total of 10-14 d.	Clinical response (cured, improved, failed, unable to evaluate). Microbiologic response (cervical and endometrial laparaoscopic cx and CT PCR at dx; in vivo micro reponse measured by clinical response since repeat laparoscopy not done. Adverse events evaluated up to 5 wks post-Rx.	Clinical efficacy: 50/51 clinically cured (98%); 1 with negative cx and PCR failed at post-treatment eval but subsequently cured with addition of metronidazole to oflox. 17/70 (24%) adverse events. At long-term f/u (3-5 wks post Rx)16 pts with pathogens isolated at admission had repeat cx -> all cx negative- except 1 pt who had new CT infection.	19/70 pts excluded from clinical efficacy analysis (10 protocol violations, 8 negative laps, 1 without final assessment).	II
27. Batteiger B, et al	Randomized, double-blind, multicenter trial to compare clinical and microbiological responses in patients given single-dose rifalazil versus azithromycin for NGU and CT.	N=170 (total); N=111 (clinically evaluable [CE]); N=42 (microbiologically evaluable); men 18-45 yo with symptomatic (acute) NGU. Of the CE, 46 (41%) had CT	Rifalazil: single PO dose of 2.5, 12.5, or 25mg versus azithro 1 g PO single dose.	Clinical cure, bacteriologic eradication rates at 2 and 5 wks post-therapy; composite endpoint was therapeutic cure (clinical and micro) at 2wk. CT detection at baseline and post-therapy by Genprobe Aptima Combo 2 or culture.	Clinical CTcure 12/14 (86%) of rifalazil 25mg grp 2wk and 8/13 (62%) 5wk; of these, 11/13 (85%) micro response at 2wk and 10/12 (83%) 5wk. In azithro grp, clinical cure CT in 9/12 (75%) 2wk and 5/11 (45%) 5wk; micro cure 10/12 (83%) at 2wk and 7/11 (64%) at 5wk. Therapeutic cure rifalazil 25mg versus Azithro 1 g was 85% vs 58%. Rifalazil noninferior to azithro. AEs in rifalazil 25mg grp 18% (HA 8%) vs azithro AE 19% (GI sx 12%).	Small sample size. Only 46 (41%) of clinically-evaluable had chlamydial NGU (others non-chlamydia). Women (cervical CT) not evaluated in this study. Some individuals received only culture (less sensitive).	I

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28. Geisler, et al	Multi-center, double-blind RCT phase III of Vibramycin (generic doxy) vs.WC2031 (experimental once daily delayed-release doxy) for urogenital CT	Men and women age 19-43 with uncomplicated urogenital CT at 41 US clinics (mostly STD or GYN) Apr-Oct 2010. MITT grp (randomized, CT+ baseline) 378 pts, but primary analyses in MITT subset with evaluable efficacy, (per protocol) that had 323 CT+ subjects.	Randomized to either Vibramycin 100 mg bid + WC2031 placebo vs. WC2031 200mg daily x 7d + Vibramycin placebo	Micro cure of CT in "evaluable" MITT by vag swab NAAT (TMA) at Day 28 (-3/+7d). Alternative micro cure analysis in full MITT. Clinical cure in subset w/ CT clinical manifestations at baseline with cure being resolution of manifestations at Day 28. Incidence of AEs.	Micro cure rate in "evaluable MITT" equivalent for WC2031 (95.5%) vs. Vibramycin (95.2%), w/ WC2031 meeting noninferiority criteria.Micro cure similar in full MITT (87% vs. 90%). In subset of 96 subjects eval for clinical cure, the clinical cure rate was 85% for WC2031 vs. 76% for Vibramycin. AEs more often in Vibramcyin than WC2031 (53% vs. 40%), esp higher nausea (21% vs 13%) and vomiting (12% vs. 8%).	Sexual behavior and partner treatment data not collected. Noninferiority based on "evaluable" MITT rather than full MITT grp. Higher risk population. Included men and women, both asx and sx, and diversity in race represented.	I
29. Ito, et al	Prospective study of sitofloxacin for sx NGU	Heterosexual men (16-69yo) w/ sx NGU Apr 2009-July 2011 at a urology clinic in Sendai Japan. Of 73 patients, 33 were CT+	Sitafloxacin 100mg bid x 7d	Micro cure of CT by urine NAAT (PCR) at f/u visit <35 days. Clinical cure of sx NGU by resolution of sx.	Microbiologic cure rate for CT NGU was 33/33 (100%). Clinical cure of NGU due to CT was33/37 (89%).	Not an RCT; no comparator drug. Unclear how many had repeat CT testing at $\leq$21 days, which is confounded by possibility of false pos NAAT.	II
30. Takahashi, et al	Prospective study of levofloxacin for NGU w/ or w/o sx	Men (18+ yo criteria) w/ sx NGU (sx + 5+ cells/hpf in urine sediment) or asx NGU (pathogen detected) Sep 2009-Apr 2010 at clinics in Sapporo Japan. Of 87 pts w/ NGU (82sx, 5 asx) who had repeat CT testing, 24 were CT+ (19sx, 5 asx)	Levofloxacin 500mg daily x 7d	Micro cure of CT by urine NAAT (PCR) at f/u visit 1-3 wks after rx started. Clinical cure of sx NGU by urine sediment w/ <5PMNs/hpf and no sx.	Microbiologic cure rate for CT NGU was 22/24 (92%). 18/19 (95%) in sx NGU vs. 4/5 (80%) in asx NGU. Clinical cure of sx NGU due to CT was18/19 (95%).	Not an RCT; no comparator drug. Micro eval by NAAT at <3wk may be confounded by false-pos NAAT. No demographic or behavior data provided.	III

CHLAMYDIAL CONJUNCTIVITIS

CITATION	STUDY DESIGN	STUDY POP/ SETTING	EXPOSURE/ INTERVENTION	OUTCOME MEASURES	REPORTED FINDINGS	DESIGN ANALYSIS QUALITY/BIASES	SUBJECTIVE QUALITY RATING
31. Katusic D, Petricek I, et al	Randomized, open, multicenter, clinical trial	N=78 (enrolled); 51 (65%) completed. 18-82yo pts with acute follicular chronic (>4wk) or recurrent (≥2 distinct remissions) chlamydial inclusion conjunctivitis by culture or DFA diagnosed in ophthalmology depts of 3 clinical hospitals in Zagreb, Croatia. Excluded: pregnant, lactating, drug allergy, significant comorbidity, conjunctivitis from etiologies other than CT, anti-CT drug Rx w/n 7d of enrollment.	Azithromycin 1 g po single dose vs doxy 100 mg po bid x 10d. Opthalmologic exams and CT culture done 10-12d and 4-6wks after initiation of therapy.	Clinical and bacteriological response at 10-12d and 4-6 wks after initiation of therapy. Occurrence and frequency of adverse events.	25 evaluable in azithro arm vs 26 in doxy arm. At 10-12d visit, 20% vs 15% still CT culture +. At 4-6wk visit, CT eradicated in 92% vs 96% and clinically cured in 60% vs 69%. All patients with CT not eradicated at the 4-6wk visit had negative CT cultures at the 10-12d visit, suggesting relapse or reinfection. Adverse effects occurred in 4% vs 8%. In 2 (8%) of pts rec doxy, noncompliance noted yet CT eradicated. No significant differences in any parameters.	First prospective study to eval azithro in inclusion conjunctivitis. Insufficient power to detect any significant differences in treatment efficacy. Unclear why 10d doxy course rather than 7d was studied. More than 70% of patients received topical treatments before enrollment. Older population than reported for genital CT: mean age was 43yrs, with one-third older than age 50.	II

CHLAMYDIA OROPHARYNGEAL (OP) INFECTION: CLINICAL FINDINGS, NATURAL HISTORY AND TREATMENT

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32. Mikamo H, Ninomiya M, and Tamaya T.	Clinical trial assessing efficacy of clarithromycin against cervical and pharyngeal CT	52 women diagnosed with cervical CT at the Dept of OB and Gyn, Gifu Univ Sch of Med, Gifu, Japan: 20 were commercial sex workers (CSW) and 32 others (students, office workers, housewives).	Pharyngeal CT PCR (Amplicor STD-1, Roche Diagnostics) prior to treatment of CT cervicitis. Clarithromycin 400mg daily for 7 or 14d.	CT eradication from cervix and pharynx, measured by PCR, at days 8, 15, and 22 post-therapy.	20 (100%) of CSW had prior orogenital exposure and 15 (75%) had pharyngeal CT detected. 17(53%) of other group had orogenital exposure and 7(22%) had pharyngeal CT detected. At days 8,15, and 22 post therapy, eradication of cervical CT did not differ in clarithro 7d group (83%/97%/100%) vs 14d (86%/96%/100%). Eradication of pharyngeal CT sig lower for 7d (53%/57%/60%) vs 14d (77%/86%/91%) ($p<0.05$).	Small sample size, ?randomization, no blinding of either intervention or outcome assessment. No documentation of criteria for cervicitis dx. Utilized PCR, for which sensitivity for pharyngeal CT not established. Culture not performed. Unclear why daily clarithro at 400mg, rather than twice daily at 500mg, was chosen: this could lead to subtherapeutic concentrations.	Ill
33. Apewokin S, et al.	Retrospective study of natural history of extragenital CT and GC prior to therapy	23 male and female subjects with extragenital CT or GC from STD and HIV clinic populations in Birmingham and Chicago. 2 subjects had OP CT	NAAT repeated at time of returning for treatment of extragenital CT found by screening	Proportion of symptomatic extragenital CT Proportion with spontaneous resolution of extragenital CT	Both OP CT asymptomatic. One of two OP CT resolved prior to therapy.	Too small of a sample size with OP CT for meaningful evaluation, however does document spontaneous resolution of OP CT occurs. Hi risk populations	III
34. Wikström et al.	Prospective observational study of pharyngeal CT and clinical manifestations	281 heterosexual men and women with suspect/confirmed CT and h/o oral sex were screened by NAAT (SDA) for OP CT in STI clinics in Stockholm.	OP CT screening by NAAT. Treatment with doxy 200mg day 1, then 100mg daily for 8d	Proportion of subjects with OP CT. Proportion with symptomatic OP CT. Proportion repeat positive post-rx.	9 (7%) women and 3 (3%) men had OP CT. All OP CT asymptomatic 8 women and 1 man retested at unknown interval and all negative.	Small sample size with OP CT. Timing of repeat CT unknown. Doxy regimen different than CDC recommended for CT. High risk patient population.	III

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35. Peters et al.	Cross-sectional study of extragenital CT prevalence and clinical manifestations during an 18mo period	4299 women seen in an STD clinic in the Netherlands had extragenital CT screening by NAAT (TMA). 87% of women had OP CT testing and 71 (1.9%) had OP CT detected.	Extragenital screening by NAAT (TMA)	Proportion of subjects with extragenital CT. Proportion with symptomatic extragenital CT.	OP CT detected in 71 (1.9%). All OP CT asymptomatic.	Limited to women. High risk population. No treatment data. Reasonable sample size of OP CT. Not prospective, so at risk for provider bias in questioning.	III
36. Karlsson et al.	Prospective observational study of pharyngeal CT and clinical manifestations	Two substudies evaluating OP CT in men and women seen in a primary care center in Sweden. Substudy 1 tested 48 subjects with OP discomfort >14d; 2 had OP CT. Substudy 2 tested for OP CT in 150 subjects with genital CT; 15 had OP CT.	OP CT screening by NAAT (SDA).	Proportion of subjects with OP CT in both substudies. Proportion of OP CT with upper resp tract (URT) sx in substudy 2. Proportion repeat positive post-rx.	In substudy 1, 2 subjects (4%) had OP CT (1 man, 1 woman). In substudy 2, 11 (12%) women and 4 (7%) men had OP CT. 10 (67%) of subjects (6 women and 4 men) had URT symptoms;all OP CT asymptomatic. Of the 2 subjects with OP CT in substudy 1, one had a clinical cure on doxy, while the other did not have a clinical cure but retested neg for OP CT.	Sample size with OP CT too small. Study did demonstrate OP CT can be symptomatic. Primary care population, with most heterosexual. Doxy regimen details not given, nor was timing of retesting. URT sx could not be specified based on collected data. Substudy 1 did testing to r/o other OP bacteria (e.g. strep) but no viral testing was performed	III
37. Wada et al.	Prospective study of OP CT prevalence and clinical manifestations	42 heterosexual men with urethritis seen in a University Hospital or urology clinic in Okayama Japan. OP CT screening by NAAT (TMA). 5 men had OP CT detected.	OP CT screening by NAAT (TMA)	Proportion of subjects with OP CT. Proportion with symptomatic OP CT.	OP CT detected in 5 (12%). All OP CT asymptomatic.	Sample size with OP CT too small. Limited to heterosexual men with urethritis. Majority high risk. No treatment data.	III
38. Peters et al.	Retrospective study of extragenital CT prevalence and clinical manifestations during an 18mo period	1455 MSM (median age 38) seen in an STD clinic in the Netherlands Jan 2007-July 2008) had extragenital CT screening by NAAT (TMA). 1283 (88%) of MSM had OP CT testing and 19 (1.5%) had OP CT detected.	Extragenital screening by NAAT (TMA)	Proportion of subjects with extragenital CT. Proportion with symptomatic extragenital CT.	OP CT detected in 19 (1.5%). OP CT asymptomatic.	Limited to MSM. High risk population. No treatment data. Small sample size of OP CT. Not prospective, so at risk for provider bias in questioning.	III

Uncomplicated Chlamydia in Adults and Adolescents

CITATION	STUDY DESIGN	STUDY POP/ SETTING	EXPOSURE/ INTERVENTION	OUTCOME MEASURES	REPORTED FINDINGS	DESIGN ANALYSIS QUALITY/BIASES	SUBJECTIVE QUALITY RATING
39. Tipple et al.	Retrospective study of OP CT prevalence and clinical manifestations	2406 patients (1601 men and 805 women) seen in a UK GUM clinic Nov 2006-Oct 2007 had OP CT screening by NAAT (SDA).	OP screening by NAAT (TMA)	Proportion of subjects with OP CT. Proportion with symptomatic OP CT.	OP CT detected in 31 (1.9%) of men and 15 (1.9%) of women. 10.9% w/ OP CT were HIV-pos, all MSM. 41 of the 46 w/ OP CT had clinical data available. 2 (4.8%) with OP CT had OP sx.	High risk population with MSW and FSW. No treatment data. Reasonable sample size of OP CT. Not prospective, so at risk for provider bias in questioning.	II
40. Marcus et al.	Cross-sectional study of urethral CT in heterosexual men that provided data on transmission from OP to urethra	A subset of 227 heterosexual men w/ urethral CT testing and behavioral data seen at San Francisco STD clinic June 2006- June 2010 whose only urethral exposure was fellatio from a woman.	urine screening by NAAT (TMA).	Proportion of this subset w/ urethral CT based on pos urine TMA.	In subset of the 227 men, urethral CT positivity was 3.5% (95% CI, 1.5%-6.8%, n = 8).	Limited to men. High risk population. Race/age info not given. Sexual behavior data restricted to 3mo, so some pt at risk for urethral CT from OP exposure may have been excluded. Not restricted to fellatio w/o condom use but use of condoms very rare in this setting. HIV status not reported.	II
41. Berstein et al.	Cross-sectional study of urethral CT in MSM that provided data on transmission from OP to urethra	A subset of 397 MSM w/ urethral CT testing and behavioral data seen at San Francisco STD clinic during 2007 whose only urethral exposure was fellatio.	urine screening by NAAT (TMA).	Proportion of this subset w/ urethral CT based on pos urine TMA.	In subset of the 397 men, urethral CT positivity was 4.8% (95% CI, 2.9%-7.4%, n = 19), with higher positivity in HIV-pos vs. HIV-neg MSM (16% vs. 3%).	Limited to men. High risk population. Race/age info not given. Sexual behavior data restricted to 3mo, so some pt at risk for urethral CT from OP exposure may have been excluded. Not restricted to fellatio w/o condom use but use of condoms very rare in this setting.	II
42. Ota et al.	Retrospective study of pharyngeal CT treatment outcomes	2 groups of MSM w/ OP CT detected in men's clinic in Toronto. 1st grp 90 MSM w/ OP CT detected by culture. 2nd group 7 MSM w/ OP detected by NAAT. Of 97 men, only 88 rec'd rx, azithro 1 g (n=46) or doxy 100mg bid x 7d (n=42). Of 88 rx, only 70 had TOC results.	1st grp had OP CT TOC by culture 2 and 3 wks after rx completion 2nd grp had OP CT TOC by NAAT and cx at 3wk and 4wk after rx	Proportion of subjects with pos OP CT TOC post-rx	Of 70 MSM who rec'd rx and had TOC results, 3 (4.3%) had a pos CT TOC. 2 w/ pos TOC rec'd azithro and both had a neg 1st TOC and pos 2nd TOC, suggesting reinfection. 1 w/ pos TOC rec'd doxy and both the 1st and 2nd TOC were pos, suggesting treatment failure.	Limited by retrospective study design and small sample size with OP CT who rec'd rx and had TOC. No mention of abstinence or safe sex education. CT genotyping not performed.	III

MISCELLANEOUS

CITATION	STUDY DESIGN	STUDY POP/ SETTING	EXPOSURE/ INTERVENTION	OUTCOME MEASURES	REPORTED FINDINGS	DESIGN ANALYSIS QUALITY/BIASES	SUBJECTIVE QUALITY RATING
43. Sanders CJG, Mulder MMM	Case series to evaluate periurethral abscess.	N=20 males with periurethral abscess, (CT from 2 aspirates and 3 urethral specimens).	Aspiration of pus from abscess cavity ->kanamycin 2 g IM ->doxycycline 100 bid x 1 wk.	Clinical response to Rx at 1 wk.	4 lost to f/u, 2 spontaneous rupture, 14/20 resolved	Descriptive, case series.	III
44. Augenbraun M, et al	Observational study	N=223. Consecutive male and female STD clinic pts (symptomatic urethritis, MPC, PID; or sexual contacts of person being rx'd for GC or chlamydial infection) in Brooklyn and Birmingham	7 d doxy course prescribed in bottle with MEMS cap.	Bottle openings as recorded by MEMS (compliance, vs non-compliance vs intermediate compliance)	Substantial levels of noncompliance found: 25% strict compliance; 24% non-compliance; 51% intermediate	Excellent design for addressing question of interest in this population.	I
45. Larsen B, et al	Cross-sectional study to determine serum erytho levels in pregnancy	N=10 pregnant women with endocervical CT (ELISA); 7 = 3rd trimester, 10 = 2nd trimester	Erythro 500 mg base	Serum erythro levels	Absorption delayed and serum levels decereased compared to values in literature for 2nd trimester women. The 2 women with the most severe GI sx never had detectable erythro levels during the 4 hrs of the study.	N/A (Cross-sectional study of erythro levels – not a clinical trial).	N/A
46. Louik C, Werler MM, et al	Analysis of data on erythromycin use during pregnancy and relation to pyloric stenosis from an ongoing case-control surveillance study evaluating birth defects.	Tertiary hospitals in Boston, Philadelphia, Toronto, and Iowa (part of the study). Cases were infants with pyloric stenosis (n=1044). Two control groups (nonmalformed infants [n=1704] and infants with a wide range of other malformations [n=15,356]).	Physicians contacted to confirm the diagnosis and for permission to contact mothers, the latter who were interviewed within 6 months of baby's birth RE drug use from 2 mos before last menstrual period up to delivery, indication for drugs, etc.	Risk of pyloric stenosis from erythromycin use in pregnancy-ORs and 95% CIs, controlling for maternal age, baby sex, study period, parity, gestational age, region	All ORs close to 1, all 95% CIs included 1, and all upper bounds 95% CIs <2 (i.e. no increased risk of pyloric stenosis to infants born from mothers with erythromycin exposure intrapartum).	Large sample size, small confidence intervals, and control groups are strengths. Women reporting unknown antibiotic use were not analyzed to reduce possible misclassification.	II

Uncomplicated Chlamydia in Adults and Adolescents

LGV

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47. Viravan C, et al	Prospective case series, (descriptive, non-randomized, not a trial of abx efficacy)	N=113 consecutive consenting men who presented to hospital outpt dept in Bangkok with inguinal buboes (most with previous abx)	Bubo aspiration, erythro given if chancroid suspected (500 qid x 7 d); tetra given if LGV suspected (500 qid x 14 d).	clinical response (symptoms, resolution of buboes, improvement of ulcers, etc)	No difference between tetra and erythro in overall response to Rx at 7 d f/u.	Entirely descriptive, not designed to determine efficay; microbiologic confirmation of dx in only 36% - probably b/o extensive prior abx.	I for determining tetracycline efficacy in LGV.

AZITHROMYCIN AND PREGNANCY

CITATION	STUDY DESIGN	STUDY POP./ SETTING	EXPOSURE/ INTERVENTION	OUTCOME MEASURES	REPORTED FINDINGS	DESIGN ANALYSIS QUALITY/BIASES	SUBJECTIVE QUALITY RATING
48. Adair DC, et al	Randomized, unblinded, clinical trial	N=106 (enrolled); 85 completed. Pregnant women with + direct DNA probe (Gen-Probe) presenting to Bowman Gray School of Medicine (predominantly indigent with 4% CT prevalence)	Azithromycin 1 g powder vs erythromycin base, 500 mg po qid x 7 d. Allocated via program-generated random numbers.	GI side effects, side effects leading to discontinuation, compliance, +f/u test of cure at 3 wks, efficacy	Az associated with fewer adverse effects and greater compliance than E (GI side effects 12% vs 58%, p= .01; discontinuation due to side effects 2% vs 19%, p = .05, compliance 98% vs 53.5%, p = .01). No significant difference between Az and E in efficacy.(88%- Az vs 93% - E, p = .68) or + f/u test of cure (12% -Az vs 7%E, p = .68).	16/106 pts lost to f/u and not included in analysis. Only 74% of E pts and 50% of Az pts completed protocol within prescribed 3 wk period. Sample size possibly not large enough to determine statistically significant difference in test of cure rates and treatment efficacy of Az and E.	II

Uncomplicated Chlamydia in Adults and Adolescents

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49. Wehbeh H, et al	Randomized clinical trial to evaluate efficacy and side effects of single dose azithro in pregnant women. (Women and partner randomized as a pair.) Subjects who received doxy or erythro were partially blind, but placebo was not used.	N=48 pregnant women with +CT cx and their sexual partners	Group 1: Pt and partner = azithro 1g. Group 2: pt = erythro 500 tid x 7 d; partner tetracycline 500 qid x 7 d. Group 3: pt = azithro 1 g; partner tetra 500 qid x 7d.	+CT cx at 7-10 d f/u and 30 d f/u	Failures at 4 wks: Azithro/azithro (Group 1) = 7%. Erythro/tetra (Group 2) = 20%. Azithro/tetra (Group 3) = 0%. When all study subjects given azithro were contrasted with those given either erythro or tetra, 4.5% of azithro CT+ at 4 wks compared to 21% of those given azithro or tetra (p=.018). Side effects severe enough to warrant change in medication: azithro 7% compared to 39% erythro (p=.02).	Biases: May have had more compliant subjects – since only enrolled women whose partners also consented to participate.	II
50. Hueston WJ, et al	Indirect (decision analysis) to determine cost effectiveness of abx selections for CT infection during pregnancy.	N/A	MEDLINE search 1988-1995 of CT, pregnancy, and comparative Rx.	Based on literature, mean cost and effectiveness determined for amox 500 tid x 7 d ($9.55, 92%), erythro 500 qid x 7 d ($10.56, 83%), clinda 450 qid x14 d ($119.54, 93%), azithro 1 g po x 1 ($26.69, 94%).	Most cost effective strategy: amox -> azithro for non-responders (cost 15% lower than azithro ->amox)		I
51. Romoren M, Rahman M, et al	Prospective/Cross-sectional study to assess differences on CT or GC prevalence in antenatal clients (ANC) prescribed no therapy vs therapy (erythromycin 500mg qid po x 10d or CTX 250mg IM x 1, respectively) earlier in pregnancy (either <5 or ≥5 wks prior to enrollment)	N=703 ANC 15-43yo . Presenting to primary care clinics in Gaborone, Botswana. Exclusion criteria: therapy within 2 wks prior to testing.	Exam, data collection, and CT/GC LCR on cervical swabs.	Proportion (prevalence) of CT or GC in those receiving vs not receiving therapy earlier in pregnancy.	53 (8%) had CT and 21 (3%) GC. 146 (21%) w/ previous Ery. CT prevalence same in those w/ vs w/o previous Ery (8%) in both. CT prevalence also not different in those w/ Ery <5 wks vs ≥5wks. 142 (20%) prior CTX. Those w/o previous CTX more likely w/ GC vs those previously Rx w/ CTX (4% vs 0%; p=0.035).	Compliance, adverse effects, and prior partner treatment data not presented. Population may not be generalizable. N/A to treatment guidelines	III

Uncomplicated Chlamydia in Adults and Adolescents

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52. Rastogi S, Das B, et al	Clinical trial assessing efficacy of CT treatment (Ery stearate 500mg qid x 7d) during pregnancy in those CT-infected and also evaluation of pregnancy outcomes in 3 antenatal groups: CT treated (grp 1), CT untreated (lost to outpatient f/u) (grp 2), CT non-infected (grp 3).	N=328 antenatal (study cohort) 19-36 yo (1st-3rd trimesters) attending OPD in New Delhi, India: comprised of 59 CT-pos by DFA and PCR and 269 CT-neg. Exclusion: abx prior 2 wks, diabetes, HTN, other medical complications of pregnancy, co-infection with other pathogens (n=22)	CT DFA and PCR on endocervical swab in all patients. Erythromycin as above for CT-infected and repeat CT DFA and PCR 2wks post-therapy in this group.	Cure in CT-infected given therapy. Pregnancy outcomes in all groups.	59 (18%) CT-infected (17 grp 1 vs 42 grp 2). Test-of-cure for available 15 of grp 1: 100% cured. Data on obstetric outcomes noted in 11, 26, and 127 patients of groups I, II, and III. Mean premature delivery gestation longer in grp 1 vs 2 (35.5 vs. 33.1 wks; p<0.05). Mean birth weight not different across grps. Stillbirths higher in grp 2 vs 3 (11.5% vs 4.7%; p<0.05), and no stillbirths in grp 1.	Only a small number of treated patients and no comparator drug, yet supports efficacy of erythromycin. No data reported on compliance and adverse effects. Obstetric outcome data supports need for test of cure, but limited applicability of data to treatment guidelines. Population may not be generalizable.	II
53. Jacobson GF, Autry AM, et al	Randomized, controlled, unblinded, clinical trial.	N=129 (enrolled); 110 (85%) completed. Pregnant women with pos cervical CT LCR seen at 2 university-based, inner-city clinics in Milwaukee, WI with CT prevalence 10%.	Azithromycin 1 g po (tabs, dose not noted) once vs amoxicillin 500 mg po tid x 7 d. Allocated via computer-generated random number table in blocks of 10, separated by clinic site.	Adverse effects (i.e. intolerance) and success of treatment (success-defined as negative f/u test and completion of all medicine; failure-defined as positive test or noncompliance).	There were 55 women in each arm. At 4 weeks, treatment success did not sig differ in amox vs azithro (58% vs 63%, p = 0.56), intolerance not sig different (5.5% vs. 10.9%; p = 0.31), and preterm delivery (<37wks) not different (16% vs 13%, p = 0.77). No outcomes differences when stratified by clinic site.	Flawed study design in including noncompliance in definition of treatment failure (infections may still be cured despite some noncompliance). Significantly lower treatment success rate than other published studies would suggest in this study either high rate of reinfection, persistence, and/or very poor compliance with amox. Data from this study population may not be representative of more community-based clinical populations. Insufficient power and recruitment was only 48% of infected.	III

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54. Kacmar J, Cheh E, et al	Randomized, controlled, single-blind, clinical trial	N=39 (enrolled and completed). Pregnant women diagnosed with CT before 33wks gestation at the Woman and Infants Hospital, Brown University, Providence, RI.	Azithromycin 1 g po single dose (n=20) vs amoxicillin 500 mg po tid x 7 d (n=19).	Adverse effects and compliance (patient interview 3-7d post-therapy), and test of cure at 4-6 wks post-therapy.	15 women in amox arm vs 19 in azithro arm returned for TOC. At 4-6 weeks, TOC pos in 20% vs 5%; p = 0.3. Overall side effects 38%, but trend towards lower GI effects in amox arm (17% vs. 40%, p = 0.11). Compliance was 84% in amox arm vs 100% in azithro arm.	Amox appeared to be tolerated better than azithro. Insufficient power to meaningfully conclude any significant differences in treatment efficacy. Pregnancy outcomes not studied.	II
55. Rahangdale L, Guerry S, et al	Retrospective cohort study	N=277 (611 met inclusion, 324 excluded). Pregnant women dx w/ CT by DNA probe at 44 N. California Kaiser-Permanente facilities from 7/1/99-12/31/00. Excluded spont AB, ther AB, ectopic preg, missing charts	Database queried within 280 days of pos CT test.	Antibiotics prescribed, side effects, test of cure (TOC) >7d post-therapy, pregnancy and neonatal complications	% prescribed / TOC: Azithro 69% / 97% Amox 9% / 95% Erytho 19% / 64% No difference in patient or neonatal complications in those exposed to azithro vs. other therapy. More ery than azithro req repeat tx for N/V: 62% vs. 31%.	Amox and Azithro higher TOC than erythromycin, the latter having high intolerance. All drugs safe. Pregnancy and neonatal outcomes a strength of study. Weaknesses include retrospective design and use of CT test with low sensitivity	I
56. Pitsouni E, Iavazzo C, et al	Meta-Analysis	Review of randomized clinical trials 1991-2006 of azithro vs erythro or amox for CT in pregnancy. ITT and CE populations. Treatment success, perinatal outcomes, and AEs evaluated.	azithro 1 g once versus either erythro 500mg tid or qid x 7d or amox 500mg tid x 7d	Treatment success (TOC) by CT culture at 2-6 wks. Primary analysis azithro vs erythro. Secondary analysis azithro vs comparators (erythro or amox). Data presented as pooled OR (>1 favored azithro vs <1 favored comparators)	8 trials met inclusion criteria, with 587 women evaluable (509 ITT and 470 CE). No difference in treatment success of azithro vs erythro in ITT (OR 2.7 [0.7-10.3]) or CE (OR 1.5 [0.6-3.8]) or vs comparators in CE (OR 1.5 [0.8-2.6]). There were fewer total adverse events and higher compliance in azithro vs erythro or comparators. Of 3 studies evaluating perinatal outcomes, there was no difference amongst the treatments.	Studies incorporated CT culture and not NAATs. TOC timing differed across studies (up to 4wks) as did gestational age (up to 8wks). Grouping amox with erythro rather than also evaluating amox individually was a study design weakness. Cure rates in general lower than trials in nonpregnant populations, mainly due to compliance or tolerability issues.	I

PATIENT-DELIVERED PARTNER TREATMENT (PDPT) OR PARTNER REFERRAL

CITATION	STUDY DESIGN	STUDY POP/ SETTING	EXPOSURE/ INTERVENTION	OUTCOME MEASURES	REPORTED FINDINGS	DESIGN ANALYSIS QUALITY/BIASES	SUBJECTIVE QUALITY RATING
57. Schillinger JA, Kissinger P, et al	Clinical trial (multicenter, randomized, controlled, unblinded)	N = 1787 women aged 14-34 years with uncomplicated CT. Outpatient settings: family planning, adolescent, primary care, and STD clinics; ER or other hospital-based departments. Eligibility criteria: lab-confirmed CT urogenital infection. Exclusion criteria: already treated, no intercourse in prior 60d, pregnant, HIV+, co-infected with GC/trichomoniasis/or syphilis at treatment, or allergy to macrolides.	Azithromycin (Az)1 g (powder) po x 1 to all at enrollment, then patients randomized 1:1 to either receive up to four 1 g Az packets for up to 4 male partners (PDPT) or self-referral for male partners. All received f/u interview and urine CT LCR/PCR at 1 month (min 21d) post-therapy and women neg for CT scheduled for similar f/u visit in 3 months.	Detection of CT in urine ≥21d post-therapy of initial CT	1454 (81%) eligible patients returned for >1 f/u visit. Cum rate of CT was 87/728 (12%) in PDPT vs. 108/726 (15%) in self-referral arm (RR 0.8; 95%CI 0.62-1.05; p=0.102). Hi compliance in PDPT arm (85% if 1 partner, 81% if >1). Overall 20% reduction in PDPT arm.	Good generalizability to real world setting: good number and diversity of study sites. Limitations: Significant difference in age distribution between arms (high % 14-19yo in PDPT arm). Almost 20% loss to f/u. Limited power.	I
58. Klausner JD, Chaw JK.	Descriptive review of prior PDPT studies (2 observational studies, 1 multicenter randomized clinical trial); descriptive cross-sectional analysis of STD clinic data aimed at reporting the clinical experience to date with PDPT at a STD clinic.	Not provided for review. For the cross-sectional study: chlamydia-infected patients seen at a municipal STD clinic in San Francisco.	Details not provided for the review other than they were PDPT studies.	For cross-sectional analysis: proportion of patients utilizing PDPT to date and the description of reasons for refusing to accept PDPT option or for inability to provide meds to partners.	For the descriptive review: concluded PDPT decreased CT incidence. For the cross-sectional analysis: 23% of CT-infected patients received PDPT. Patients not taking PDPT believed partners will seek evaluation or unable to deliver PDPT to partners (not knowing name or not comfortable)	Review informal, not meta-analysis. Cross-sectional analysis provides data on real-world experience.	Review: III Cross-sectional analysis: II

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59. Postma MJ, Welte R, et al	Decision analysis constructed for health outcomes of a CT screening program (averted PID, infertility, etc.); reinfection in absence of partner treatment (partners provided prescription by patient or provider) was included in the model. Outcomes linked with costs and productivity losses.	Estimated from a pilot study (n = 2403) of sexually active women undergoing routine CT screening in 22 general practices in Amsterdam.	Outcomes estimated for prevalence data from the pilot study. Women tested by CT LCR and infected patients and partners received azithro 1 g. Authors made assumptions: LCR sensitivity 80%/specificity 100%; noncompliance in 10%; azithro 95% efficacy in eliminating complications, numerous partner transmission assumptions; based on partner referral, 86% current and 33% ex-partners offered treatment; 90% of male partners would take therapy.	Cost-effectiveness expressed as the ratio of monetary costs and benefits to the number of complications averted for 3 options: A (reinfection not considered and no partner therapy; B (prob of reinfection 68% and no partner therapy; C (prob of reinfection 68%, reinfection offset by partner therapy)—option B vs C reflects benefit of partner therapy.	Partner therapy reduces net costs per outcome averted by approx 50%. Sensitivity analyses indicated cost-effectiveness even when assumptions varied.	Numerous assumptions in this model and prevalence estimated from a small pilot study (relative to the population size). Demonstrates partner referral leading to treatment cost-effective through averting negative outcomes. PDPM not included in this model (only prescriptions).	II
60. Golden MR, et al	Randomized, controlled, unblinded clinical trial	Heterosexual men (n=646 randomized) and women (n=2105 randomized) age >13yo in King Co., WA. Eligibility criteria: CT or GC infection reported to Public Health-Seattle and King Co. Exclusion criteria: partners already treated, inability to contact patient ≤14d post-therapy, homeless, intoxicated or psychotic at consent, not at a participating clinical site, STD part of eval for sexual assault, enrolled in another partner study, diagnosing provider refused, non-English speaker, incarcerated, MSM.	Randomized to expedited partner treatment (by patient or by assisting provider) vs partner referral (by patient or assisting provider). Expedited partner packet had condoms/instructions/Rx (azithro 1 g po for CT; azithro 1g and cefixime 400mg po for GC) vs no packet for partner in self-referral grp. Interview and CT or GC rescreening by urine LCR or Gen-Probe Aptima Combo 2 at 10-18wks post-therapy.	Detection of CT or GC in urine 10-18 wks post-therapy	1860 (68%) completed the study (931 expedited arm, 929 partner referral); other 32% lost to f/u. CT recurred in 191 (12%) of 1595 and GC recurred in 25 (7%) of 358. Expedited therapy significantly more effective than referral in reducing recurrent/persistent infection in those with GC (3.4% vs. 10.6%, p=.01) than in those with CT (10.8% vs. 13.2%, p=.17) (p=.05 comparing GC vs CT treatment effects). Expedited arm more often reported all partners treated and less often having sex with untreated partner.	Large study, yet over 30% lost to f/u. Repeat CT and GC within 18wks post-therapy is common. Irrespective of randomized arm, higher proportion of women with CT who denied intercourse post-therapy had repeat CT detection (8%) compared with women with GC having repeat GC (3%), and no men denying intercourse post-therapy had CT or GC: this finding is concerning for treatment failures of CT cervicitis.	I

REPEAT CHLAMYDIAL INFECTION FOLLOWING THERAPY

CITATION	STUDY DESIGN	STUDY POP/ SETTING	EXPOSURE/ INTERVENTION	OUTCOME MEASURES	REPORTED FINDINGS	DESIGN ANALYSIS QUALITY/BIASES	SUBJECTIVE QUALITY RATING
61. Xu F, Schillinger JA, et al	Retrospective analysis	Retrospective cohort of 32698 women aged 10-44 years with appropriately treated uncomplicated CT between 1/1/93-6/30/98 who were registered in Washington's STD surveillance system.	Review of surveillance system data.	Incidence of repeat CT detection 30 or more days after appropriate treatment and predictors of repeat infection.	15% developed ≥1 repeat infection during mean f/u time 3.4y. Among those <20yo, 6% reinfected by 6mo, 11% by 1yr, and 17% by 2y. Young age was the strongest predictor.	Large number of patients. Retrospective analysis and passive surveillance system likely underestimated incidence of repeat chlamydia.	II
62. Kjaer HO, Dimcevski G, et al	Prospective follow-up study	Prospective cohort of 42 CT-infected patients (12 men and 30 women) aged >18yo in Denmark who had not yet received therapy and who agreed to participate.	CT rescreening via LCR on urine and/or vaginal swab specimens collected at home (patients given collection containers by their providers to take home) and mailed baseline (time of therapy), 2, 4, 8, 12, and 24 weeks post-therapy.	Cumulative incidence of repeat CT infection and predictors of repeat infection.	2 men do not mail in samples after baseline testing and treatment. Cum incidence was 29% (95% CI 12%-46%) during the 24 weeks. 10% of women had repeat infection at 4wk and 10% of men by 12wk post-therapy testing. Current or previous STD other than CT predicted CT recurrence.	Small sample size. Selection bias a major concern. Including testing at 2 wk post-therapy may have allowed false-pos infections to be counted towards cum incidence.	II
63. Whittington WLH, Kent C, et al	Prospective follow-up study	Prospective cohort of 1194 CT-infected women aged 14-34yo attending STD, adolesc, or repro health clinics in 5 U.S. cities.	CT rescreening via urine LCR at 1mo and 4mo post-therapy.	Rate of recurrent or persistent CT infection and associated predictors.	Of 792 (66.4%) returning at 1st f/u, 50 (6.3%) reinfected and resuming sex since therapy was a predictor. Among those testing neg at 1st f/u, 36 (7.1%) of 505 had repeat CT infection at 2nd f/u, without predictors identified. Overall 13.4% reinfected median 4.3 months.	About one-third of patients lost to f/u. In some sites, chlamydial assays with lower sensitivity utilized. Considerable variability in actual time interval patients returned for scheduled visits.	II

CITATION	STUDY DESIGN	STUDY POP/ SETTING	EXPOSURE/ INTERVENTION	OUTCOME MEASURES	REPORTED FINDINGS	DESIGN ANALYSIS QUALITY/BIASES	SUBJECTIVE QUALITY RATING
64. Burstein GR, Snyder MH, et al	Retrospective analysis of electronic medical records	43,205 female and 44,133 male managed care organization (MCO) members ages 12-19yo women aged 10-44 years seen in 1998-1999 at an MCO serving several NE states.	Records were reviewed to identify a CT-infected cohort and the rate of reinfection post-therapy in this cohort.	CT prevalence in the study population. Proportion of CT-infected individuals with recurrent infection and median time to repeat infection.	Baseline CT detected in 943 (14%) females and 126 (19%) males. Of 761 undergoing rescreening, repeat CT in 182 (16%; 17% in female and 11% in males). Median time to repeat CT diagnosis was 6mo (25% or repeats occurred within 3mo.	Retrospective analysis, passive surveillance system, and use of nonamplified DNA testing likely underestimated incidence of repeat chlamydia. No race/ethnicity or behavioral data to assess predictors of recurrent CT.	II
65. Joesoef MR, Weinstock HS, et al	Prospective follow-up study	Women (n=126,894) 16-24yo entering National Job Training Program who underwent CT screening and repeat testing. Women with missing demographical info were excluded	CT testing at baseline and 1-2mo after treatment completion (most azithro). Most tests were GenProbe PACE 2 on cervical specimens (10% initial tests and 26% f/u tests were urine BD SDA).	Baseline CT prevalence. Rates of repeat CT and associated predictors.	At baseline, 13550 (10.7%) had CT. Of 5892 retested at f/u, 332 (5.6%) had recurrent CT and was predicted by younger age, living in South, and being tested by BD SDA (similar to predictors for baseline infection).	Large sample size a strength. Limited by use of nonamplified DNA test for most testing, inability to assess impact of test type on repeat CT, and potential underestimate of recurrence rate as lower risk women more likely to be retested.	II
66. Niccolai LM, and Hochberg AL, et al	Prospective cohort follow-up study	Prospective cohort of 411 HIV-neg females 14-19yo undergoing evaluation at one of 10 public health clinics in Connecticut. 49% were pregnant at enrollment.	Active and passive data collected from a variety of data collection methods. CT rescreening via urine LCR at 6mo intervals up to 18mo.	Incidence of repeat CT infection, which had to occur >30d after prior diagnosis.	F/u period of 23,318 person-mos (mean 4.7 years per person). 216 (53%) diagnoses with CT, and 123 (57%) of these had repeat CT (42.1 per 1000 person mos). Median time to recurrent infection 5.2mo. 54% had repeat CT within 4mo. Repeat CT not associated with age.	Limitations included urine LCR (less sensitive than newer NAAT) and lack of treatment data. Multiple data collection methods both a strength (in capturing data) and a weakness (in self reported chlamydia accuracy). Population in which 49% pregnancy may not be generalizable.	II

Uncomplicated Chlamydia in Adults and Adolescents

CITATION	STUDY DESIGN	STUDY POP/ SETTING	EXPOSURE/ INTERVENTION	OUTCOME MEASURES	REPORTED FINDINGS	DESIGN ANALYSIS QUALITY/BIASES	SUBJECTIVE QUALITY RATING
67. LaMontagne DS, Baster K, et al	Prospective cohort follow-up study	Prospective cohort of 1971 females 16-24yo undergoing evaluation at GP, FP, and GUM clinics in England 2002-2003.	Urine tested by NAAT (LCR or SDA) and behavioral data collected every 6mo. Extra CT test and questionnaire 3mo after initial pos CT test. Roche PCR used for discrepant results.	Incidence of repeat CT infection and associated factors.	592 women were evaluable for reinfection: 547 baseline CT and 45 incident CT. Of these women, 417 had at least one f/u visit and contributed 332 years of at-risk f/u. Repeat CT per 100 person-yrs by clinic: GUM 21, 22 in FP, and GP 30; % of these by 6mo was 50%, 73%, and 73%. Recurrent CT predicted by new partners and failure to treat all partners.	Limitations included urine LCR (less sensitive than newer NAAT) and lack of treatment failure data.	II
68. Lee VF, Tobin JM, et al	Retrospective study	Retrospective study of 224 females 16-24yo and 61 males who were diagnosed with CT at a GUM clinic in Portsmouth England 1999-2000 and had repeat CT testing through Sep 2002.	Records reviewed. CT testing could have occurred with either cervical EIA or urine LCR in females and was urine LCR in males..	Proportion of repeat CT infections and associated factors.	46 (21%) females and 10 (16.4%) males had repeat CT and >75% had changed sexual partners in the prior 3mo. 33% of repeat Ct in females and 40% of repeat CT in men dx within 6mo after initial CT.	Limitations included retrospective data collection, less sensitive methods - EIA and urine LCR (less sensitive than newer NAAT), lack of treatment failure data, and small sample size.	II
69. Newman LM, Warner L, et al	Retrospective study	Retrospective study of 2841 females diagnosed with CT and 2553 males diagnosed with CT or NGU at STD clinics in 4 U.S. cities 1997-1998 and had repeat CT testing in a 12mo f/u period through 1999.	Records reviewed. Diagnostic test used for repeat CT testing diagnosis not reported.	Proportion of repeat CT infections in females and repeat CT or NGU in males.	4.8% of females had repeat CT diagnosis and 10.2% of males had repeat CT or NGU diagnosis.	Limitations included not being able to determine timing of repeat CT and influence of age on repeat CT as these data were only presented for all STDs, not specifically chlamydia. Repeat CT in men likely overestimated as was combined with NGU diagnoses, some which are likely etiologies other than CT. Also retrospective study design and CT test used not reported.	II

Uncomplicated Chlamydia in Adults and Adolescents

CITATION	STUDY DESIGN	STUDY POP/ SETTING	EXPOSURE/ INTERVENTION	OUTCOME MEASURES	REPORTED FINDINGS	DESIGN ANALYSIS QUALITY/BIASES	SUBJECTIVE QUALITY RATING
70. Gaydos CA, Wright C, et al.	Retrospective study	Retrospective study of 897 females 12-20yo who were diagnosed with CT at school-based health centers in Baltimore and had repeat CT testing within one year in 1996-2003.	Records reviewed. CT testing by a urine or cervical NAAT. could have occurred with either cervical EIA or urine LCR.	Proportion of repeat CT infections and associated factors. Repeat CT diagnosed 30 or more days after initial CT.	Mean time to 1st retesting was 4.3 mos. 236 (26%) had repeat CT and was associated with younger age.	Limitations included retrospective data collection and unable to determine timing of repeat CT. Unclear what NAAT was used.	II
71. Veldhuijzen IK, Van Bergen JE, et al	Prospective follow-up study	Women (n=39) and men (n=9) 15-29yo who previously tested CT pos with home screening in the Netherlands who accepted to undergo repeat CT testing at one year.	Urine samples were mailed and tested by Roche PCR. OmpA type of repeat pos CT strains was determined.	Proportion of repeat CT infections. Proportion of repeat CT with same or difference CT OmpA types.	5 (12.8%) of women and 0% of men had repeat CT. 3 of the 5 were infected with different CT OmpA types from their baseline infection.	Limited by the small sample size. Potential bias in women who agreed to have repeat home screening and this could have influence repeat CT rate.	II
72. Dunne EF, Chapin JB, et al	Prospective follow-up study	Men 15-35yo (n=272) who screened CT pos by urine NAAT (LCR,PCR, or SDA) at various venues in 3 U.S. cities from a demonstration project 2001-2003 who participated in longitudinal f/u with repeat CT testing.	Repeat NAAT testing at 1mo and 4mo. Demographical and behavioral data collected.	Proportion and incidence of repeat CT infections and associated factors. Repeat CT diagnosed 21 or more days after initial CT.	34 (13%) had repeat CT and predicted by history of an STD and the venue. Repeat CT incidence was 45.4 infections per 100 person years. Median time to infection was 52 days. Of men with 2 f/u visits, most men (76%) had their infection detected at the 1st visit.	Limited by incomplete partner treatment data that could have influence CT recurrence.	I
73. Fung M, Scott KC, et al	Data Review to Determine CT Reinfection Rates in Men	Study population in review was men, mostly <35yo.	Pub Med search and abstract review 1995-2006 for data on CT reinfection in men. Only included studies using NAAT and with f/u starting at least 2 wk after treatment. 12 articles met inclusion criteria and were reviewed.	Proportion of men with repeat CT (# of repeat CT pos men per f/u enrollees) and summary medians. Associated factors evaluated.	Median repeat CT probability of 11.3% and was higher in passive f/u studies (17.4%) vs active f/u (10.9%). Repeat CT associated w/ prior STD and younger age and inconsistently associated with risky sexual behavior.	Limitation was differences in study design, f/u interval, treatment verification, and inclusion of symptomatic vs asymptomatic men.	I

74. Batteiger, et al	Prospective longitudinal study in adolescent women evaluating repeated CT infections	365 adolescent women (age 14-17yo) enrolled from 3 primary care clinics in Indianapolis and followed for up to 27 months during Apr 1999-July 2009 who had repeat CT testing to eval for repeated infections and who had at least one quarterly visit.	CT PCR on vaginal and cervical swabs collected quarterly. Weekly self-collected vaginal swabs for select periods that were tested by CT PCR quarterly. OmpA typing. Interview quarterly and diaries for select periods. Azithro rx for repeated CT.	CT incidence (episodes per 100 women-yrs). Repeated CT classified as 1) definite, prob, or poss reinfections 2) poss or prob treatment failures or 3) persisting CT (w/o rx). Estimated azithro efficacy.	478 episodes repeated CT in 210 subjects; incidence 34 episodes/ 100 women-yrs. Of 183 episode pairs w/ complete data to classify repeated CT, 84% were classified as def/prob/poss reinfection, 14% prob/poss rx failure, and 2% persisting CT. For 318 evaluable infections, estimated azithro efficacy was 92%.	Advantages include multiple CT testing timepoints, use of OmpA typing, and thorough behavioral data. Men and adults not studied. Most (89%) Afr Am. Did not study doxycycline.	I

CHLAMYDIAL RESCREENING IN THE THIRD TRIMESTER OF PREGNANCY

CITATION	STUDY DESIGN	STUDY POP/ SETTING	EXPOSURE/ INTERVENTION	OUTCOME MEASURES	REPORTED FINDINGS	DESIGN ANALYSIS QUALITY/BIASES	SUBJECTIVE QUALITY RATING
75. Aggarwal A, et al	Retrospective study of STIs in pregnancy at prenatal visit, 3rd trimester rescreening, and postpartum	201 adolescent (13-18yo) women w/ 211 pregnancies from Jan 2003-Dec 2007 at prenatal program in a Toronto hospital. 173 rescreened 3rd trimester and 161 screened about 6wks postpartum.	CT testing on cervical or vaginal swabs (diagnostic test not mentioned)	STI prevalence at prenatal visit, STI incidence at rescreening and postpartum screening. TOC 2 wks post-rx of prenatal STI dx (rx used not provided)	Prenatal visit CT prevalence was 30/211 (14%). Rescreening CT incidence was 6/173 (3.5%) and post partum incidence 3/161 (1.9%). Of the 6 (20%) women w/ prenatal visit CT who had TOC, all 6 (100%) were still CT+	Limited by retrospective design. CT diagnostic and treatment used not provided. TOC 2wks post-rx may be confounded by false-pos NAAT. Diverse race/ethnicity distribution. No data provided on perinatal outcomes.	II

Uncomplicated Chlamydia in Adults and Adolescents

CITATION	STUDY DESIGN	STUDY POP/ SETTING	EXPOSURE/ INTERVENTION	OUTCOME MEASURES	REPORTED FINDINGS	DESIGN ANALYSIS QUALITY/BIASES	SUBJECTIVE QUALITY RATING
76. Blatt AJ, et al	Retrospective study of CT and GC during pregnancy and proportion of CT+ or GC+ retested and the results	STI laboratory data extracted from large U.S. database (Quest Diagnostics). 1,293,423 women (age 16-40) determined pregnant if had a rubella aby performed. Only 1st pregnancy data considered.	CT testing (80% had NAAT [SDA or TMA] vs. 20% DNA probe)	Proportion with CT testing and % CT+ at any visit and at 1st prenatal visit. Proportion retested and proportion of these that were repeat CT+. Proportion w/ TOC and proportion of those CT+	CT screening at any visit in 59% and at 1st prenatal visit in 37%. CT screening rates higher in younger women and Afr Am. CT+ 3.5% any visit and 2.7% 1st prenatal visit. CT rescreening in 78% initially CT+ vs. 13% initially CTneg. Repeat CT+ in 18% initially CT+ (6% CT+ at their last CT test) vs. 2.2% initially CTneg (1.2% CT+ at their last test). TOC done in 33% initial CT+ w/n 6wks and 15% had CT+ TOC. In subanalysis women 16-25 yo with initial CT neg test who had repeat screening during pregnancy, 3.4% had a subsequent positive CT test (1.9% CT+ at their last test).	Very large sample size from nationally representative sample, biased towards women seeking testing (likely those w/ health care access).No clinical data on treatment. Women may have been tested at other labs. Pregnancy classification based on rubella serology not pregnancy test. Gestational period of retesting not provided or could not be determined. 20% had DNA probe which could have underestimated CT+ rates.	II
77. Hood EE, et al	Retrospective study of CT retesting at 34-36 wks gestation.	181 pregnant women (≤25yo) with CT retesting 34-36wks gestation from May 2005-Nov 2007 at OB/GYN office and clinic in Huntington WV.	Cervical swab DNA probe for CT	Proportion CT+ at 1st prenatal visit and rescreening at 34-36wks gestation	6/181 (3.3%) CT+ at 1st prenatal visit. Of the 175 CTneg at 1st prenatal visit, 5 (2.9%) CT+ at rescreening. Of the 6 CT+ at 1st prenatal visit, 1 (16.7%) CT+ at rescreening; overall 6 of 181 (3.3%) were CT positive at rescreening.	Limited by retrospective design. DNA probe test likely underestimated CT+ at prenatal and rescreening visits. No treatment or TOC data. No race data. No data provided on perinatal outcomes.	II

EXTRAGENITAL CHLAMYDIAL NAATS

CITATION	STUDY DESIGN	STUDY POP/ SETTING	EXPOSURE/ INTERVENTION	OUTCOME MEASURES	REPORTED FINDINGS	DESIGN ANALYSIS QUALITY/BIASES	SUBJECTIVE QUALITY RATING
78. Kent CK, Chaw JK, et al	Prospective study of CT prevalence at urethral and extragenital sites in MSM.	MSM tested for CT at an STD clinic (n=5539) and Gay men's health center (GMHC) (n=895) in San Francisco in 2003. Age range not given, but included men >35yo. Eligibility criteria: lab-confirmed CT urogenital infection. Inclusion criteria for rectal testing: receptive anal sex in prior 6mo. Inclusion criteria for pharyngeal testing: receptive oral in prior 2wks with >1 partner. Inclusion criteria for urethral testing: insertive sex.	BD ProbeTec, 2 other NAATs, and culture for CT testing on rectal and pharyngeal specimens (both collecting with ProbeTec swabs) and urine if inclusion criteria met for the anatomical site.	Prevalence of CT by anatomical site and study site (STD clinic vs GMHC). Performance of NAATs vs culture at extragenital sites.	Overall CT prevalence 10.7%: rectal 7.9%, urethral 5.2%, and pharyngeal 1.4%. CT prevalence higher at STD clinic vs GMHC for rectal (8.8% vs 5.7%) and urethral (5.5% vs 3.3%) but not pharyngeal (1.3% vs 1.7%). 86% of rectal CT were asx. 53% of CT infections would have been missed if only urine screening done.	Large sample size and intuitive analyses demonstrating clinical applicability. Limitations: Only studied in MSM, not heterosexual men or women. Prevalence in MSM population tested at the public health clinics may not be representative of all MSM.	II
79. Lister NA, Smith A, et al	Retrospective study of rectal CT/GC reinfection prevalence at in MSM.	MSM with rectal CT/GC detected by NAAT (BD SDA) at Melbourne Sexual Health Centre clinics 2002-2003 who were retested within 12-18 months (n=68 of the original 126). Mean age 33 (range not given). Rectals swabs either clinician or self-collected. Eligibility criteria: lab-confirmed rectal CT urogenital infection. Exclusion criteria: positive test of cure from original infection.	Records were reviewed to identify a rectal CT/GC-infected cohort who had repeat rectal testing within 12-18 mos after original diagnosis	Proportion of rectal CT/GC-infected individuals with recurrent infection, mean time to repeat infection, and incidence of new infection	25% were HIV+. 21 (31%) had repeat CT/NG: 9 GC (6 asx), 10 CT (9 asx), 2 co-infection (1 asx). CT recurrence was 18%. Higher repeat CT/GC in HIV+ vs HIV- or unknown (47% vs 26%). Mean time to retest was 9.6 months. Incidence of new CT/GC was 47 per 100 person-yrs, and was higher in HIV+ (80 vs 37 per 100 person-yrs).	Limitations included retrospective design, insufficient data to separate reinfection rate for CT or GC individually (original dx only presented as CT/GC), no behavioral data, limited to MSM. Also unclear how many had testing on self collected specimens and assay sensitivity on these specimens. Still, high repeat pos CT/GC rates supports repeat testing.	II
80. Ivens D, MacDonald K, et al	Retrospective study of rectal CT prevalence and associated clinical and behavioral factors.	MSM (n=1171) and women (n=16) tested for rectal CT by NAAT (BD SDA) at a UK GU medicine 2002-2005. Age range 30-40yo. Eligibility criteria: receptive anal.	Records were reviewed to identify eligible cohort who received rectal CT testing.	CT prevalence and associations with behavioral and clinical factors by multivariate analyses.	CT prevalence 8.5%. Of the patient without any rectal sx (n=996), 5.1% had CT. Factors associated with CT included rectal sx (OR 2-8.1), HIV+ (OR 2.2), and >10PMNs/hpf on rectal Gram stain (OR 2.5).	Limitations included retrospective analysis, not presenting sufficient data to separate reinfection rate for CT or GC individually (the original dx was only presented as CT/GC), no behavioral data, limited mostly to MSM, and rectal STIs other than CT or GC	II

						not tested (which could have influenced symptoms.	
CITATION	**STUDY DESIGN**	**STUDY POP/ SETTING**	**EXPOSURE/ INTERVENTION**	**OUTCOME MEASURES**	**REPORTED FINDINGS**	**DESIGN ANALYSIS QUALITY/BIASES**	**SUBJECTIVE QUALITY RATING**
81. Jin F, Prestage GP, et al	Prospective study of rectal CT incidence in HIV-negative MSM.	MSM (n=1427) 18-75yo recruited 2001-2004 from community sources in Sydney for urine and rectal NAAT (both self collected) and interview. Eligibility criteria: sex with other men last 5 yr, tested HIV neg at baseline.	Baseline and annual urine and rectal NAATs by BD SDA and face-to-face interviews. Semiannual telephone interviews.	CT incidence and associated risk factors. Incidence rates included interval CT diagnoses (self report), study visit diagnoses, and combined.	Median f/u 2.3 yrs. Combined CT incidence or urethral and rectal were 7.4 and 5 per 100 person-years. Most urine diagnoses were interval visits and majority (55%) of rectal diagnoses were with study visits. Anal CT assoc. with unprotected anal sex (intercourse and non-intercourse practices), number of casual partners 6mo and CT contact.	Limitations included potential misclassification of self-reported CT diagnoses and limited to MSM. Only evaluated self-collected rectal swabs.	II
82. Templeton DJ, Jin F, et al	Prospective study of pharyngeal CT incidence and baseline prevalence in HIV-negative MSM.	MSM (n=1427) 18-75yo recruited 2001-2004 from community sources in Sydney for urine and rectal NAAT (both self collected) and interview. Eligibility criteria: sex with other men last 5 yr, tested HIV neg at baseline.	Baseline and annual urine and rectal NAATs by BD SDA and face-to-face interviews. Semiannual telephone interviews.	CT incidence and associated risk factors. Incidence rates included interval CT diagnoses (self report), study visit diagnoses, and combined.	Median f/u 2.3 yrs. Pharyngeal CT baseline prevalence 1.1% and incidence was 0.58 per 100-person years. Majority (>50%) of infections were detected at baseline. No repeat pharyngeal CT after azithro rx. 68% of men with pharyngeal CT had no concurrent anogenital CT. No association with sore throat. Associated with frequency of receptive oral sex with ejac with casual partners.	Limitations included not performing alternative NAATs for confirmation and the small sample size of positive subjects for behavioral data analyses.	II

Uncomplicated Chlamydia in Adults and Adolescents

CITATION	STUDY DESIGN	STUDY POP/ SETTING	EXPOSURE/ INTERVENTION	OUTCOME MEASURES	REPORTED FINDINGS	DESIGN ANALYSIS QUALITY/BIASES	SUBJECTIVE QUALITY RATING
83. Schachter J, Moncada J, et al	Prospective study of CT detection by NAATs in oropharyngeal (throat) and rectal swabs.	MSM tested for CT at the San Francisco STD clinic (n=1110). Age range not given, but included median age 35yo. 25% HIV pos. Exclusion criteria: abx in prior 21 days	CT culture, Aptima Combo (AC) 2, and BD SDA performed on throat and rectal swab specimens collected by block randomization schedule.	Evaluation of performance of NAAT on throat and rectal specimens. Subject considered CT infected at a site if culture pos or 2 pos NAATs or if single NAAT pos confirmed by alternative NAAT with different target.	61% were symptomatic. Higher CT prevalence in throat with NAATs vs culture (0.8% vs 0.4%) and in rectum 6.1% vs 1.6%). Sensitivity of tests for throat: culture 44%, SDA 67%, and AC2 100%. Sensitivity of tests for rectum: culture 27%, SDA 63%, and AC2 93%. Specificity >99.3% both NAAT at both sites. NAAT better than culture regardless of symptoms.	Limited to MSM and not women. Large sample size and excellent NAAT strategy to assess test performance.	I
84. Mimiaga MJ, Mayer KH, et al	Prospective study of rectal and orophyarngeal (throat) CT prevalence and behavioral factors.	Asymptomatic MSM 19-68yo (n=114) tested for rectal and throat CT by NAAT (BD SDA) at a community clinic in Boston in 2007. Eligibility criteria: receptive anal or oral sex within past yr.	BD SDA (validated) was performed on throat and rectal swabs. Clinical and behavioral data extracted from databank.	CT prevalence at throat and rectum and associations with behavioral factors.	Rectal CT detected in 6.1% and no throat CT detected. Those infected with CT (or GC) more often had prior STD hx, but no significant differences in psychosocial or behavioral factors in infected vs noninfected.	Limitations included small sample size and not separately analyzing CT (it was merged with GC infected) in the analysis of associated behavioral factors.	II
85. Bachmann LH, Johnson R, et al	Prospective study of CT detection by NAATs in rectal swabs.	MSM and females >15yo undergoing rectal CT testing in 2003-2006 (n=284 MSM and 41 females): MSM and women at a Birmingham AL STD clinic, MSM at 2 Bham AL HIV clinics, and MSM at a Chicago HIV clinic. Eligibility criteria: Receptive anal sex in prior 2mo. Women denying anal sex eligible if they were a CT contact. Exclusion criteria: abx with CT activity in prior 30 days.	CT culture, Aptima Combo (AC) 2, BD SDA, and Roche PCR performed on rectal swab specimens; swab order rotated every 3mo throughout the study.	Evaluation of performance of NAAT on rectal specimens. Subject considered CT infected by primary standard in which 2 of 4 tests were positive.	9.9% of MSM and 22% females classified as having rectal CT. Sensitivity of rectal tests: culture 34%, PCR 81%, SDA 93%, and AC2 100%. Specificity: culture 99.7%, PCR 98.6%, SDA 96.1%, and AC2 95%.	Limited by not performing CT Aptima (alternative target) on samples pos only by 1 NAAT: this would increase specificity of the NAATs, esp AC2. Strength of the study is its inclusion of women, although high rate of rectal CT pos was bias by inclusion of women who were contacts to T-infected men.	I

SELF-COLLECTED VAGINAL SWABS

CITATION	STUDY DESIGN	STUDY POP/ SETTING	EXPOSURE/ INTERVENTION	OUTCOME MEASURES	REPORTED FINDINGS	DESIGN ANALYSIS QUALITY/BIASES	SUBJECTIVE QUALITY RATING
86. Keane FEA, Bendall R, et al	Prospective study of CT detection on endocervical and self-collected vaginal swabs.	Women 16-25yo (n=333) undergoing genital exam at a GU med clinic in Cornwall UK in 2004 had CT PCR on cervical and self-collected vag swabs.	CT PCR performed on endocervical and self-collected vaginal swabs.	Comparison of CT PCR positivity in both specimen types. CT pos specimens had repeat PCR and if negative, had repeat PCR again. Specimens that were initial pos but neg on two subsequent tests were "equivocal"	58 (17.4%) CT positive for at least one specimen. No significant difference by site: endocervical 53 (15.9%) vs vaginal 56 (16.8%). 4.7% of vag swabs were "equivocal".	Limitations included using NAAT that may be less sensitive than newer NAATs, lab testing not blinded, and the number of equivocal results on the vaginal specimens. No clinical data.	II
87. Schachter J, Chernesky MA, et al	Prospective study of CT detection in clinician- and self-collected vaginal swabs, urine, and endocervical swabs.	Women 16-25yo (n=1464) undergoing genital exam at STD/FP/OB clinics in 9 North American centers had CT NAATs performed on multiple specimens.	Aptima CT and AC2 performed on multiple specimens collected in following order: urine, self vag swab (PVS), clinician vag swab (CVS), then one of two randomized endocervical swabs. BD SDA also performed on urine	Evaluation of performance of Aptima assays on vaginal swabs specimens. Subject considered CT infected if any 2 of the NAAT tested cervical and urine specimens were positive.	56% were symptomatic. CT detected in 12%. Performance of Aptima CT on PVS vs CVS: Sens 98% vs 97% and spec 96% vs 95%. AC2 similar sensitivity and specificity. Vag swab specimens detected as many CT as endocervical and more than urine. False CT pos in vag specimens were low when tested by both Aptima assays.	Large sample size and excellent multiple specimen and NAAT strategy to assess test performance on vaginal specimens. CT performance stratified by study site not provided. No analysis on relationship of genital sx to test performance.	I
88. Rose SB, Lawton BA, et al	Prospective study of preference of self- (PVS) vs clinician- collected (CVS) vag swab for CT testing.	Women <25yo (n=300) presenting to a termination of pregnancy clinic in New Zealand 2005-2006 who were given choice of PVS vs CVS for CT testing. Eligibility criteria: lab-confirmed rectal CT urogenital infection.	Choice of vag swab collection method was recorded. CT PCR performed.	Proportion of women choosing PVS vs CVS and associated factors.	47 (15.7%) were CT pos. 66% of women chose PVS. Women more likely to choose PVS, after controlling for age, ethnicity, and early gestational age.	Limitations included lack of data on reasons for opting for PVS vs CVS. Alternative specimens or NAATs were not used in this study to assess performance.	II

CITATION	STUDY DESIGN	STUDY POP/ SETTING	EXPOSURE/ INTERVENTION	OUTCOME MEASURES	REPORTED FINDINGS	DESIGN ANALYSIS QUALITY/BIASES	SUBJECTIVE QUALITY RATING
89. Hoebe CJPA, Rademaker CW, et al	Prospective study of acceptability and feasibility of self-collected vaginal swab (PVS) and urine for CT testing.	Women 16-35yo (n=413) presenting to an Amsterdam STD clinic 2003-2004 for STD testing. 5% were CSWs.	Women provided PVS and urine for CT testing by BD SDA. Questionnaire with clinical data and patient preferences performed.	Proportion of women testing CT positive and feasibility and acceptability of PVS and urine methods.	45 (10.9%) were CT pos. Agreement for both tests was 98.9%. Most women preferred to collect their own swab and felt the PVS was easy to perform and would opt for PVS next time. Only 2% though PVS was unpleasant. of women chose PVS. Women more likely to choose PVS, after controlling for age, ethnicity, and early gestational age.	Endocervical specimens or other NAATs were not used in this study to assess performance.	II
90. Doshi JS, Power J, et al	Prospective study of acceptability of CT screening by self-collected vaginal swab (PVS) and urine.	Women 16-24yo (n=4998) presenting to contraceptive and advisory clinics in England in 2003-2004 who accepted an offer for STD testing.	Women offered PVS for CT testing by CT PCR. Those refusing PVS were offered urine testing. Those requiring pelvic exams had cervical swabs collected. Questionnaire with clinical data and reasons for accepting or declining CT screening.	Proportion of women accepting CT screening by PVS or urine and number that were CT positive.	79% accepted CT screening 90% chose PVS and 6% urine: of these, 7.3% were CT pos. Women >19yo and of Asian race/ethnicity most likely to decline CT screening. No women stated reluctance of PVS as a reason for declining screening.	Unclear proportion testing CT positive by PVS vs urine. Other NAATs were not used in this study to assess performance.	II
91. Skidmore S, Herring A, et al	Prospective study of CT detection in patient-collected vaginal swabs (PVS) and urine.	Women 16-39yo in Birmingham (n=1476) and Bristol (n=1269) UK who responded to a mailed invite to participate in CT screening project.	CT PCR and BD SDA performed mailed urine and PVS. Mailed questionnaire reviewed. In a substudy, PVS were tested by a polymer conjugate-enhanced EIA.	Evaluation of performance of both NAAT assays on PVS and urine and the EIA on PVS. CT positive status determined by an algorithm including NAATs and EIA and required at least 2 positive results.	CT detected in 146 (5.3%). Sensitivity of the NAATs on PVS were 97% and urine 91%-93%. Specificity both specimens types >99.5%. The sensitivity of EIA on PVS was 58%-74% (depending on comparator test).	The study did not evaluate acceptability and did not collect data on who/why declined, hence potential selection bias. Unclear if inclusion of the EIA in the infected status algorithm impacted performance results. No analysis on relationship of genital sx to test performance.	I

CITATION	STUDY DESIGN	STUDY POP/ SETTING	EXPOSURE/ INTERVENTION	OUTCOME MEASURES	REPORTED FINDINGS	DESIGN ANALYSIS QUALITY/BIASES	SUBJECTIVE QUALITY RATING
92. Gaydos C, Dwyer K, et al	Prospective study of internet-based CT screen with patient-collected vaginal swabs (PVS).	Women (n=508) >13yo in Maryland who agreed to participate in an internet-based CT screening study 2004-2005.	Women obtain self-adm vaginal swab (PVS) kits for home sampling via community center, email/internet request, or phone. PVS mailed to lab and tested by 3 NAATS: PCR, BD SDA, and AC2. Questionnaire completed addressing acceptability of internet and PVS	CT positivity in and associated CT risk factors. Acceptibility and satisfaction with internet-based screening and PVS. CT pos status required 2 NAAT pos.	400 (79%) submitted PVS and CT detected in 10.3%. 108 (21%) took questionnaire but did not submit PVS. Of kit users, 90% preferred a self collection method (54% PVS, 13% PVS or urine). 91% found PVS easy or very easy. Those who did not submit PVS more likely to prefer pelvic and if self collect, they more often preferred urine and to pick up the test kit at a pharmacy.	Selective bias towards subjects with computer access, though this is likely most adolescents. Strengths include use of 3 NAAT strategy and collecting data on those who did not submit PVS.	II

SELF-COLLECTED PENILE, OROPHARYNGEAL (OP), AND RECTAL SPECIMENS IN MEN

CITATION	STUDY DESIGN	STUDY POP/ SETTING	EXPOSURE/ INTERVENTION	OUTCOME MEASURES	REPORTED FINDINGS	DESIGN ANALYSIS QUALITY/BIASES	SUBJECTIVE QUALITY RATING
93. Hamasuna, et al	Prospective study of OP CT detection in oral washes vs. OP swabs	18 female CSWs with a recent CT+ OP swab (by PCR) and 48 heterosexual male college students with CT+ urine (by PCR) in Miyazaki Japan were screened for OP CT by oral wash and OP swab. CSW tested Feb-June 2003. Males tested Apr-Oct 2002.	CT PCR on oral washes and OP swabs	Comparison of CT PCR positivity in both specimen types.	In CSWs time from previous OP swab testing to current testing was 8 +/- 6d and none had interval rx. In CSWs, 11/18 (61%) CT+ by oral wash vs. 8/18 (44%) by OP swab. In males, 5/48 (10%) CT+ by oral wash vs. 3/48 (6%) by OP swab. All patients denied OP sx. In CSWs 6/18 (33.3%) had spontaneous clearance of OP CT between previous and current testing.	Small sample size. Age not provided. No comparator NAAT.	II

CITATION	STUDY DESIGN	STUDY POP/ SETTING	EXPOSURE/ INTERVENTION	OUTCOME MEASURES	REPORTED FINDINGS	DESIGN ANALYSIS QUALITY/BIASES	SUBJECTIVE QUALITY RATING
94. Papp, et al	Diagnostic eval of CT detection and clearance in spiked mouthwash vs. water. Prospective study of OP CT detection in oral washes (mouthwash, water) vs. OP swabs	A commercial mouthwash and water spike w/ 10-107 CT IFU and tested by CT TMA at 1,2,3,4,7, and14d. 561 MSM 18+yo seen at San Francisco STD clinic Jan-June 2006 were screened for OP CT by TMA on OP swab and either mouthwash (n=250) or water rinse (n=311).	CT NAAT (TMA) on OP swabs, mouthwash, and water Acceptability survey	CT detection over time from spike oral samples. CT detection in OP swab vs. oral mouthwash or water rinse from MSM Eval of acceptability.	CT detected in spike mouthwash and water for up to 2wk. 8/561 (1.4%) MSM were OP CT+ and all 8 were positive from OP swab and OP wash/rinse tested. Oral wash/rinse had sensitivity 100% and specificity $\geq$99.7%. Mouthwash and OP water rinse highly acceptable	Small number of OP CT+ prevented reliable performance estimates of the specimens. Women not studied. Age/race not provided. No comparator NAAT.	II
95. Freeman, et al.	Prospective study of OP CT detection in patient-collected vs. clinician-collected OP swabs.	480 MSM reporting fellatio prior 2 wks seen at San Francisco STD clinic Mar-May 2009 who provided self-collected and clinician-collected OP specimens for OP CT testing by NAAT (TMA).	CT NAAT (TMA) on OP swabs. Acceptability survey performed.	Proportion OP CT positive by collection method and percent agreement of CT positivity in self- vs. clinican-collected OP swabs. Acceptability of self-collected OP swabs on a 5-pt scale ranging from stongly disagree to strongly agree.	6 of 480 (1.3%) MSM were OP CT+ based on the clinician-collected swab, with 99.4% percent agreement for OP CT test results between self- and clinician-collected OP swabs. Of 7 CT OP pos by self-collected swab, 5 of 7 were positive by clinician-collected swab. Of 6 CT OP pos by clinician collected swab, 5 of 6 were positive by self-collected swab. 92% willing to self collect OP swab at home. 54% no preference between self vs clinician-collected strategy. Majority agreed or strongly agreed that instructions were easy and specimen easy to collect.	Small number of OP CT+. Women not studied. Race and age info not given. No comparator NAAT. Only 55% (480/870) men participated in the study, suggesting those participating were biased towards a more favorable attitude towards self-collection and this confounds the results of the acceptability survey. No comparator NAAT.	II
96. Wayal, et al	Prospective study in MSM on feasibility and acceptability of MSM self-sampling for OP and rectal STIs.	301 MSM (median 34yo, IQR 29-41) seen at a Brighton UK GUM clinic Oct 2005-May 2007 who consented for having routine urethra, rectal, and OP specimens collected, then offered self sampling OP and rectal specimens and a questionnaire.	Self-sampling OP (mouth pad, gargle, swab) and rectal (swab) Feasibility and acceptability questionnaire	Feasibility and acceptability scores rated on a five-point Likert-type response scale.	301 participants self-sample OP gargle/swab and rectal, while 288 self sampled OP mouth pad. Of 274 with complete questionnaire data, feasibility and acceptability of self-sampling w/ OP gargle/mouth pad higher than OP swabs (92% vs 76%). Self sample rectal swabs acceptable to 82%.Despite some discomfort, 76% willing to use all 4 self-sampling methods. 84% found home sampling acceptable.	Quality study provided important insight into OP and rectal self sampling in MSM. Most pts were white. High risk population. Women not studied. Likely bias in the subjects who agreed to participate vs. refused, though 90% of eligible participated. STI testing not done.	II

Uncomplicated Chlamydia in Adults and Adolescents

CITATION	STUDY DESIGN	STUDY POP/ SETTING	EXPOSURE/ INTERVENTION	OUTCOME MEASURES	REPORTED FINDINGS	DESIGN ANALYSIS QUALITY/BIASES	SUBJECTIVE QUALITY RATING
97. Sexton, et al	Prospective study of OP and rectal CT detection in patient-collected vs. provider collected OP and rectal swabs.	374 MSM (median age 33, range not given) w/ OP and rectal CT screening (by TMA) Sep15,2009 – Apr 19,2011 at Wash DC clinics (STD, HIV, primary care). 367 self-collected OP specimens and 276 self collected rectal specimens.	CT NAAT (TMA) on OP and rectal swabs self-collected and provider-collected. Randomized to pt vs provider testing first.	CT detection from OP and rectal swabs	5 of 367 (1.4%) MSM were OP CT+, with all 5 CT+ detected by self-collected OP swab vs. only 3 detected from provider-collected OP swabs. 35 of 276 (12.7%) were rectal CT+ , with all 35 CT+ identified by pt-collected rectal swab vs. only 32 identified by provider collected rectal swabs. Discordance in pt-collected vs. provider collected not statistically significant.	Small number of OP CT+. Women not studied. Diverse race/ethnicity distribution. No comparator NAAT. No eval of acceptability of self-collected OP and rectal swabs.	II
98. Dize, et al	Prospective study of STI testing on self-collected penile-meatal swabs and urine.	634 men (likely from several U.S. states) received home penile-meatal and urine test kits from an online request and mailed to a lab in Baltimore for STI testing by TMA Sep 2006 – Nov 2009.	CT NAAT (TMA) on penile-meatal flocked swab and urine. Pts instructed to collect swab first.	CT detection from swab and urine and performance of TMA on these specimens. True pos CT required either both specimens CT+ or one CT+ confirmed by different TMA target	81 (12.8%) swabs and 66 (10.4%) urine CT+. 86 (13.6%) true CT+. Swab sensitivity for CT was 94% vs. for urine was 77%.	Due to self collect at home, unclear if pts collected swab first and if specimens correctly collected. Return rate of kits <50% suggesting the self-collected swab and/or urine might not be acceptable to the majority of men. Likely some bias in men choosing screening by internet. Age not given. No comparator NAAT.	II
99. Chernesky, et al	Prospective study of CT and GC testing on self-collected meatal swabs and urine and acceptability of self-collection experience.	511 men (15-24yo) seen at high risk street youth clinic in Ontario provided self collected meatal swab(s) and urine for CT and GC testing by TMA Aug-Oct 2005. 80% w/o urethral sx.	Grp A (n=293) CT NAAT (TMA) on meatal APTIMA swab and urine. Grp B (n=218) CT NAAT (TMA) on meatal APTIMA swab, meatal flocked swab and urine. Each grp alternated specimen order.	CT detection from swab(s) and urine and performance of TMA on these specimens. True pos CT required either two specimens CT+ or one CT+ confirmed by different TMA target. Acceptability survey in GrpB.	Grp A: 20/293 (6.8%) CT+. Aptima swab detected more than urine – 18 (90%) vs. 17 (85%). Swab higher sensitivity than urine (90% vs 85%). Grp B: 20/218 (9.1%) CT+. Of CT+, Aptima and flocked swab both detected 17 (85%), more than urine 16/20 (80%). Swabs higher sensitivity than urine (85% vs 80%). 63% men preferred urine over swab. Most no difficulty collecting swab, and 60% preferred flocked over aptima swab.	No race or behavior data reported. No comparator NAAT.Hi risk population. Collecting urine before swab in some pts could have decreased swab sensitivity. Most pts uncircumcised and unclear if performance of meatal swab would be comparable in mostly circumcised population.	II

Uncomplicated Chlamydia in Adults and Adolescents

CITATION	STUDY DESIGN	STUDY POP/ SETTING	EXPOSURE/ INTERVENTION	OUTCOME MEASURES	REPORTED FINDINGS	DESIGN ANALYSIS QUALITY/BIASES	SUBJECTIVE QUALITY RATING
100. Dodge, et al	Prospective qualitative study of MSM experience with rectal swab self-sampling.	75 MSM (18-57yo) underwent closed- and open-ended interviews and offered to self-collect a rectal swab at diverse venues (STD clinic, CBOs, bath house, etc) in Indianapolis.	Semi-structured interview. Offer for self-collected rectal swab.	Pt reactions to ideal of self sampling with rectal swab. Proportion agreeing to collect rectal swab and their experience. CT (PCR) results for those agreeing to testing	68/75 (91%) self collected a rectal swab and most reported high level of acceptability and comfort with the experience. 62 of 68 (91%) agree to CT testing and 5/62 (8%) tested CT+. All providing rectal swabs would agree to have rectal testing in the future. Given the option, most would prefer self collection at home.	Quality study provided important insight into self sampling with rectal swab in MSM. Diverse clinical population in terms of venues and race/ethnicity distribution. Women not studied. Likely bias in the subjects who agreed to interview vs. refused.	II
101. Dodge, et al	Prospective qualitative study of experience of bisexual men with rectal swab self-sampling.	75 “diverse” bisexual men in Indianapolis underwent closed- and open-ended interviews and offered to self-collect a rectal swab.	Semistructured interview. Offer for self-collected rectal swab.	Pt reactions to ideal of self sampling with rectal swab. Proportion agreeing to collect rectal swab and their experience. CT (PCR) results for those agreeing to testing .	58/75 (77%) self collected a rectal swab and most reported high level of acceptability and comfort with the experience, even those not engaging in receptive anal sex. 6/58 (10.3%) tested CT+. Of 38 who had recepted anal sex and self-collected a rectal swab, 6 (16%) were CT+. Patients collecting swabs reported acceptability and comfort w/ the process. Privacy was the most common concern.	Provided some insight into self sampling with rectal swab in bisexuals. Age, race, and venue info not provided. Women not studied. Likely bias in the subjects who agreed to interview vs. refused.	II
102. van der Helm, et al	Prospective study of CT and GC testing on self-collected rectal swabs, and acceptability of self-collection experience.	936 women (age IQR 22-35) and 1458 MSM (age IQR 26-44) seen 2006-2007 at Amsterdam and S. Limburg STI clinics who engaged in receptive anal sex were interviewed, provided a self collected rectal swab and permitted a provider rectal swab for CT and GC testing.	CT NAAT (PCR [98%] or SDA) on rectal swabs	CT detection from self-collected vs. provider-collected swabs and NAAT performance on these specimens. True pos CT required just one specimens to be CT+ Acceptability interview.	Due initial procedure chgs, 901 women and 1411 MSM had CT NAAT done for comparing swab collection strategies. CTprevalence in provider- vs. self-collected swabs comparable for women 9.4% vs 9.3% and for MSM 10.8% vs. 10.5%. Self-collected and provider collected were concordant for CT in 98% women and MSM. Sensitivity slighter higher for provider collected vs self collected in MSM (92% vs. 89%) and women (90% vs. 89%). Majority of of MSM (57%) and women (62%) preferred self-collected. 97% of pts would visit STI clinic again if self collected swabs were routine.	No comparator NAAT. True CT positive classification based on one sample pos by one NAAT may over estimate sensitivity and would have been improved by requiring a 2nd NAAT with different amplification target. High risk population.	II

Uncomplicated Chlamydia in Adults and Adolescents

CITATION	STUDY DESIGN	STUDY POP/ SETTING	EXPOSURE/ INTERVENTION	OUTCOME MEASURES	REPORTED FINDINGS	DESIGN ANALYSIS QUALITY/BIASES	SUBJECTIVE QUALITY RATING
103. Raherison, et al	Prospective study of CT testing on self-collected glans swabs and urine.	603 asx MSM and heterosexual men (<30yo) seen at an STI screening center in Bordeaux France Feb-Dec 2007 provided self collected flocked glans swab and urine for NAAT.	CT NAAT (PCR) on swab and urine, either tested separately in 344 men (method 1) or urine alone tested and swab placed in urine and tested together in 259 men (method 2).	CT detection from swab and urine. True pos CT required either both specimens CT+ or one CT+ confirmed by different NAAT PCR target.	For method 1, 27/344 (7.8%) were considered true CT+. Higher sensitivity for urine 89% (24/27) than swab 67% (18/27). For method 2, 19/259 (7.3%) were considered true CT+. The sensitivity for urine alone vs. urine spike w/ swab the same 18/19 (95%), therefore spiking urine w/ swab did not improve detection over urine alone.	No comparator NAAT.	II
104. Moncada, et al	Prospective study of CT and GC testing on self-collected glans swabs, urine, and self- and clinician collected rectal swabs.	907 MSM (52%sx) seen at San Francisco STD clinic provided self collected glans dacron swab (roled over meatus [method 1] or inserted in the urethra method 2]), urine, and self- and clinician-collected rectal swab for NAAT.	CT NAAT on all swabs (SDA and TMA) and urine (TMA), and CT culture on rectal swab.	CT detection from swabs and urine. True pos CT on swabs required both pos NAAT or single pos NAAT confirmed by alternate NAAT target. Glans swab true pos could be confirmed by urine NAAT pos.	CT prevalence by urine 12.2% (108/882). Sensitivity of glans swab 56%-68%. CT prevalence in rectal was 7.3% (66/907). Sensitivities of self- vs. clinician-collected rectal swabs comparable but higher using TMA (82% and 71%) than using SDA (41% and 44%).	No info provided on age, race/ethnicity, or study period. Excellent strategy for establishing true positive CT for eval test performance on different specimens.	I
105. Alexander, et al	Prospective study of OP and rectal CT and GC detection in patient- and nurse-collected OP and rectal swabs.	272 asx MSM attending a GUM clinic in Brighton Oct 2005-May 2007. Most MSM had recent CT/GC OP or rectal CT NAAT (SDA), with some testing CT/GC+ and others tested negative.	CT NAAT (TMA) on OP and rectal swabs self- and nurse - collected. Pts also had routine clinic rectal CT NAAT (SDA).	CT detection by NAAT (TMA) from OP and rectal swabs that were self- vs nurse-collected. Performance of TMA on self- vs nurse-collected rectal specimens compared to the gold std defined as NAAT (SDA) on routinely collected rectal swab. Any discrepancy in NAAT results on research or routine swabs were retested by TMA w/ different target.	By gold std, 35/258 (13.6%) rectal CT+. 246/258 (95.3%) rectal CT test results concordance between self- vs nurse-collected. sensitivity for rectal CT higher for self- vs nurse-collected (91.4% vs. 80%) though not significant; specificity high (>98%) for both. No gold std at clinic for OP CT. There were 8/265 (3%) OP CT+ by either self- or nurse-collected OP specimens (3 detected by both), for which 260 of 265 (98.1%) OP specimens were concordant; there was no difference in OP detection rate by self- vs. nurse-collected.	Women not studied. No age or race/ethnicity data. No eval of acceptability of self-collected OP and rectal swabs. No mention of randomization of order of self- vs. nurse-collected swabs.	II

106. Templeton, et al	Retrospective study of rectal CT prevalence and clinical manifestations in MSM who had rectal CT testing by provider or they self-collected a rectal swab	239 asx MSM seen at a sexual health men's clinic in Sydney in 2009 who underwent rectal CT testing by NAAT (type not specified).	Review of type of rectal testing performed (provider vs. self-collected), rectal CT prevalence by NAAT, and rectal clinical manifestations in those examined.	Proportion who provided self-collected swab, CT prevalence, proportion w/ rectal clinical manifestations.	Of 70 pts examined, only 5 (7.1%) had any abnormal anal exam findings. 177 (74%) self-collected a rectal swab, but only 8 (4.5%) of these were examined. Self collected rectal swabs more often in those seen for a return visit (vs first), seen by a nurse (vs doctor), and reporting any casual partners (vs none). 6 of the 177 (3.4%) self-collected rectal CT swabs were CT positive.	Retrospective study design a limitation. Age and race info not provided. Women not studied. Type of NAAT not provided. Small sample size of those w/ rectal CT infection. MSM w/ self collected rectal swab rarely had exam peformed. Study design did not have data allowing one to evaluated concordance of rectal CT test results in patients who self collected ahd had clinician-collected swabs.	III

CHLAMYDIA TESTING FROM LIQUID BASED CYTOLOGY SPECIMENS

CITATION	STUDY DESIGN	STUDY POP/ SETTING	EXPOSURE/ INTERVENTION	OUTCOME MEASURES	REPORTED FINDINGS	DESIGN ANALYSIS QUALITY/BIASES	SUBJECTIVE QUALITY RATING
107. Hopwood J, Mallinson H, et al	Prospective study of chlamydia positivity from liquid based cervical cytology specimens and conventional endocervical specimens.	Females mostly <30yo (n=581) presenting to colposcopy clinics in Wirral UK in 2001-2002. Eligibility criteria: those seeking colposcopy and had to have satisfactory cellular content in cytology smear.	CT LCR performed on residual ThinPrep specimen and on conventional endocervical swab specimen. Chlamydia PCR was used if LCR gave indeterminate results	Chlamydia positivity and concordance of chlamydia test results for both specimen types.	There were 19 concordant positive and 562 concordant negative results (after 3 indeteminate results were reported negative by PCR). The stability of chlamydia in the ThinPrep specimen was maintained at least 5mo.	Large sample size. Limitations included cervical examination findings not provided and LCR used (which may be less sensitive than newer NAATs).	II
108. Koumans EH, Black CM, et al	Prospective study of chlamydia positivity from liquid based cervical cytology specimens, conventional endocervical specimens, and urine.	Females 12-19yo (n=255) presenting to public peds hospital in Atlanta for a pelvic exam. Eligibility criteria: sexually active, nonpregnant, HIV-neg. Exclusion criteria: antibiotics in prior month.	CT LCR on residual ThinPrep specimen, endocervical swab specimen, and urine. Culture, TMA, and PCR done on cervical specimens (also vaginal/urine for PCR) for eval of LCR performance.	Chlamydia positivity by LCR and concordance of chlamydia test results for both specimen types. Comparison of performance of LCR vs culture and other NAATs.	64% normal cytology, 22% ASCUS, 14% LSIL, and 0.5% HSIL. 27% had CT. High agreement (0.97) between LCR-PreservCyt and LCR-cervix (kappa=0.92). Test performances similar for LCR-urine, LCR-ThinPrep, and LCR-cervix (sensitivity 93-99% and specificities 95.5-99%).	Strengths include random order swab collection and use of multiple site reference stds using alternate NAATs. Use of ThinPrep broom instead of spatula and cytobrush could have lower CT detection in the ThinPrep specimen.	I

109. Chernesky M, Freund GG, et al	Prospective study of chlamydia positivity from liquid based cervical cytology specimens and conventional endocervical specimens.	Females (n=1615) presenting to one of six sites in U.S. or Canada in 2004 who underwent pap. Overall mean age 29.6 .	Aptima CT and Aptima Combo (AC) 2 performed on residual SurePath specimen and conventional endocervical swab specimen.	Chlamydia detection results in SurePath, with subject infected status reference determined as both NAATs positive on endocervical swab.	Chlamydia prevalence 7.9% by reference. Performance on SurePath with Aptima CT vs AC2: Sens 85.2% vs 89.1%, Spec 99.5% vs 98.7%, PPV 93.2% vs 85.7%, NPV 98.7% vs 99.8%.	Strengths include use of two of the most sensitive NAATs for reference stds Limited possibly by using only cervical broom instead of spatula and cytobrush and there was variation in sensitivity of assays across sites.	I

GENITAL CHLAMYDIA NATURAL HISTORY

CITATION	STUDY DESIGN	STUDY POP/ SETTING	EXPOSURE/ INTERVENTION	OUTCOME MEASURES	REPORTED FINDINGS	DESIGN ANALYSIS QUALITY/BIASES	SUBJECTIVE QUALITY RATING
110. Geisler WM, Wang C, et al.	Prospective Genital Chlamydia Natural History Study	Subjects 17-54yo (n=129; 115 female, 14 male) screening CT-positive by culture or NAAT at a Birmingham, AL STD clinic 2002-2006 who returned for treatment	Repeat CT testing by NAAT (Roche PCR or GC AC2) at return treatment visit. Demographical and clinical data collected	CT resolution versus persistence at treatment visit. OmpA genotyping of isolates from both visits to confirm persistence.	Median 13d between visits. 18% CT resolution. Trend towards higher resolution in longer interval between visits (14d vs. 12d, P = 0.079), men vs. women (36% vs. 16%, P = 0.13), and history of CT. Subjects with persisting CT more often developed interval signs of infection (urethritis, cervicitis). 2 women had interval PID and one male epididymitis.	Prospective design, use of NAAT, and inclusion of OmpA typing are strengths. High risk, mostly black STD clinic population may not be widely generalizable. Short follow-up period.	I
111. Joyner JL, Douglas JM, et al.	Retrospective Genital Chlamydia Natural History Study	Adolescents/adults (n=94; 58 female, 36 male) screening CT-positive by Roche PCR at a Denver STD clinic in 1996 who returned for treatment. Age range not given but includes subjects >30yo	Roche PCR at treatment visit. Medical records reviewed.	CT persistence by Roche PCR at treatment visit.	Median interval between visits 9d for men and 10d for women. CT persisted in 81% of men and 78% of women. PCR positivity not associated with length of interval between visits. Persisting CT predicted by nonwhite race (OR 4.1), >3d since last sex before initial testing (OR 6.3), and PCR OD $\geq$3 at initial visit. No data on prior CT.	Use of PCR and diversity of races studied were strengths. Lack of OmpA typing to confirm persistence and short follow-up periods were limitations. High risk STD clinic population may not be widely generalizable.	II

Uncomplicated Chlamydia in Adults and Adolescents

CITATION	STUDY DESIGN	STUDY POP/ SETTING	EXPOSURE/ INTERVENTION	OUTCOME MEASURES	REPORTED FINDINGS	DESIGN ANALYSIS QUALITY/BIASES	SUBJECTIVE QUALITY RATING
112. Molano M, Meijer CJLM, et al.	Retrospective Cohort Genital Chlamydia Natural History Study	Columbian adult females (n=82) previously enrolled in an HPV natural history study 1993-2000 who retrospectively were noted to have CT detected from stored cervical specimens at baseline visit. Age range not given, but 71% >25yo.	Retrospective CT plasmid PCR of cervical scrapings and review of questionnaire data collected from patients. Only included CT-infected at baseline but never Rx for active CT during f/u. Data collected every 6-9mo for median f/u 5.7 yrs. Initial CT strains underwent OmpA typing.	Time to CT resolution by CT plasmid PCR and associated factors.	Median 8mo between visits and median # visits 6.5. CT resolution – 54% by 1yr, 82% 2yr, 94% 4yr. Higher CT resolution in those ever on OCPs (RR 1.7) and those with 1st sex >19yo (RR 4.3). No association of age and clearance. Of 55 (67%) patients with single serovars determined initially and at f/u, serogroups B and C had lower CT resolution than intermediate group (RR 0.4 and 0.5). No data on prior CT.	Longitudinal data, study cohort design, and use of CT PCR are strengths. Serovar data helpful, but OmpA genotyping more informative in assessing CT persistence. Unclear how many visits with CT persistence had serotyping performed. Columbian female population may not be widely generalizable. Men not studied.	I
113. Morré SA, van den Brule AJC, et al.	Cohort Based Nested Case Control Genital Chlamydia Natural History Study	Females 18-40yo in Amsterdam undergoing CT PCR screening on mailed urine specimens 1995-1997. N = 30 cases (CT+) and 186 random controls (CT-).	Repeat urine CT PCR (via mail) and questionnaires at 1, 6, and 12 mo. CT+ subjects all asymptomatic and not Rx. CT Strains were OmpA genotyped.	Person / yr CT clearance rate at 1 year for CT+ at baseline and person / yr CT incidence in CT- at baseline.	CT clearance rate was 4.9% per mo (44.7% per yr). CT incidence rate was 3% per year. Though not significant, women with persistent CT more often had OmpA type E vs. those with resolved CT (67% vs. 37%). No PID developed by 1 yr f/u. Impact of age on CT clearance not evaluated. No data on prior CT.	Longitudinal data, PCR, and inclusion of OmpA typing are strengths. Limited in that f/u data N/A for many case patients and OmpA typing only done on initial specimen. Assumption was urine PCR as sensitive as cervical PCR, o/w may overestimate CT clearance. Amsterdam female population and study by mail design may not be widely generalizable. Men not studied.	II
114. Parks KS, Dixon PB, et al.	Retrospective Genital Chlamydia Natural History Study	Subjects 15 to >30yo (n=74; 69 female and 5 male) screening CT-positive at a Birmingham, AL STD clinic 1992-1996 who returned for treatment.	Patients undergoing repeat CT culture/DFA at treatment visit were identified through chart review. CT PCR done on culture-negative samples.	CT resolution by culture/DFA or PCR at treatment visit..	Interval between visits was >20d in 14%, with the rest having 4-20d interval. 28% CT resolution. Older age predicted CT resolution (RR 1.5), as did longer interval between visits (>20d vs. 4-20d, RR 1.9). Prior CT history did not predict outcome.	Use of PCR was a strength. Limitations included lack of OmpA typing to confirm persistence, short follow-up period, small # men, lengthy storage of specimens before testing, and inclusion of subjects Rx with β-lactams. High risk mostly black STD clinic population may not be widely generalizable.	II

Uncomplicated Chlamydia in Adults and Adolescents

CITATION	STUDY DESIGN	STUDY POP/ SETTING	EXPOSURE/ INTERVENTION	OUTCOME MEASURES	REPORTED FINDINGS	DESIGN ANALYSIS QUALITY/BIASES	SUBJECTIVE QUALITY RATING
115. Rogers SM, Turner CF, et al.	Prospective Genital Chlamydia Natural History and Partner Concordance Study	Adults screening CT-positive by PCR/LCR at Baltimore ER 2002-2005 and their partners were recruited for f/u CT testing; N = 166 index patients (102 heterosexual partners participated); 83 partnerships for CT concordance evaluation. Mean age 22.5 (range not given).	Index patients underwent repeat CT testing by PCR/LCR and by traditional (culture/DFA) at f/u treatment visit and partners underwent testing once.	CT resolution by LCR/PCR at treatment visit for index patients; CT concordance within partnerships by NAAT vs. traditional tests.	Mean 22d between index patient visits. Prior CT or GC in 38% of index pts. 17% CT resolution in index patients, and higher in women than men (23% vs. 6%). Impact of prior CT on CT resolution not studied. Higher CT+ partner concordance in NAAT+/Traditional + vs. NAAT+/Traditional - index patients (75% vs. 45%, Prevalence Ratio 1.7) and did not differ by index or partner gender, age, or prior CT. Partners of index pts with persistent CT more often tested positive than partners of index patients with resolution (70% vs. 11%).	Prospective design, large sample size, use of NAAT, and evaluation of partner concordance were strengths. Limitations included lack of OmpA typing to confirm persistence and short f/u period. ER setting with mostly black subjects may not be widely generalizable.	I
116. Sheffield JS, Andrews WW, et al.	Retrospective Genital Chlamydia Natural History Study	Pregnant adolescents and adults (n=140) from a multicenter BV Rx trial who were LCR CT+ at BV Rx trial randomization and had f/u CT LCR performed and were untreated. Majority <26yo.	Archived urine from BV trial enrollment tested by CT LCR on subjects at $16^{0/7}$ wks – $23^{6/7}$ wks gestation and repeat urine LCR at $24^{0/7}$- $29^{6/7}$ wks gestation f/u visit.	CT resolution by LCR at f/u visit.	44% CT resolution. Predictors of CT resolution were increasing age (P = 0.01) and longer interval between visits (resolution 26% at <5wk vs. 74% 5+ wk, P = 0.02). For every 5yr increase in age, odds of +LCR at f/u decreased by 40%. BV findings and BV Rx did not influence CT resolution. No data on prior CT was reported.	Use of LCR, large sample size, longer f/u, and analysis of BV influence on CT are strengths. Limitations include lack of OmpA typing. Pregnant population, mostly black, with high BV prevalence may not be widely generalizable. Immunosuppression from pregnancy could influence CT resolution.	II
117. van den Brule AJC, Munk C, et al.	Prospective Genital Chlamydia Natural History Study	Male adult Danish military recruits (N=9) screening urine CT PCR positive in 1998 who returned for f/u testing in 5-8mo in 1999 and were untreated.	Repeat urine CT PCR testing at follow-up visit.	CT resolution by PCR at follow-up visit.	1 of 9 (11%) CT resolution. Patient characteristics and their relationship to CT resolution not provided specifically for these 9 men. No data on prior CT.	Prosp design and PCR are strengths. Very small sample size, lack of OmpA typing, and lack of info on pt characteristics are limitations. Danish pop may not be widely generalizable. Women not studied.	II

Uncomplicated Chlamydia in Adults and Adolescents

CITATION	STUDY DESIGN	STUDY POP/ SETTING	EXPOSURE/ INTERVENTION	OUTCOME MEASURES	REPORTED FINDINGS	DESIGN ANALYSIS QUALITY/BIASES	SUBJECTIVE QUALITY RATING
118. van Valkengoed IGM, Morre SA, et al.	Prospective Genital Chlamydia Natural History Study	Subjects 15-40yo (n=110; 35 men and 75 women) in Amsterdam with mailed-in urine 1997-1998 that screened CT LCR+ who returned for diagnostic confirmation and treatment; 65% female.	Repeat CT LCR on urine and genital swab at confirmation / treatment visit.	CT resolution by LCR at confirmation / treatment visit.	Interval between visits not provided. 16% CT resolution. No association of gender and age with resolution (data not shown). Data on prior CT not provided.	Prospective design and LCR are strengths. Lack of OmpA typing and sufficient details on patient characteristics (as they relate to resolution) are limitations. Danish population may not be widely generalizable.	II
119. Hu D, Hook EW, et al.	Analysis of the Impact of Natural History Parameters on Cost Effectiveness of CT Screening Strategies in Women	Population entered into the model was cohort of 15yo nonpregnant females without STDs at baseline	State-transition Markov model that simulated the natural history of CT in women. Cohort followed till death. Every 6mo, women faced a risk for CT. Natural history parameters entered. Model compared 7 screening strategies targeted by age groups.	Modified societal perspective used for the model. Outcome measures were direct medical costs, costs of time lost from work, yrs of life saved, and QALYs gained.	Cost-effectiveness varies by natural history assumption. Assumptions about risk of persistent and repeat CT had greatest impact on screening strategies. Assumptions about PID risk most greatly influenced magnitude of incremental cost-effectiveness ratios.	Primary limitation was the natural history assumptions: rate of CT clearance, PID risk, transmission risk, etc.)	II
120. Geisler WM, Black CM, et al.	Analysis of the Influence of *C. trachomatis* OmpA genotypes on Chlamydia Natural History.	Subjects 17-54yo (n=102; 92 female, 10 male) screening CT-positive by culture or NAAT at a Birmingham, AL STD clinic 2002-2006 who returned for treatment and had *C. trachomatis* strains available for OmpA typing	*C. trachomatis ompA* genotyping performed on all strains from the screening visit and on strains at the treatment visit in those with had persistent chlamydia.	Association of initial OmpA type and chlamydia resolution vs persistence (determined by NAAT at the treatment visit).	The most prevalent OmpA types detected at the initial screening visit were E (28%), D/Da (23%), J/Ja (19%), and I/Ia (15%). OmpA type J/Ja was associated with *C. trachomatis* clearance. 5% of individuals categorized as persistent chlamydia before OmpA typing were found to have discordant genotypes between screening and treatment visits, suggesting new infection and not persistence.	Prospective design is a strength, but the small number of men and short follow-up is a limitation. High risk, mostly black STD clinic population may not be widely generalizable.	II

CHLAMYDIA SCREENING IN MEN

CITATION	STUDY DESIGN	STUDY POP. TYPE/ SETTING	EXPOSURE/ INTERVENTION	OUTCOME MEASURES	REPORTED FINDINGS	DESIGN ANALYSIS QUALITY/BIASES	SUBJECTIVE QUALITY RATING
121. Satterwhite CL, Joesoef MR, et al.	Data Review to Determine Estimates of CT Among U.S. Men	Heterosexual men and MSM ages 14-80. Data included general population and specific populations 1999-2005.	Data reviewed: national CT morbidity data and prevalence data from NHANES, AddHealth, National Job Training Program, MSM Prevalence Monitoring Project, and juvenile and adult corrections facilities.	Data reported as CT cases reported or CT prevalence in general or specific populations.	In 2005, 232,781 cases reported - 161 per 100,000 men (an increase vs 2001, 112 per 100,000). General population CT prevalence for NHANES and Addhealth was 3.2% and 3.7% (higher in Blacks, 5.3% and 11.1%). Prevalence in Job Training 8.1%. Specific population CT prevalence for MSM project, adult corrections, and juvenile corrections was 6%, 7.8%, and 6.7%	Limitations included potential underreporting of cases, CT prevalence data just an estimate as CT testing methods varied, and prevalence in MSM may have been underestimated as not all had rectal CT testing.	II
122. Rietmeijer CA, Hopkins E, et al.	Data Review to Determine CT Positivity Rates Among U.S. Men Tested in Select Venues	Asymptomatic heterosexual men and MSM in non-STD clinic venues. Most studies had men ages <35yo. Data on men in STD clinic venues or symptomatic men excluded.	Pub Med search for data on CT positivity rates among asx men in non-STD clinic venues 1995-2007. 54 articles met inclusion criteria and were reviewed.	CT positivity rate by venue, demographics, and geographic region.	Median CT positivity rate was 5.1% and highest in: juvenile detention (7.9%), adult detention (6.8%), blacks (6.7%), 15-19yo (6.1%), 20-24yo (6.5%), and men screened in southern U.S. (6.4%).	Limitations included potential underreporting of cases, South and West Coast regions overrepresented, difficulty with determination of symptoms status in some studies, methodological and testing differences across studies, and rates in MSM may have been underestimated as not all had rectal CT testing.	II
123. Gift TL, Black DR, et al.	Data Review to Determine Cost Effectiveness of CT Screening in Men.	Asymptomatic heterosexual men and MSM in non-STD clinic venues. Most studies had men ages <35yo. Data on men in STD clinic venues or symptomatic men excluded.	Ovid Medline search for data on cost-effectiveness of CT screening in men from 1990-2006. 25 articles met inclusion criteria and were reviewed.	Summary of key findings from cost-effectiveness studies.	Studies included proactive and opportunistic screening programs and populations both general and specific risk groups. Most studies reported screening men from general population not preferred to screening women from the general population. Some studies found combined male and female screening programs cost-saving.	Major limitations are the assumptions in the models (PID costs, incidence of PID, CT transmission rates, natural history of CT, partner rx and new partner impact, which population would be screened [general, risk-based],etc.) and the differences in CT testing technology utilized across studies.	II

124. Gift TL, Gaydos CA, et al.	Analysis of Cost Effectiveness of CT Screening in Men from Data from a Multistate Demonstration Project and Longitudinal Study.	Population from which model data primarily derived was a demonstration project in which >23,000 men had CT screening by urine NAAT (LCR, PCR, or SDA) in non-STD clinic venues in 4 U.S. cities 2001-2003.	Dynamic Cost-effectiveness model. Data was derived from a demonstration project where men had CT screening and data on partners, treatment, and reinfection also derived from a longitudinal substudy of the demonstration project. Other data for assumptions in the model derived from the literature.	Primary outcomes measures were QALYs lost and cases of PID. Also evaluated new cases of CT treated and prevented in men and women. Societal perspective used for the model. Time frame 5 years and analytic horizon up to 20yr	Program targeting high-risk men was cost-saving versus equivalent program dollars to expand screening of lower-risk women. Combining partner notification with CT screening in men more effective than screening alone. Male screening program not always cost effective but avg $10,520 per QALY saved over expanded screening in women.	Limitations included not modeling partnerships explicitly which impacts infection and reinfection events and the assumptions in such models (PID costs, incidence of PID, CT transmission rates, natural history of CT, partners treatment and new partner impact, etc.).	II

CHLAMYDIA SCREENING IN WOMEN OVER 25 YEARS OF AGE

CITATION	STUDY DESIGN	STUDY POP/ SETTING	EXPOSURE/ INTERVENTION	OUTCOME MEASURES	REPORTED FINDINGS	DESIGN ANALYSIS QUALITY/BIASES	SUBJECTIVE QUALITY RATING
125. Torrone et al.	Retrospective analysis of prospectively collected nationally representative data to determine predictors of chlamydia in women >25yo.	Epi/clinical data and CT test results collected from 3875 U.S. women 26-39yo during six 2-year NHANES cycles (1999-2010) were reviewed to eval CT predictors in women>25yo.	NHANES epi/clinical and CT test results data reviewed. CT tests were all urine NAAT (early cycles LCR, later SDA).	Differences in weighted CT prevalence estimates among different clinical/epi factors. Estimates w/ relative std errors (RSE) >40% not reported and RSE 30-40% range interpreted w/ caution.	Overall CT prev 1.2%, which significantly varied by race (highest in Afr Am 2.5%), marital status (highest in women widowed/ divorced/ separated 2.7%), education (highest in <HS edu or GED 2%), sex partner # (highest w 2+ partners last 12mo 2.9%), and hormone use (highest in women who never used OCP or DEPO 3.4%).	Nationally representative sample a study strength. NAAT less sens on urine. LCR used in early cycles less sens than newer NAATs. By combining survey cycles, prevalence chg over time not accouted for. Overall a low CT prevalence population compared w/ select venues.	I

Uncomplicated Chlamydia in Adults and Adolescents

CITATION	STUDY DESIGN	STUDY POP. TYPE/ SETTING	EXPOSURE/ INTERVENTION	OUTCOME MEASURES	REPORTED FINDINGS	DESIGN ANALYSIS QUALITY/BIASES	SUBJECTIVE QUALITY RATING
126. Beydoun, et al.	Retrospective analysis of prospectively collected nationally representative data to eval gender and age disparities in CT prevalence.	Epi/clinical data and CT test results collected from 5611 U.S. men and women 20-39yo during four 2-year NHANES cycles (1999-2006) were reviewed to gender and age disparities in CT prevalence. There were 2311 women 25-39yo.	NHANES epi/clinical and CT test results data reviewed. CT tests were all urine NAAT (1st 2 cycles LCR, last 2 SDA).	Differences in weighted CT prevalence estimates among different clinical/epi factors.	Overall CT prev 1.6%, which not different by gender but higher in <25yo vs ≥25yo (2.7% vs 1.3%). CT significantly varied by race (highest in Afr Am 4.9%), marital status (highest in never married 2.6%), education (highest in <HS edu 2.8%), annual income (highest <20k 3.3%), age 1st sex(highest ≤15yo 2.3%), and unprotected sex past mo (highest in women w/ unprotect sex past mo 2.3%). CT prevalence was 1.3% in 2311 women 25-39yo, and significantly differed by race (highest in Afr Am 3.1%), marital status (highest in never married 3%), and education (highest in <HS edu 3%).	Nationally representative sample a study strength. NAAT less sens on urine. LCR used in early cycles less sens than newer NAATs. By combining survey cycles, prevalence chg over time not accouted for. Overall a low CT prevalence population compared w/ select venues. RSEs not considered in interpreting significance of estimates. Associations in women ≥25yo based on a small number of sexually experienced women (about 30).	II
127. Howard, et al.	Cross-sectional study to evaluate predictors of chlamydia in women >25yo.	1243 nonpreg women (age 26-30) seen in FP clinics in California May 2003-Nov2005 had interview and CT testing to eval CT predictors in women>25yo.	Self-administered questionnaire and clinician interview. CT testing (specific test not provided, but likely NAAT)	Differences in CT prevalence estimates among different clinical/epi factors.	CT detected in 39/1243 (3.1%). Prevalence higher in women w/ clinical indiciation for CT testing vs routine screening (4.5% vs 2.9%). Predictors of CT: pt indicated partner(s) poss had concurrent partners, >1 or 2 partners past 3 or 12mo, BV diagnosis, and new partner past 3 months. Negative association for CT in married or stable relationship (married, engaged, living w partner).	Abstract data not a published study, so limited info. No race data. Convenience sample. CT test used not provided.	II

POINT OF CARE (POC) CHLAMYDIA TESTS

CITATION	STUDY DESIGN	STUDY POP. TYPE/ SETTING	EXPOSURE/ INTERVENTION	OUTCOME MEASURES	REPORTED FINDINGS	DESIGN ANALYSIS QUALITY/BIASES	SUBJECTIVE QUALITY RATING
128. Hislop et al.	Systematic Review of clinical- and cost-effectiveness of CT POC tests	11 databases searched thru Nov 2008 for studies of adolescents and adults tested w/ CT POC tests (n=8817 patients). Study focused on the CT Rapid Test (CRT) vs other POC tests.	Systematic review of data	Clinical effectiveness (performance) of POC tests using NAAT (PCR) as ref. Relative cost-effectiveness from health service perspective	13 studies reviewed. Pooled estimates for CRT: sens 80% vag swab, 77% urine; spec 99% both. Lower performance other POC tests/ Clearview sens 52% on genital swabs combined (64% cervical only) and spec 97% genital swabs. CRT and the Clearview were more costly than NAAT from a health service perspective.	Limitations included not incorporating impact of rapid treatment with POC results, use of a high baseline rx rate (95%), and using PCR (less sens than new NAAT) as ref std.	II
129. Bandea, et al.	Prospective study evaluating performance of Biostar CT OIA vs. ref std 2 NAATs vs. culture	261 female adolescents 13-19yo enrolled in a larger study at a pediatric clinic in Atlanta who had cervical swabs collected for CT testing.	CT OIA, NAAT (LCR and TMA) and culture performed on cervical swabs.	Performance of Biostar CT OIA vs. ref std 2 concordant NAATs vs. culture	With culture as ref std, OIA had sens 78.6% and spec 97.2%. With NAATs as ref std, OIA had sens 59.4% and spec 98.4%	Strength is the using NAAT for ref std test. Men not studied. Race and study period not provided.	II
130. Sabidó, et al.	Prospective study evaluating performance of CT Test Card vs. ref std CT PCR	278 female CSWs 18+yo seen in STI clinics in Gautemala Apr-Aug 2007 who had cervical swabs collected for CT testing.	CT Test Card and NAAT (PCR) performed on cervical swabs.	Performance of CT Test Card vs. ref std NAAT	With PCR as ref std, CT test card had sens 62.9% and spec 99.6%.	Strength is the using NAAT for ref std test. Men not studied. Age not provided. High risk population.	II
131. van Dommelen, et al.	Prospective study evaluating performance of 3 CT POC tests vs. ref std CT PCR	772 females (16-64yo) seen in an STI clinic in the Netherlands Sep 2007-Apr 2008 who self-collected 6 vag swabs for CT testing.	3 POC tests (Handilab-C, Biorapid CT Ag test, QuickVue CT test) and NAAT (PCR) performed on vag swabs. CT IFU quantified across vaginal swabs.	Performance of the POC tests vs. ref std NAAT	CT prevalence by PCR was 11% (84/772). With PCR as ref std, the sens of Handilab-C, Biorapid CT Ag test, QuickVue CT test were 12%, 17%, and 27%. Spec were 92%, 93.5%, and 99.7%.	Strength is the using NAAT for ref std test and quantifying IFU to ensure sufficient CT for eval assay performance. Men not studied. High risk population. Menstrual blood may have affected the performance of the POC tests and was a limitation.	II

Uncomplicated Chlamydia in Adults and Adolescents

CITATION	STUDY DESIGN	STUDY POP. TYPE/ SETTING	EXPOSURE/ INTERVENTION	OUTCOME MEASURES	REPORTED FINDINGS	DESIGN ANALYSIS QUALITY/BIASES	SUBJECTIVE QUALITY RATING
132. Hesse, et al.	Prospective pilot study evaluating feasibility and performance of new prototype devices as CT POC tests vs. ref NAAT and discussion of rapid communication approach w/ manufacturer to improve each POC prototype	84 females (eligible if 14-30yo, mean age 18.3yo) seen in an STI clinic, teen clinic, or ED in Cincinatti who provided self- collected vag swab and clinician- collected cervical swabs for CT testing.	4 POC prototypes were eval in succession (A-D), each altered after communication w/ manufacturer. NAAT (SDA) performed on swabs.	Feasibility description and performance of the POC prototypes vs. ref std NAAT on vag swab and cervical swab.	The final prototype improved earlier problems, though still had difficulties w/ readability of test results. Due to small sample size, earlier prototypes combined (A-B) and later prototypes (C-D) combined for performance eval. With NAAT as ref, A-B had sens 38% both samples and spec 77% cervical / 64% vaginal. C-D had sens 80% both samples and spec 37% cervical / 25% vaginal.	Limited by small sample size per prototype and not all prototypes usedd on the same sample. Description of approach to prototype improvement was informative. Strength is the using NAAT for ref std test. Most pts Afr Am. Men not studied.	II
133. Nadala, et al.	Prospective study evaluating performance of CT Rapid Test vs. ref std CT PCR	1211 men (16-73yo) seen in sex health centre Bham UK (n=454) and a London GUM clinic (n=757) Mar-Nov 2007 who had urine collected for CT testing.	CT Rapid Test and NAAT (PCR) performed on urine.	Performance of CT Rapid Test vs. ref std NAAT on urine.	CT prevalence by PCR was 4.4% site 1 and 11.9% at site 2. With PCR as ref std, CT Rapid Test had sens 82.6% and spec 98.3%.	Strength is the using NAAT for ref std test. Women not studied. High risk population. Some authors affiliated w/ manufacturer of CT rapid test.	II
134. van der Helm, et al.	Prospective study evaluating performance of CT Rapid Test vs. ref std NAAT (TMA)	912 women (age IQR 25-36yo) seen in a high- and a low-STI risk clinic in Suriname July 2009-Feb 2010 in whom nurse collected vaginal swabs for CT testing.	CT Rapid Test and NAAT (TMA) performed on vag swabs.	Performance of CT Rapid Test vs. ref std NAAT on vaginal swabs.	CT prevalence 20.8% in high risk site and 9.2% in low risk site. With NAAT as ref std, CT Rapid Test sens 41.2% and spec 96.4%. The sens of CT rapid test differed by CT load (stratified by median load), being 12.5% with low CT load and 73.5% with high CT load.	Strength is the using NAAT for ref std test and quantifying CT load for eval of test performance.. Men not studied. The low risk population had a high CT prevalence.	II
135. Dean, et al.	Prospective study evaluating performance of a new microfluidic multiplex PCR POC test vs. CT PCR	263 high risk women (age 15-24yo) seen in an STD clinic in San Francisco in whom a cervical swab was collected for CT testing.	Multiplex PCR POC test and NAAT (PCR) performed on cervical swabs. Discordant results eval by microfluidic Sanger sequencing.	Performance of Multiplex assay vs. NAAT on cervical swabs.	There were 76 CT+ both assays, 53 CT+ by multiplex only (all confirmed CT+ by sequencing), and 18 CT+ by NAAT only (12 confirmed CT+ by sequencing). Therefore, true CT prevalence was 141 (54%). Sens and spec for multiplex 91.5% and 100% vs. NAAT 62.4% and 95.9%.	Strength is use of sequencing to eval discordant results. Limited by choosing a lower sens NAAT for comparison. Men not studied. Multiplex suggested for POC use though on avg take 1 hour to get data (under ideal lab conditions). Study period not noted.	II

CITATION	STUDY DESIGN	STUDY POP/ SETTING	EXPOSURE/ INTERVENTION	OUTCOME MEASURES	REPORTED FINDINGS	DESIGN ANALYSIS QUALITY/BIASES	SUBJECTIVE QUALITY RATING
136. Huang, et al.	Prospective study evaluating performance and cost-effectiveness of a new CT POC test vs. ref std NAAT	149 women (median 27yo) seen in STD clinics in Baltimore Apr 2010-Feb 2011 in whom urogenital specimens were collected for CT testing.	A new CT POC performed on a self-collected swab. NAAT (TMA) performed on cervical, self-collected vag swab, and urine. Decision analysis model.	Performance of new CT POC test vs. ref std NAAT on cervical, vag, and urine specimen (true CT+ if 2 or 3 specimens CT+ by NAAT). Model estimates for #PID cases averted and cost incurred/ saved per PID averted.	True CT prevalence was 9.4%. Sens and spec of new POC CT test were 92.9% and 98.5%. One-way sens analyses indicated POC would be favorable over NAAT if sens $\geq$87.1% and test cost <$41.52. Mean incremental cost-effectiveness ratio indicated POC strategy would save $28 in total and avert 14 PID cases.	Model parameters for population (prevalence, test sens, and % women willing to wait 40min for POC test result) might not be applicable to different clinical populations. Most pts were Afr Am. Men not studied.New POC test not eval on urogenital specimens other than vag swab.	II
137. Pearce, et al.	Prospective study evaluating performance of a new CT POC test vs. ref std NAAT	306 clinical samples pre-typed as CT pos (n=107) or CT neg (n=199) by either TMA or PCR. Clincial investigators were from Johns Hopkins.	A new CT POC test (electrochemical detection method) performed on pre-NAAT typed (CT pos vs. neg) clinical samples.	Performance of new CT POC test vs. ref std NAAT previously performed on the pre-typed specimens.	Sens and spec of new POC CT test was 98.1% and 98.0%. Time or result around 25 min.	Demographics and anatomical site of clinical sample not provided. 2nd NAAT to eval discordant results either not used or not discussed.	II

TIMING OF CHLAMYDIA DNA/RNA CLEARANCE AFTER THERAPY

CITATION	STUDY DESIGN	STUDY POP/ SETTING	EXPOSURE/ INTERVENTION	OUTCOME MEASURES	REPORTED FINDINGS	DESIGN ANALYSIS QUALITY/BIASES	SUBJECTIVE QUALITY RATING
138. Dukers-Muijrers et al.	Prospective study evaluating detection of CT DNA and RNA after CT rx	52 sx NAAT CT+ pts (46 women, 6 men) seen in an STD clinic in Amsterdam in whom provider collected cervicovaginal +/- anorectal specimens from women and anorectal specimens from men for CT testing.	PCR (DNA) and TMA (rRNA) performed on these specimens at 23, 26, 30, 37, 44, and 51d post azithro 1g Rx	Detection of CT DNA vs. rRNA between 23-51d post azithro Rx	In 52 pts, there were 59 CT infections (7 women had both genital and anorectal CT). rRNA or DNA was detected at 23d, 26d, 30d, 37d, 44d, and 51d in 14%, 20%, 16%, 17%, 22%, and 24%. Overall 42% (n=25) of the 59 infections tested pos at least once 23-51d post rx and there was substantial inter- and intra-individual variation over time and by NAAT, most infections testing pos intermittently.	Studied clearance of both CT DNA and RNA. Patients rx w/ doxy not studied. Age and study period info not given. Abstinence or safe sex 1wk post rx rec as was partner rx. Rarely samples did not contain sufficient DNA. Info on whether partner rec'd rx not provided. CT typing not performed to eval whether repeat pos same CT strain.	II

Uncomplicated Chlamydia in Adults and Adolescents

CITATION	STUDY DESIGN	STUDY POP/ SETTING	EXPOSURE/ INTERVENTION	OUTCOME MEASURES	REPORTED FINDINGS	DESIGN ANALYSIS QUALITY/BIASES	SUBJECTIVE QUALITY RATING
139. Renault, et al.	Prospective study evaluating time to clearance of CT RNA after CT rx	61 NAAT CT+ adolescent women (median 18yo) seen in 4 adolescent clinics in San Mateo County Jan 2007-Nov 2008 who provided self collected vaginal swabs for CT testing.	NAAT TMA (rRNA) performed on self collected vag swabs at time of azithro and then day 3,7,10,14 after azithro Rx given.	Duration of detection of CT rRNA post time of azithro given	CT rRNA detected; 54/61 (88%) day3, 33/61 (54%) on day 7, 21/61 (34%) day 10, and 13/61 (21%) day 14. Multi linear regression analysis predicted full clearance at 17d.	Studied clearance only CT RNA. Men and patients rx w/ doxy not studied. Limited to all patients who completed the study and agreed to abstinence. Diverse race/ethnicity distribution.	I
140. Morré SA et al.	Prospective study evaluating time to clearance of CT DNA and RNA after CT rx	25 sx EIA CT+ women seen in a GYN Dept of hosp in Amsterdam in whom provider collected cervical brush specimens and a urine in a subset of pts for CT testing.	PCR (DNA) and NASBA (16S rRNA) performed on cervical brush specimen and a subset also on urine before doxy Rx and weekly for 5wks post start Rx	Duration of detection of CT DNA vs. RNA post start of doxy Rx	1wk post start Rx – 2/25 RNA pos, 21/25 DNA pos 2wk post start Rx – rRNA no longer detected; DNA pos in 6/21 (wk2), 5/20 (wk3), 1/6 (wk4).	Studied clearance of both CT DNA and RNA. Men and patients rx w/ azithro not studied. Age, study period, and abstinence info not given. Not all patients completed the study. CT genotyping not performed.	II
141. Workowski KA, et al.	Prospective study evaluating time to clearance of CT DNA and culture negativity after CT rx	20 CT NAAT pos (19 culture pos) women (mean age 21.5 yr, range not given) seen in a University student health clinic in Seattle, in whom a cervical, urethral, and rectal swabs were collected for CT testing.	PCR (DNA) and culture performed on anogenital swabs at the following time intervals after enrollment: 1, 2, 4, 8, 12, 16, and 20wks	Duration of detection of CT DNA and culture positivity at any anatomical site at the f/u CT testing visits after initiating doxycycline	End of Rx (1 wk visit)– all culture neg and 10/20 PCR pos 2 wk visit – 3/20 PCR pos 4-20wk visits – all pcr and culture neg	Studied clearance only CT DNA. Men and patients rx w/ azithro not studied. Population predominately white. Abstinence info not given. All patients completed at least visits thru 4wks of enrollment.	II
142. Gaydos CA, et al.	Prospective study evaluating time to clearance of CT DNA after CT rx	33 baseline NAAT CT+ female high school students (w/n age range 14-21) seen in student clinics in Baltimore Spe 1995-June 1996 who volunteered to return at multiple time points to provide urine for CT testing and who provided specimens in a timely fashion.	NAAT PCR and LCR (both DNA) performed on urine about every other school day after Rx.	Duration of detection of CT DNA after completion of azithro (n=26) or doxycycline (n=7). If only the PCR or LCR were pos, then true pos confirmed by PCR w/ a different target.	1-3d post-rx – PCR pos 40%, LCR pos 73.3% 4-6d post-rx – PCR pos 21%, LCR pos 37% 7-9d post-rx - PCR pos 25%, LCR pos 13% 10-12d post-rx – PCR pos 0%, LCR pos 10% 13-15d post-rx – PCR pos 14%, LCR pos 0% >16d post-rx – no PCR or LCR pos	Both doxy and azithro studied, though most subjects who rec'd doxy did not return for testing before 7 days. Subjects were educated about abstinence. Men not studied. Poor specimen collection compliance as <1/3 of subjects had urine tested 10 or more days post-rx. Most Afr Am.	II

143. Bianchi A et al.	Prospective study evaluating time to clearance of CT DNA and RNA after CT rx	19 baseline NAAT CT+ asx or sx female (n=14) and asx male (n=5) patients in France who had a positive CT screening PCR. who volunteered to provide urine at multiple time points following azithromycin treatment.	NAAT PCR (DNA) and TMA (RNA) performed on urine daily for one week after azithro rx and then in a subset returning at 14d after azithro rx.	Duration of detection of CT DNA and RNA after azithro rx.	Females – all PCR/TMA neg by day 6 after azithro Male – 1/5 PCR pos and none TMA pos day 7 after azithro Day 14 post azithro rx (n=5) all had neg PCR (TMA not mentioned)	Only azithro studied. Less than half of pts returned for 14d testing. No info on age, race, study period, clinical setting, or abstinence. Sample size of men small. Did eval DNA and RNA. No mention of additional NAAT w/ different target to eval for true pos if only one of the NAAT were positive.	II

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