

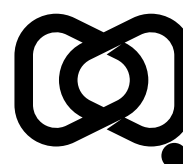


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***Neisseria gonorrhoeae* notifications, resistance and management in the Pilbara Region, Western Australia, July 2023 – June 2024**

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Abstract

Background

In October 2024, Pilbara treatment guidance for uncomplicated urogenital gonorrhoea shifted from routine ZAP pack (amoxicillin 3 g and probenecid 1 g and azithromycin 1 g oral as a single treatment) to ceftriaxone-based LAC pack (ceftriaxone 500 mg in 2 mL 1% lignocaine intramuscularly and azithromycin 1 g oral, as a single treatment) in response to rising penicillinase-producing *N. gonorrhoeae* (PPNG) and the threat of imported ciprofloxacin resistance.

Design

A retrospective clinical audit to describe demographics, compare treatment and resistance data collected for *N. gonorrhoeae* notifications for Pilbara health region residents meeting the surveillance case definitions in the Western Australian Notifiable Infectious Diseases Database (WANIDD) against clinical guidelines.

Setting

All Pilbara health region resident *N. gonorrhoeae* notifications in the Western Australian Notifiable Infectious Diseases Database (WANIDD) from 1 July 2023 to 30 June 2024.

Main outcome measures

The proportion of notifications that reported treatment with a ZAP pack or LAC pack as per Western Australian and national clinical guidelines. Secondary outcomes included the proportion of notifications undertaken by the WA Country Health Service that reported test of cure at 1–2 weeks; the proportion that reported rescreening at 3 months post notification; and the proportion of notifications that reported PPNG and ciprofloxacin resistance.

Results

A total of 188 *N. gonorrhoeae* notifications were received over the audit time frame. One hundred and twenty-seven notifications of a total of 156 *N. gonorrhoeae* notifications (81%) reported receiving treatment consistent with WA and National STI treatment guidelines, i.e. ZAP or LAC pack. Fifteen notifications of a total of 188 notifications (8%) reported detection of PPNG and 20 notifications of a total of 188 notifications (11%) reported ciprofloxacin resistance. For WA Country Health service notifications, 9 of 27 (33%) reported re-testing at 1–2 weeks or 3 months.

Conclusions

The majority of notifications (81%) reported *N. gonorrhoeae* treatment consistent with guidelines. A significant proportion of notifications (8%) indicated likely penicillin resistance due to the detection of PPNG. Reinforcing treatment consistent with the updated treatment guidelines of October 2024 for the Pilbara region will reduce the risk of ineffective treatment. Improving the rate of test of cure and test for reinfection (33%) would improve the likelihood of detecting treatment failure and detecting resistance.

Keywords: *Neisseria gonorrhoeae*; gonococcal infection; notifications; management; treatment; antimicrobial resistance; Pilbara; Western Australia

Introduction

Neisseria gonorrhoeae remains an ongoing challenge, with 40,029 notifications in Australia in 2023; this represents a 155% increase in notifications from 2014 (15,671 notifications).¹ In 2023, the age-standardised gonorrhoea notification rate among Aboriginal and Torres Strait Islander peoples living in remote areas was almost 15 times as high as the rate among non-Indigenous persons (1819.3 vs. 117.6 per 100,000 persons).² The remote Pilbara region of Western Australia (WA) has the second highest Aboriginal population proportion in WA, comprising 14.8% of the population vs. 3.3% in the rest of WA and 3.2% in Australia.³

The Pilbara has challenges in tracking gonococcal resistance due to lack of access to clinical services to undertake testing; logistical difficulties in getting viable culture specimens from regional and remote sites to laboratories to culture and undertake resistance testing; and reliance on GeneXpert point-of-care testing that does not result in a culture specimen that can undergo resistance testing. This audit assisted with validating local empirical sexually transmitted infection (STI) treatment guideline changes.

Neisseria gonorrhoeae treatment guidance is continually updated as antimicrobial resistance evolves.⁴ The United States Centers for Disease Control (US CDC) guidelines for treatment of gonorrhoeae were last updated in 2020, with the recommended regime for uncomplicated gonococcal infection of ceftriaxone 500 mg intramuscular injection (IMI), ceasing the previous recommendation for dual therapy (ceftriaxone and azithromycin) due to potential microbiome harm and effect on other pathogens.^{5–7} Australian STI treatment guidelines recommend ceftriaxone 500 mg in 2 mL 1% lignocaine IM plus azithromycin 1 g oral (LAC pack) for uncomplicated genital or anorectal infection, with the alternative treatment amoxicillin 3 g plus probenecid 1 g plus azithromycin 1 g oral (single observed dose) (ZAP pack) for some remote Australian locations such as the Pilbara.⁸ However, in October 2024 the Pilbara region empirical gonococcal treatment guidelines changed to exclude the use of amoxicillin-based treatment due to unacceptable levels of penicillin resistance to treatment: i.e., cessation of the use of the amoxicillin-based ZAP pack.⁴

A key risk to the Pilbara is the direct importation of ceftriaxone-resistant *N. gonorrhoeae* strains from the Asia-Pacific region, where there is demonstrated spread of ceftriaxone-resistant strains, via the large fly-in-fly-out working population.⁹ Concurrently, the spread of PPNG strains reduce the effectiveness of ZAP packs, which rely on amoxicillin activity and does not contain clavulanic acid. Although amoxicillin-clavulanate regimens have been used historically in settings such as Papua New Guinea and in the ZAP packs used in the neighbouring Northern Territory, increasing PPNG prevalence in these regions requires a shift away from penicillin-based therapy towards ceftriaxone-based regimens.^{10–12} In addition, the detection of multi-drug resistant (MDR) or extensively drug resistant (XDR) gonorrhoea prior to its widespread dissemination is unlikely in the Pilbara due to the limitations in gonococcal culture and resistance testing.

Gonococcal reinfection is a recognised issue, with a recent Australian analysis in the Australian Capital Territory showing a reinfection rate of over 20%, highlighting the importance of testing for reinfection in addition to effective health promotion, education and counselling as well as pharmacological strategies.¹³ This indicates that the recommendations in the Western Australian Silver Book (*WA Sexually Transmissible Infection/ Blood-Borne Virus (STI/BBV) management guidelines*), to follow up cases, to consider test of cure in specific circumstances, as well as to consider testing for reinfection at 3 months, are important interventions to reduce disease.⁴

The purposes of the *Neisseria gonorrhoeae* Notification, Susceptibility Testing and Test of Cure/Reinfection Audit were to describe the epidemiology of gonococcal infections in the Pilbara region of Western Australia; to quantify compliance with retesting recommendations; and to describe available resistance data. Additionally, the retrospective audit of 1 July 2023 to 30 June 2024 notifications provides a pre-October 2024 baseline for the Pilbara (historical-control context), to support the October 2024 gonococcal empirical treatment guideline change (removal of amoxicillin-based ZAP packs) and to enable future comparison with post-change data.

Methods

A retrospective clinical audit was undertaken to compare information collected for *Neisseria gonorrhoeae* notifications against clinical guidelines and evidence-based best practice in the WA STI and BBV guidelines and the Australian STI treatment guidelines for use in primary care.^{4,8} Notifications of *N. gonorrhoeae* included in the audit were those meeting the surveillance case definitions for notifiable infectious diseases and related conditions in Western Australia¹⁴ and received by the Pilbara Public Health Unit (PHU) between 1 July 2023 and 30 June 2024.¹⁴ This period was selected to establish a pre-implementation baseline for practice and resistance profiling against which post-October 2024 outcomes can be compared. The Pilbara PHU extracted data from the WA Notifiable Infectious Diseases Database (WANIDD) which included pathology, clinician details and enhanced surveillance form data for de-identified *N. gonorrhoeae* cases above 14 years of age. The analysis for these cases also included their penicillinase-producing *N. gonorrhoeae* (PPNG) and ciprofloxacin resistance status, where recorded, as well as *N. gonorrhoeae* re-testing at 1–2 weeks and 3 months for WA Country Health services notifications.

This data was extracted, de-identified, from WANIDD to an Excel spreadsheet used to complete the Gonorrhoea Data Collection Tool Variables in a REDCap survey. Resistance data for *N. gonorrhoeae* was verified with accessible pathology reports. WA Country Health-provided services management data was extracted from the Community Health Information System. The REDCap survey entries were reviewed by a clinician to assess whether the case was managed and treated in accordance with WA and national guidelines.^{4,8} This audit also acted as a quality assurance activity against National Safety and Quality Health Service (NSQHS) Standard 1.¹⁵

Descriptive statistics were used to summarise demographics by individual notifications. All further statistics were based on individual notification numbers and proportions. Inferential analyses used Fisher's Exact test (two-tailed) in RStudio; statistical significance was set at $p < 0.05$.

Ethics approval statement

The audit was reviewed and approved by the WA Health Human Ethics Research Committee (RGS635) and the WA Aboriginal Health Ethics Committee (HREC1343).

Results

A total of 188 *N. gonorrhoeae* notifications were received over the audit time frame. Aboriginal persons comprised 82% of notifications; 4% of notifications were of unknown ethnicity. Females comprised 51% of notifications, with 49% male. The highest numbers of notifications were observed among those aged 20–24 years of age (28%) and 14–19 years of age (24%). Notifications were received from Pilbara WA Country Health Services (38%); Pilbara Aboriginal Medical Services (32%); other Pilbara general practitioners (GPs; 10%); or from the Royal Flying Doctor Service, Corrective Services, or services outside the Pilbara (20%). Of the 188 notifications, 156 reported treatment; 9 reported no treatment; and 23 did not report any treatment details.

For context, the gonorrhoea notification rate in the Pilbara is typically two to three times higher than the statewide WA rate.¹⁶ In 2024, the Pilbara reported 403.7 notifications per 100,000 population, compared with 192.2 per 100,000 population in WA.¹⁶ These rates represent an increase from 2021, when annual notification rates were 388.5 per 100,000 population in the Pilbara and 109.7 per 100,000 population in WA.¹⁶

Of treated notifications, 81% (127/156) were consistent with WA/national guidance current to October 2024 (Table 1).⁴ In general, this meant that the LAC pack treatment was used for people with suspected or confirmed gonorrhoea, particularly when laboratory testing was not available, or where there was a concern about antibiotic resistance. The ZAP pack treatment was usually avoided in situations where resistance to penicillin was known or suspected, and was used in more limited situations where earlier local practices suggested it was an effective treatment e.g. in remote Aboriginal communities. Of 156 cases recorded as receiving treatment 31% received a ZAP pack and 50% received a LAC pack (Table 1). ZAP packs used in WA do not contain clavulanic acid, which has been used with amoxicillin in other settings to reduce penicillin mediated resistance.

Table 1: Number of *N. gonorrhoeae* notifications by reported treatment, sex and ethnicity,^a Pilbara, Western Australia, 1 July 2023 – 30 June 2024

Demographics		Treatment given				Total
Sex	Ethnicity	LAC pack ^b	ZAP pack ^c	Unknown treatment	Other treatment	
Female	Aboriginal and/or Torres Strait Islander	33	23	1	12	69
	Other	5	—	—	3	8
Male	Aboriginal and/or Torres Strait Islander	28	25	1	10	64
	Other	12	1	—	2	15
Total	—	78 (50%)	49 (31%)	2 (1%)	27 (17%)	156

a A further nine notifications were reported not treated, and for a further 23 notifications, it was unknown whether treatment was offered.

b LAC pack: ceftriaxone 500 mg in 2 mL 1% lignocaine IM plus azithromycin 1 g oral (single observed dose).

c ZAP pack: amoxicillin 3 g plus probenecid 1 g plus azithromycin 1 g oral (single observed dose).

Table 2: Number of *N. gonorrhoeae* notifications by penicillinase-producing *Neisseria gonorrhoeae* (PPNG) status, sex and ethnicity, Pilbara, Western Australia, 1 July 2023 – 30 June 2024

Demographics		PPNG detected		PPNG not detected	No culture results	Unknown	Total
Sex	Ethnicity	n	Proportion				
Female	Any	6	7%	74	—	12	92
	Aboriginal and/or Torres Strait Islander	6	8%	64	—	9	79
	Other	—	—	7	—	3	10
	Unknown	—	—	3	—	—	3
Male	Any	9	9%	63	1	23	96
	Aboriginal and/or Torres Strait Islander	6	8%	49	1	19	75
	Other	3	19%	11	—	2	16
	Unknown	—	—	3	—	2	5
Total	—	15	8%	137	1	35	188

Table 2 demonstrates the penicillinase-producing *Neisseria gonorrhoeae* (PPNG) resistance profile of *N. gonorrhoeae*. The rate of PPNG detection was consistently above 5 % in Aboriginal and non-Aboriginal cases; among cases, PPNG was detected in 9% of Aboriginal males and 7% of Aboriginal females. Polymerase chain reaction (PCR) PPNG testing on non-cultured clinical samples is the mainstay of antibiotic resistance profiling in the Pilbara region due to the challenges of obtaining *N. gonorrhoeae* cultures.

Ciprofloxacin resistance (Table 3) was 11%, supporting the restriction on ciprofloxacin use to circumstances where rapid ciprofloxacin-resistance testing supports sensitivity, as per the Australian STI Management Guidelines for Use in Primary Care.⁸

Table 3: Number of *N. gonorrhoeae* notifications by ciprofloxacin resistance status, sex and ethnicity, Pilbara, Western Australia, 1 July 2023 – 30 June 2024

Demographics		Ciprofloxacin resistance status				
Sex	Ethnicity	Detected	Not detected	Unknown	Indeterminate	Total
Female	Any	7 (8%)	58	26	1	92
	Aboriginal and/or Torres Strait Islander	6	52	20	1	79
	Other	1	5	4	—	10
	Unknown	—	1	2	—	3
Male	Any	13 (14%)	56	27	—	96
	Aboriginal and/or Torres Strait Islander	7	47	21	—	75
	Other	6	7	3	—	16
	Unknown	—	2	3	—	5
Total	—	20 (11%)	114	53	1	188

Off the 96 males notified, 47 (49%) were reported to have presented with symptoms of either dysuria or discharge, while 22% of females notified (20/92) were reported to have been symptomatic. This difference in symptoms at presentation was statistically significant (Fisher's Exact Test: $p = 0.0012$).

Time to treatment of *N. gonorrhoeae* in days was 9.7 days in Aboriginal people (6.4 days in Aboriginal males versus 12.7 days in Aboriginal females), as compared to 2.9 days in non-Aboriginal persons. The proportion receiving effective (guideline-compliant) treatment did not differ between Aboriginal and non-Aboriginal people ($p = 1.00$; comparison of effective vs non-effective treatment among Aboriginal vs non-Aboriginal groups).

Among 27 notifications reported by the WA Country Health Service, 33% (9/27) were followed up with re testing at either 1–2 weeks or 3 months; follow up could not be ascertained for notifications from other providers due to unavailable clinical notes.

Discussion

Due to historically low gonococcal antimicrobial resistance rates, the Pilbara region of Western Australia was one of the last regions in Australia to have penicillin-based oral treatment guidelines for symptomatic gonorrhoea: amoxicillin, probenecid and azithromycin.¹⁷ However, the 2023 Western Australian Gonococcal Surveillance Program (WAGSP) *Neisseria gonorrhoeae* Antimicrobial Susceptibility Report reported penicillin resistance in 9% of isolates that underwent PCR assay to detect penicillinase-producing *Neisseria gonorrhoeae* (PPNG); 35% of cultured Pilbara specimens (n = 7/20) were reported as either PPNG or demonstrating chromosomally mediated resistance to penicillin.¹⁷ The World Health Organization recommends that a first line empirical therapy should effect cure in at least 95% of gonorrhoea cases; therefore, with the detections of penicillin resistance, the Pilbara no longer meets this requirement for treatment of gonorrhoea with penicillin-based antibiotic regimes such as ZAP packs.¹⁸

The majority of Pilbara gonorrhoea notification treatments received (81%) were consistent with the current [pre-October 2024] WA treatment guidelines in the Silver Book and WA Structured Administration and Supply Arrangements.^{4,19} Given the PPNG detections within the Pilbara (and unmeasured chromosomal penicillin resistance), approximately 31% of notifications treated with a ZAP pack were theoretically at risk of ineffective treatment, rather than confirmed failures on an individual basis. Half of the gonorrhoea notifications reviewed in this audit indicated that a LAC pack (ceftriaxone 500 mg in 2 mL 1% lignocaine intramuscularly and azithromycin 1 g oral, given together as a single treatment) was provided as treatment. The substantial use of LAC packs suggests strongly that local Pilbara clinicians were already changing practice in response to resistance profiles before the changes to the formal guidelines in October 2024.^{4,19} Ciprofloxacin resistance was detected (11%), but there were no reports of the use of ciprofloxacin when 'other medications' reported for treatment were reviewed, despite its inclusion in the Australian STI management guidelines for use in primary care.

There was no significant difference, by Fisher's Exact Test, in the proportions of Aboriginal people vs. non-Aboriginal people receiving effective (guideline compliant) treatment. However, there was a significant difference in time to treatment for Aboriginal people vs. non-Aboriginal people.

This highlights the need to provide effective empirical treatment, particularly for Aboriginal people who are symptomatic at the first presentation, to reduce the likelihood of ongoing transmission due to delayed treatment.

Finally given the low numbers of notifications within the WA Country Health Service that had follow-up (33%) and re-testing, resistant organisms and reinfections may not be detected effectively. Improving the rate of test of cure, and test for reinfection, would improve the likelihood of detecting treatment failure and detecting resistance.

Limitations

Pilbara region acquired *N. gonorrhoeae* infections in temporary residents will likely be underreported in this audit, as the notifications are grouped by permanent address, and the Pilbara has a large number of fly-in-fly-out temporary workers who do not have a Pilbara permanent address and therefore are not included within the dataset reviewed for this audit.

As molecular PPNG PCR testing does not detect chromosomally mediated resistance to penicillin, the latter type of resistance to penicillin-based *N. gonorrhoeae* treatment may be underestimated in this audit.

A limitation of extracting the data from the WANIDD was the lack of complete data available in the database. Only 88% of notifications had a completed Disease Notification Form and 82% had a completed Enhanced Surveillance Form. This increased the difficulty of getting full and accurate data to complete the audit and to assess for appropriateness of clinical management.

Conclusions

The change to the Pilbara regional Gonococcal treatment guidelines on 24 October 2024, to ensure empirical treatment of symptomatic patients with likely uncomplicated urogenital gonorrhoea ± chlamydia with a 'LAC pack', comprising azithromycin 1 g oral and ceftriaxone 500 mg with 2 ml lidocaine 1% injection, is justified considering the resistance profile demonstrated in this audit. Most of the treatment reported complied with the current treatment guidelines up to October 2024, including effective treatment in Aboriginal people. However, the updated Pilbara October 2024 treatment guidelines should be promoted and implemented, due to the significant likelihood of penicillin resistant *N. gonorrhoeae* among Pilbara region residents. Education to notifiers to undertake review and retesting at 1–2 weeks, and to test for reinfection at 3 months, needs to be reinforced to increase the likelihood of detection of challenging resistance, such as imported ceftriaxone resistance.

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