THE UNIVERSITY OF QUEENSLAND
AUSTRALIA
CREATE CHANGE

Mycoplasma genitalium
Evidence Based Prescribing?

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Overview

Safe Prescription Good Practice Guidelines

Treatment Options

RCTs

Licencing & Access

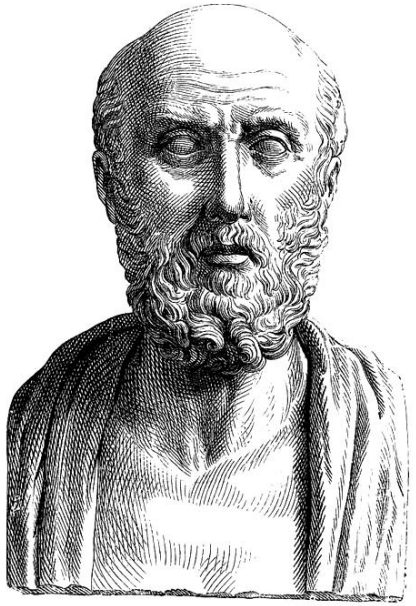
Side-effects

Cost

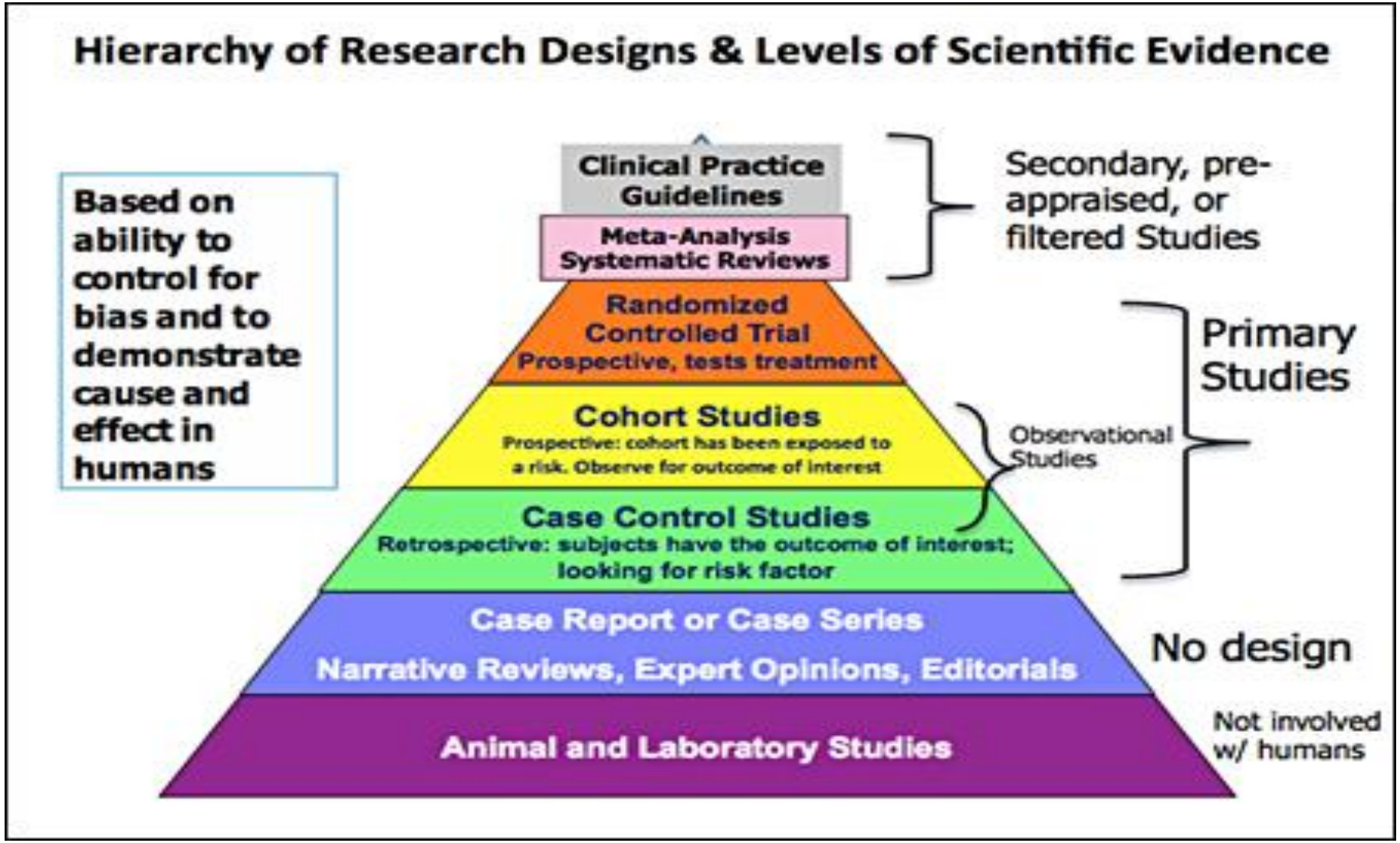
Future

Hippocratic Oath AD245
Primum non nocere *(First do no harm)*

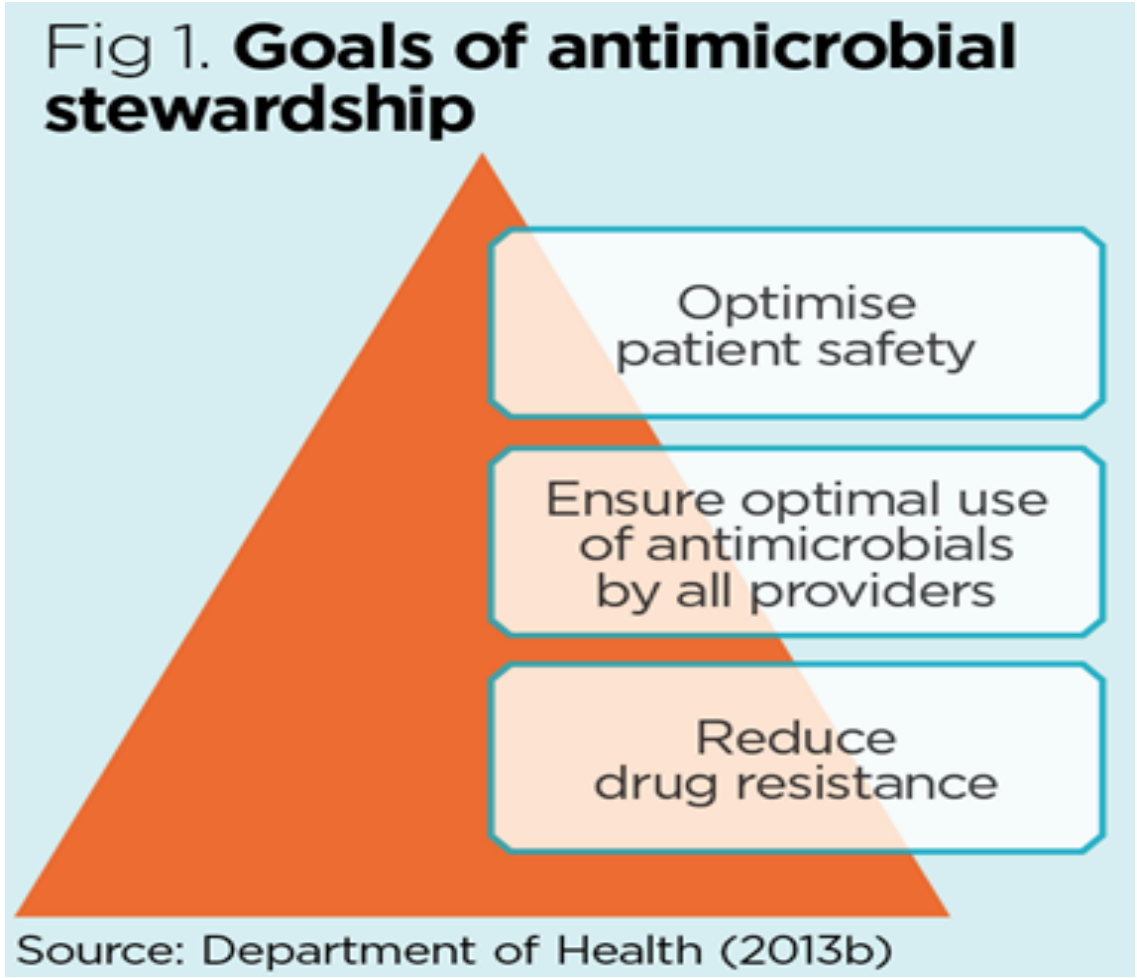
…..,but never with a view to injury and wrong-doing. Neither will I administer a poison to anybody….
…, and I will abstain from all intentional wrong-doing and harm,…



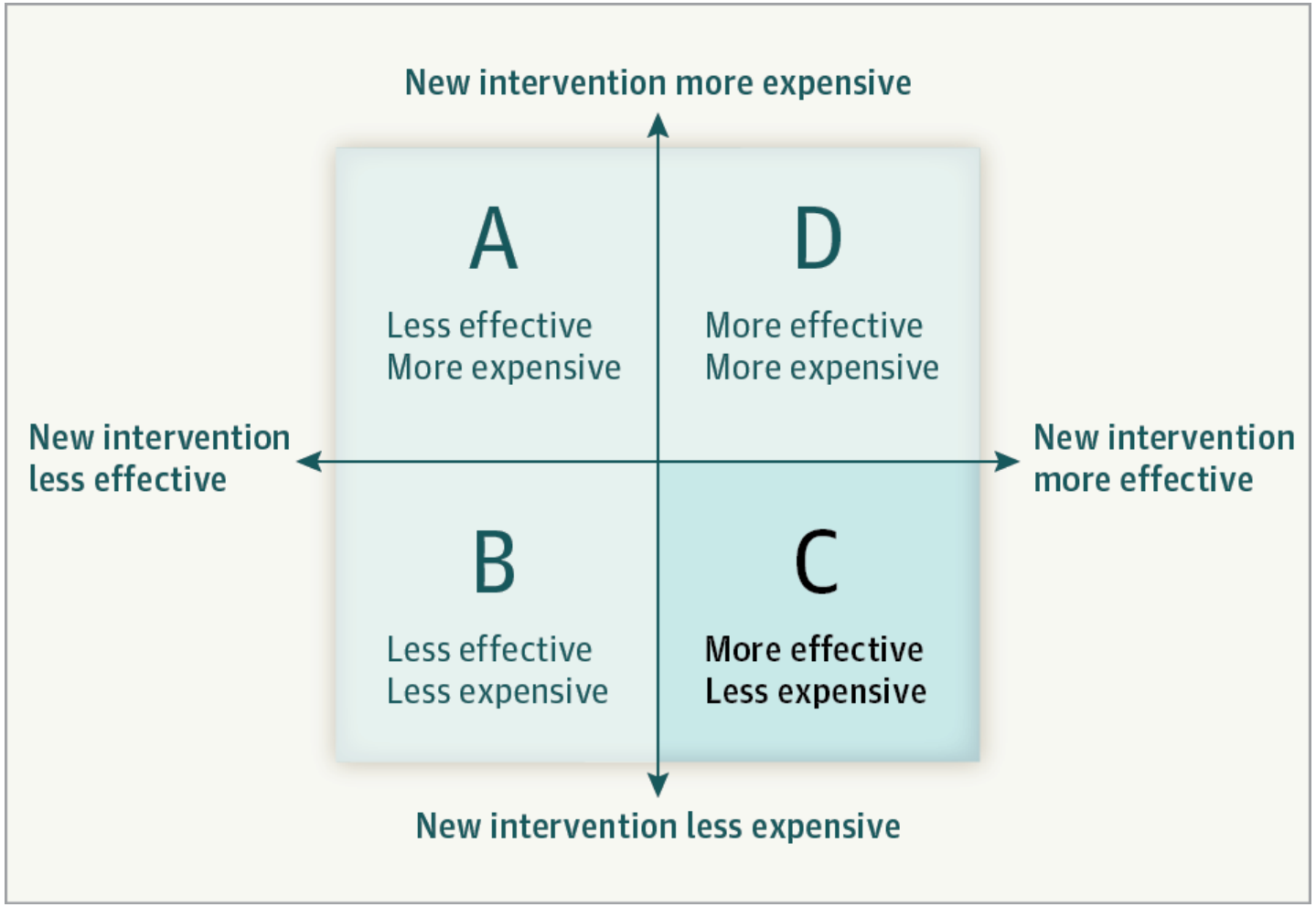
Evidence Based Practice



Antimicrobial Stewardship

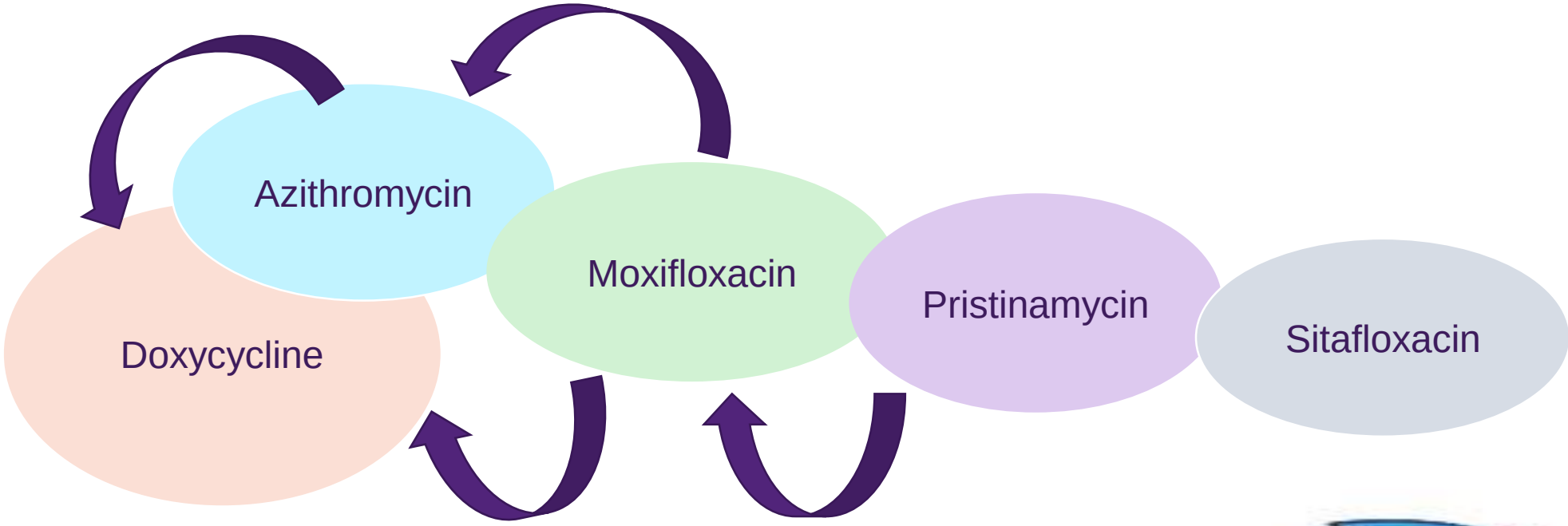


Cost-effectiveness (AUD$)



Typical reaction of a clinicians to *Mycoplamsa genitalium* initial and TOC positive results:

South QLD: WMD against Mycoplasma genitalium



RCT & *Mycoplasma genitalium*

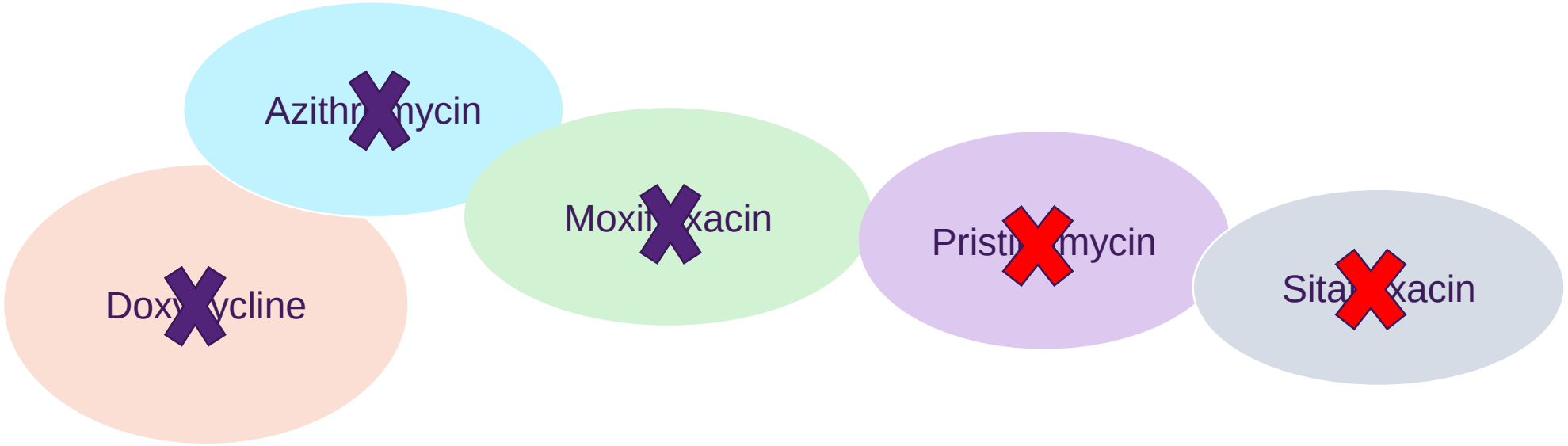
- RDBPCT, 2018, multicentre, France: Will **josamycin** prevent premature delivery in MGEN pos **pregnan**t mothers? 238 pregnant mothers, amniocentesis to test for Down Sydrome was also tested for MGEN, positive PCR were randomized to receive josamycin or placebo. **Terminated** due to low colonisation rate with MGEN (only 29/1043 samples were pos (3%)). *(Kayem G. et al)*
- RDCT, 2014, Uganda: 437 male subjects vs 394 male controls, randomised to be **circumcised** to test if MGEN prevalence was reduced in their female partners. Results: circumcision of men did not reduce MGEN prevalence of women. *(Tobian AA et al.)*
- RDBPCT, 2013, Seattle (USA): **48 vs 27 men** with MGEN, 50:50 Azithro (1g) vs Doxy (100 mg BD 7/7), **Clinical cure rate**: 63% Azithro vs 48% Doxy, ***p= 0.38***; **Microbiological cure**: 40% Azithro vs 30% Doxy, *p= 0.89 (Manhart LE et al.)*
- RDBPCT, 2011, multicentre, Golf States (USA): Will addition of **tinidazole** to azithro or doxy improve cure? n= 305, men with NGU, but only n= 42 treated for MGEN and divided into 4 arms; Tinidazole did not improve outcome. (*Schwebke JR et al.)*

Licencing & Access

Therapeutic Good Administration : A register of therapeutic goods that can be lawfully supplied in Australia.

Queensland Health: TGA Special Access Scheme (SAS) and List of approved medicines (LAM)

Question: Which antibiotic is licensed and available to treat *Mycoplasma genitalium*?



Good Practice: Must seek informed consent from patient before prescribing a non-licenced drug.

Health Professional

MSHC Treatment Guidelines
STI Tool
Australian STI Management
Australasian Contact Tracing
PrEP
STI Clinical Hints
STI Notification
Sexual Health Nurse
Online Services
Online Education
Career

Mycoplasma genitalium

Mycoplasma genitalium (MG) is a sexually transmitted bacterium only detectable by nucleic acid amplification tests (NAAT). It causes urethritis in men, cervicitis in women, and (often asymptomatic) rectal infection. It is associated with pelvic inflammatory disease (PID) and is a possible cause of preterm delivery, spontaneous abortion and tubal infertility.

DIAGNOSIS

Most laboratories now offer NAAT testing for *M. genitalium* or can forward to others such as Molecular Microbiology at the Royal Women's Hospital or the Victorian Infectious Diseases Reference Laboratory. Some NAA tests also detect

For MG infections known or suspected to be macrolide resistant (MG in MSM, persisting symptoms >7 days, positive MG result >21 days after azithromycin, MG resistance mutation detected) use

- doxycycline 100mg bd, 7 days, followed immediately by
- moxifloxacin 400mg daily for seven days

Moxifloxacin is not approved by the Therapeutic Goods Administration (TGA) for this infection and may cause significant side-effects including diarrhoea or tendonitis. We recommend discussing this with patients. Pharmacies typically charge over $70 for five tablets. There are limited efficacy data and no data for treatment courses of less than seven days.[6]

Side-Effects

Doxycycline	Azithromycin	Moxifloxacin	Pristinamycin	Sitafloxacin
Pregnancy D	Pregnancy B1	Pregnancy B3	Pregnancy ? Reproted OK by CDC: Read et al Feb 2018	Pregnancy: ?? B3 for Ciprofloxacin
Diarrhea	Diarrhoea	Diarrhoea/C Diff associated	Diarrhea	Diarrhea
Difficulty swallowing	Nausea/Vomiting	Nausea/Vomiting	Nausea/Vomiting	Nausea/Vomiting
Drug rash	Abdominal pain	Abdominal pain	Abdominal pain	Sleepiness
Esophageal ulcer	Mouth sores	Dizziness	Rash	**Drug Resistant Bacteria**
Esophagitis	Headache	Blurred vision	Exfoliative Dermatitis	
Facial redness	Constipation	Anxiety/Agitation	Abnormal LFTs	
Headache	Dizziness	Skin itching	Abnormal FBCs	
Hives	Tiredness	Vaginal itch & burning	**Drug Resistant Bacteria**	
Vaginal itch & brurning	Vaginal itch & brurning	Tendinitis/ Rupture Tendons		
Drug Resistant Bacteria	**Drug Resistant Bacteria**	QT prolongation		
		Drug Resistant Bacteria		

Cost

Drug	Tablets	AUD$	AUD$ Sub-totals
Doxycycline	14	3	
Azithromycin	6	3	6
Moxiflixacin	10	50	56
Pristinamycin	64	145	201
Sitafloxacin	28	150	351

Caution! Consider, Explain, Apologies:

Lack of high quality evidence.

Lack of ability to confidently predict the efficacy of antibiotic treatment vs ‘wait and monitor’ outcome.

Lack of ability to confidently predict adverse health outcomes with or without treatment.

Lack of licensing and/or access to antibiotics.

Side-effects, provide prophylactic Rx for thrush if history of recurrent thrush.

Exclude pregnancy at time of prescription; arrange for reliable contraception during treatment and up to 2 weeks thereafter.

Check for history of prolonged QT or co-medication with drugs which increase QT interval.

Potential treatment failure.

Risk of future drug resistance.

Avoid testing asymptomatic clients.

Should we do a TOC of clinically cured patients? We don’t do it for Chlamydia!

Should we test asymptomatic contacts?

Future

RCDBCT: Randomised controlled double blind placebo controlled clinical trials in different risk groups

Observational:

- Longitudinal natural course of asymptomatic carriers
- Longitudinal of clinical cure vs microbiological cure

Qualitative studies: Client and Clinicians satisfaction?

Cost-efficacy: Improvement of short and long-term outcome without interventions compared to different interventions available

National Multicentre Audits:

- Prevalence?
- Resistance patterns?
- Prescription practice?
- Treatment response?
- Side-effects, adverse outcomes?
- Partner notification?
- TOC in asymptomatic people: pro & cons?
- Client and clinicians satisfaction?
- Cost-efficacy?

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