District Health Board 1 General Practitioner, Dr B Registered Nurse, RN C Medical Centre Registered Nurse, RN D District Health Board 2

A Report by the Deputy Health and Disability Commissioner

(Case 19HDC01891)



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Executive summary

1. This report concerns the care provided to a man by numerous providers both before and after he was diagnosed with syphilis. In particular, the report concerns multiple inadequate sexual health assessments, and delays in testing, receiving results, and actioning his positive syphilis result.

Findings

- 2. The Deputy Commissioner found that a district health board (DHB1) breached Right 4(1) of the Code by failing to have in place an adequate system to support its staff.
- 3. Adverse comment is made about the care provided by a general practitioner (GP) at a sexual health service. However, the Deputy Commissioner considered that although the GP's omissions contributed to the man not receiving care that met accepted practice, primarily the failings identified were the result of a wider systemic issue. Adverse comment is also made about the care provided by a registered nurse at the clinic, who omitted to undertake the necessary throat and rectal swabs when the man presented to DHB1.
- 4. The Deputy Commissioner found a registered nurse at a medical centre in breach of Right 4(1) of the Code for failing to undertake all the tests required when the man presented to the centre, failing to obtain the man's abnormal blood test results from the system, failing to hand over the man's positive syphilis result or undertake an action plan before going on leave, and for documenting the care provided inadequately.
- 5. Adverse comment is made about the medical centre for not having in place a formal policy or procedure for reviewing patient test results.
- 6. A second DHB (DHB2) was found to have breached Right 4(1) of the Code for failing to report the man's two test results within the standard turnaround time.

Recommendations

- 7. The Deputy Commissioner recommended that DHB1 provide HDC with an update on the changes being undertaken in its sexual health service; develop a process for formalised yearly performance reviews for all staff; undertake a review of the staffing levels at the sexual health clinic, and consider the recruitment of more staff to provide leave cover for current staff when needed; and provide the man with a written apology for DHB1's breach of the Code.
- 8. The Deputy Commissioner recommended that the GP provide the man with an apology letter for the failures outlined in this report.
- 9. The Deputy Commissioner recommended that the registered nurse at the medical centre organise for an experienced nurse to carry out a review of his documentation, and provide the man with a written apology for the breach of the Code identified. It was also recommended that the New Zealand Nursing Council consider whether a review of the nurse's competence is warranted.



- 10. The Deputy Commissioner recommended that the medical centre provide evidence to HDC of staff training and orientation on the new policies it has developed as a result of this complaint.
- 11. It was recommended that DHB2 undertake an audit of its test list to identify test codes not used in the past two years, and, if any test codes are identified as no longer active, that these are retired. DHB2 offered to provide the man with a written apology.

Complaint and investigation

- 12. The Health and Disability Commissioner (HDC) received a complaint from Mr A about the sexual health services provided to him by multiple providers. The following issues were identified for investigation:
 - Whether DHB1 provided Mr A with an appropriate standard of care in Month1¹ and Month2 2018.
 - Whether Dr B provided Mr A with an appropriate standard of care in Month1 and Month2 2018.
 - Whether RN C provided Mr A with an appropriate standard of care in Month1 2018.
 - Whether the medical centre provided Mr A with an appropriate standard of care in 2018 and 2019.
 - Whether RN D provided Mr A with an appropriate standard of care in Month4 2018.
 - Whether DHB2 provided Mr A with an appropriate standard of care in 2018 and 2019.
- 13. This report is the decision of Deputy Health and Disability Commissioner Deborah James, and is made in accordance with the power delegated to her by the Commissioner.
- 14. The parties directly involved in the investigation were:

Mr A	Consumer
DHB1	Provider
Dr B	Provider/general practitioner (GP)
Registered Nurse (RN) C	Provider/nurse
Provider/medical centre	
RN D	Provider/nurse
DHB2	Provider

¹ Relevant months are referred to as Months 1–13 to protect privacy.



Names have been removed (except the experts who advised on this case) to protect privacy. Identifying letters are assigned in alphabetical order and bear no relationship to the person's actual name.

15. Also mentioned in this report:

Dr E	General practitioner
RN F	Nurse

16. Independent expert advice was obtained from a rural GP (with sexual health experience), Dr Liz Humm (Appendix A), and a registered nurse, RN Sharon Hansen (Appendix B). In-house clinical advice was obtained from GP Dr David Maplesden (Appendix C).

Information gathered during investigation

Background

17. This report concerns the sexual health services provided to Mr A (aged in his twenties at the time of events) by multiple healthcare providers both before and after he was diagnosed with syphilis.² Mr A falls into the sexual health category of "man who has sex with men" (MSM).

Sexual health clinic

Initial presentation — 27 Month1

- 18. On 27 Month1, Mr A presented to a sexual health clinic (the clinic), after having had unprotected anal sex approximately one week previously.
- ^{19.} The clinic is a GP-led clinic, owned and operated by DHB1. Dr B³ is the sole doctor at the clinic, and works alongside two registered nurses who alternate to provide leave cover for each other.
- 20. Dr B was on leave on the day of Mr A's initial presentation, and, as such, the service was being run by the two registered nurses, who could seek advice from the Accident and Emergency doctors where needed. On arrival, Mr A was seen by RN C, who documented his presenting problem as: "[W]ould like HIV test, had unprotected sex. Haemorrhoids — pain and bleeding."
- 21. RN C obtained Mr A's medical and sexual history, symptoms, social history, current sexual history, and history of any high-risk activities all of which was unremarkable other than Mr A's report of recent unprotected sex. RN C then took the required urine sample for testing of chlamydia⁴ and gonorrhoea,⁵ and bloods for testing of hepatitis B and C, HIV, and

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² Syphilis is a bacterial infection usually spread by sexual contact. It starts as a painless sore on the genitals, rectum, or mouth and, if left untreated, can develop into a rash and can result in damage to the brain, nerves, eyes, or heart.

³ Dr B is a Fellow of the Royal New Zealand College of General Practitioners, and has been employed by DHB1 as a GP for many years.

⁴ A common sexually transmitted bacterial infection.

⁵ A sexually transmitted bacterial infection.

syphilis. As per the New Zealand Sexual Health Service (NZSHS) guidelines (discussed in more detail at Appendix D), throat and rectal swabs are also recommended when testing for sexually transmitted infection (STI) in MSM; however, at this presentation RN C did not carry out these swabs.

22. RN C told HDC:

"The history of being MSM should have alerted me to both throat and anal swabs being needed ... I believe on the day I was more focused on [Mr A's] comments regarding his rectal bleeding issue. Hence my thoughts had been distracted for the need for both throat and anal swabs.

Because of the anal bleeding issue, I was unsure whether an anal swab would be compromised by the bleeding and was reluctant to take the swab without advice from the doctor. I knew that [Mr A] was going to come back to see the Doctor where the throat and anal swabs would be taken."

- ^{23.} The documentation completed by RN C included a checklist of tests undertaken, and showed that throat and rectum tests had not been done at this time. It was arranged for Mr A to return for repeat testing in two weeks' time with Dr B, and then again in three months' time.
- On 29 Month1, Mr A's blood tests were negative for the following: hepatitis C, hepatitis B, HIV, chlamydia, gonorrhoea, and syphilis. Under "syphilis", the laboratory results form stated: "[I]f primary⁶ infection is suspected please repeat serology in two weeks." Under "HIV", the form stated: "[N]egative tests do not rule out HIV infection as there is a window period between infection and the production of antibodies."

Follow-up appointments with Dr B

- 25. On 10 Month2, Mr A presented to the clinic for his follow-up appointment with Dr B. Dr B advised Mr A that a repeat HIV test would be needed, and that it was too early to exclude transmission because of the window period between infection and the production of antibodies. It was therefore arranged for Mr A to return to the clinic in two weeks' time for the required repeat HIV testing.
- ^{26.} Dr B did not examine Mr A at this appointment, or address that he had not had the full recommended STI check at his previous appointment with RN C. In addition, Dr B did not discuss the need for Mr A to undergo repeat syphilis testing as per the NZSHS guidelines⁷ and the instructions on the laboratory form.
- 27. Dr B told HDC that a contributing factor in this case was that she was dealing with a family crisis on this day. She said that as a result, she was "internally anguished and distracted" at Mr A's presentation.



⁶ The first (and earliest) stage of syphilis.

⁷ The NZSHS guidelines for the management of syphilis state that if a patient is asymptomatic and not a syphilis contact but is concerned about a specific recent sexual event, it is recommended to do a baseline test at the time of presentation and do a repeat test three months from the time of last sexual intercourse.

- 28. When Mr A returned to the clinic as planned on 24 Month2, Dr B had just returned from leave that day. She told HDC that she suspects that she looked at the last entry in Mr A's notes, and picked up where she left off, by giving him the laboratory form to retest for HIV.
- 29. Dr B stated that at the time, she did not feel that there was provision for time out available for her, and she did not see any options to delegate the clinic or postpone patient contact. She told HDC:

"There was pressure on me to see [Mr A] immediately as he had indicated to the nurse or receptionist that he had to leave. In retrospect, delaying patient contact on this occasion may have averted my oversights."

- 30. On 1 Month3, Dr B emailed Mr A to let him know that his repeat HIV test had come back negative.
- 31. Dr B told HDC that her plan had been to repeat STI testing (including the repeat syphilis test) at the three-month mark (after the sexual activity) to allow for the syphilis incubation window period, but unfortunately she did not make a plan with Mr A for this on her last clinical contact with him. She acknowledged that a repeat syphilis test should have been included alongside the repeat HIV test, or arranged at the three-month mark, and unreservedly apologised that this did not occur.

Medical centre

Initial presentation — 19 Month4

- ^{32.} The medical centre is a Cornerstone⁸ accredited medical practice that services approximately 5,500 patients, and comprises one GP, Dr E, and six practice nurses.
- ^{33.} Mr A presented to the medical centre on 19 Month4 with a recent onset of penile lesions and a rash on the palms of his hands and soles of his feet. He also complained of a sore throat and haemorrhoids.
- 34. Mr A was seen by practice nurse RN D, who documented:

"Has been living overseas, newly returned to [region] comes in with;

- 1. Spots to penis, tip and shaft, plus sole of foot and ? R hands. Had unprotected homosexual SI [sexual intercourse].
- 2. haemorrhoids has been using over the counter cream from [overseas]. Pain on passing a motion.
- 3. Sore throat Lymph gland swelled yesterday, ears NAD [no abnormality detected], throat tonsils not inflamed but does have white pustule RHS [right-hand side] swab taken ..."

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⁸ A quality programme run by the Royal New Zealand College of General Practitioners.

- ^{35.} Vital signs were taken⁹ and a sexual health screen was completed, which included a throat swab, genital swabs, and blood¹⁰ tests for hepatitis B and C, HIV, and syphilis.
- ^{36.} As per the NZSHS guidelines, a urine test for chlamydia and gonorrhoea is also recommended when testing for STIs in MSM, but RN D did not take a urine sample for testing.
- 37. RN D discussed Mr A's presentation with RN F another nurse at the practice. RN D told HDC that RN F had "vastly more experience in the genito-urinary field" than himself, and RN F suggested a provisional diagnosis of syphilis. RN D documented this as "S/b Bi-? VDRL [seen by RN F, query syphilis]".
- ^{38.} Both Mr A and RN D confirmed that Mr A was advised of this provisional diagnosis, and advised to refrain from sexual activity while awaiting the results of the test. However, there is no documentation of this advice.
- ^{39.} In the medical centre's practice management system, a task was set by RN D to check the results of the above tests, with a due date of 27 Month4.

Receipt of blood test result and test result process

- 40. On 23 Month4, Mr A was asked by RN D to return to the medical centre because the laboratory required a dry swab from the penile lesion to run a polymerase chain reaction (PCR) test for syphilis (in addition to the blood test). The previously omitted urine sample to test for chlamydia and gonorrhoea was also sent to the laboratory at this time.
- 41. Mr A's blood test results were sent to the medical centre on the evening of 23 Month4, and were noted to be "reactive", indicating that Mr A had tested positive for syphilis. Mr A's PCR result (taken on 23 Month4), which would also indicate syphilis, was outstanding at this time, but treatment was still indicated based on the blood test result alone. The medical centre stated that as 23 Month4 was a Friday, the blood test results would not have been seen by medical centre staff until Monday 26 Month4, as the centre is closed at weekends. Along with his PCR result, the results from his throat swab, genital swab, and urine test were also outstanding.
- 42. RN D told HDC that at the medical centre, results such as blood test results would come into the GP's inbox, not directly to the nurses, and, as such, the nurses relied on the GP to pass on any test results. In contrast, the medical centre told HDC that its practice nurses are required to create a task to check for results they have ordered by checking the inbox, and they are allocated time each day to do this. The medical centre stated that the nurses are expected to inform the GP of any abnormal or time-critical results, or arrange for further care if the GP is not available.
- 43. In addition, the medical centre told HDC that Dr E starts work at 7am each day and looks for any abnormal results in an arranged approach, to ensure that any abnormal results are not

¹⁰ The serology request form did not include the suspicion of syphilis.



⁹ The vital signs were within normal range.

missed. However, Mr A's blood test results were not flagged by the laboratory as abnormal,¹¹ and therefore were not picked up by Dr E during her regular daily checks. However, RN D did check for results. An audit of the database was provided to HDC, and showed that RN D accessed Mr A's profile to check for results three times on the morning of 23 Month4, and twice on 27 Month4.

- ^{44.} On 27 Month4, Mr A's throat swab results were received at the medical centre and showed a finding of a strep throat.¹² Despite the fact that both the blood test and throat swab results had been received by the medical centre, when RN D telephoned Mr A to advise him of the results, he gave him only the throat swab results, and documented: "[P]honed with throat swab results ... still awaiting other results (due Monday 3. [Month5])."
- 45. On behalf of RN D, his lawyer told HDC:

"There is no reason that [RN D] would not have advised [Mr A] of the positive test result if he had that information available when he rang [Mr A] on 27 [Month4]."

- ^{46.} Mr A telephoned the medical centre and spoke to RN D on 30 Month4, asking for the results of his outstanding blood test. RN D told HDC that he then checked to see if any new results had come in, and found that Mr A's syphilis blood test had been reported, and was reactive. At this point, the results from Mr A's genital swab, PCR test, and urine test were still outstanding.
- 47. RN D documented:

"Phoned for results — given. Advised VDRL¹³ blood 'reactive'. Awaiting VDRL swab [(the PCR test)] next Tuesday. Advised to contact any sexual partners to get checked."

48. RN D stated that although he cannot recall the specifics of his conversations with Mr A, he would have also advised him on the next steps for treatment.

Annual leave handover

^{49.} Mr A has stated that during the phone call on 30 Month4, when he was informed of his reactive blood test result:

"I very vaguely recall an explanation that it was too late to do anything because it was a Friday ... and that on Tuesday I would need to come in to [the medical centre] and pick up a prescription to take to [the pharmacy] and that I would have an appointment on Wednesday to receive the first of the injections and then each Wednesday after that for two weeks."



¹¹ The medical centre stated that this case has highlighted that the laboratory does not highlight each abnormal result, and currently the medical centre is in the process of considering how the laboratory can "flag" abnormal results.

¹² An infection of the throat and tonsils caused by Streptococcal bacteria.

¹³ Venereal Disease Research Laboratory test.

- 50. However, RN D went on leave from Monday 3 Month5. Before going on leave, RN D did not inform Dr E of Mr A's reactive blood test result or reassign another clinical staff member to action the task to check for the outstanding PCR result. RN D accepts that he should have provided handover to Dr E before he went on leave. He also did not make arrangements for a colleague to monitor the return of the outstanding urine test and genital swab results.
- 51. Dr E came across Mr A's reactive syphilis blood test result on the day RN D went on leave (Monday 3 Month5) while dealing with incoming results on a day off. She stated that she was both disappointed and concerned that she had not been informed of the result, but was unable to discuss this with RN D as he was on annual leave. After obtaining information about syphilis treatment from the Centre for Disease Control's website, a script for benzathine penicillin (an antibiotic medication used to treat a number of bacterial infections) was generated and the medication was ordered.
- 52. Once the medication had arrived, on 6 Month5, Mr A returned to the medical centre and received the first of the advised three benzathine penicillin injections to treat his syphilis.
- ^{53.} Mr A's penile swab results were eventually reported to the medical centre on 10 Month5,¹⁴ and further confirmed the diagnosis of syphilis. The urine and genital swab test results were also received.

Medical Laboratory 2

First result — swab for PCR test taken 23 Month4

- 54. As discussed above in paragraph 40, Mr A was asked to re-present to the medical centre on 23 Month4 for a dry swab from his penile lesion to run a PCR test. Initially the swab was sent to DHB1 laboratory, before being referred to Medical Laboratory 2 (a division of DHB2 that provides tertiary pathology services to the DHB2 area and other referrers).
- ^{55.} The result for this swab arrived at Medical Laboratory 2 on 26 Month4. However, it was not reported to the medical centre until 10 Month5, which exceeded Medical Laboratory 2's standard reporting turnaround time of one week.
- ^{56.} Medical Laboratory 2 told HDC that its management system automatically uploads the results of tests to a form, which has a section in place to allow for an interpretive comment to be added to the report. Medical Laboratory 2 stated that the interpretive comment field had been set to require an action, even if no comment was added. As such, the operator would have had to delete the blank field if no comment was added, so that the result could be authorised for release.
- 57. The error in Mr A's case occurred when the comment field (which was blank) was not deleted, and the result was not authorised for release. Medical Laboratory 2 told HDC that the error was discovered the next time a syphilis PCR analysis was performed, which was on 10 Month5. Medical Laboratory 2 stated:

¹⁴ Mr A's swab result from 23 Month4 was not reported to the medical centre until 10 Month5. This delay is discussed further below, from paragraph 54.

"[T]he operator found the unauthorised result from the 3 [Month5] [analysis] in the test list and finalised the report which was then authorised and issued on 10 [Month5]."

58. Medical Laboratory 2 noted, however, that the blood tests originally requested by the medical centre on 19 Month4 were performed and reported without delay, and would have provided a diagnosis of syphilis. Medical Laboratory 2 stated that as such, the delay of the PCR result should not have altered the advice or treatment provided by Mr A's GP.

Second result — RPR test¹⁵ taken 30 Month12

- 59. On 30 Month12, Mr A presented to the medical centre to undertake an RPR test to check whether the treatment commenced in Month5 had been successful. The sample was received by DHB1 laboratory the same day and then referred to Medical Laboratory 2. At the time of referral, DHB1 used an incorrect registration code that was an old code specific to DHB1 only and had since become redundant.
- ^{60.} The sample was received by Medical Laboratory 2 on 31 Month12. It was noted that the Medical Laboratory 2 transfer code was missing (as the incorrect DHB1-specific code had been used), and the correct code was added. However, Medical Laboratory 2 told HDC:

"[The] person [who added the Medical Laboratory 2 code] assumed that this would correct the error. However, the system required a correction of this kind to be requested by the referring laboratory. We have educated the staff member concerned and taken this opportunity to remind all our registration staff that transfer codes must be corrected by the referrer."

- ^{61.} Dr E rang the DHB1 laboratory on 13 Month13 to chase up Mr A's test results. On investigation, the coding error was identified and corrected, and the test was added to the worksheet ready to be performed on the next available test run.
- ^{62.} The test was reported on 19 Month13, and the results indicated that Mr A was responding to treatment.
- ^{63.} Medical Laboratory 2's usual turnaround time for this type of test is 1–3 working days from receipt. However, as a result of the error, Mr A's test result was reported 14 working days from receipt.
- 64. Medical Laboratory 2 told HDC that at the time of Mr A's testing, there was already a programme of work in place to decommission redundant test codes. Medical Laboratory 2 advised that DHB1 has removed the redundant code from the registration code database, and should have removed it at an earlier date to prevent accidental use.



Names have been removed (except the experts who advised on this case) to protect privacy. Identifying letters are assigned in alphabetical order and bear no relationship to the person's actual name.

¹⁵ A rapid plasma reagin (RPR) test is a blood test used to screen for syphilis, and works by detecting the nonspecific antibodies that the body produces while fighting the infection.

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Further information

DHB1 (owner and operator of the sexual health clinic)

- ^{65.} DHB1 told HDC that Dr B and RN C are long-time employees of DHB1, and records for their orientation and induction were not saved electronically, and no paper-based records can be found in their employee files.
- ^{66.} DHB1 asked that the Commissioner take into account a number of relevant circumstances that affected the care provided by the DHB and its staff, for which the DHB as an organisation takes responsibility.
- ^{67.} The DHB submitted that the first relevant factor is the impact of the paper-based system on the functionality of the sexual health service. DHB1 recognises that an electronic system would enable best practice, and would negate the current paper-based processes that are prone to human error. Dr B noted that an electronic system would enable screening templates and standard orders in respect to screening, diagnosis, and treatment of STIs, as well as a much safer and effective recall system that is attached to the patient's record. She also told HDC that RN C has also previously tried to progress a computer system for the clinic.
- 68. However, the DHB noted that other requirements have taken priority, and its limited financial resources may mean that the DHB is unable to progress work on an electronic system in the foreseeable future.
- ^{69.} Secondly, the DHB stated that the challenges of staffing specialist services in a rural location affected the care provided to Mr A. The DHB said that recruitment and retention of medical staff remains a significant issue and, as a result, there is significant pressure on the dedicated staff who work to provide a service to the community. The DHB stated: "[DHB1] are aware that the risk of human errors such as which occurred in this case are more likely when staff are unable to take a break from their clinical duties."
- 70. DHB1 said that it "apologises unreservedly to [Mr A] for not ensuring that the services that [the DHB] provided met the needs of the consumer".

Medical centre (employer of RN D and Dr E)

- 71. At the time of these events, the medical centre did not have a policy or procedure for reviewing results. In addition, during the exercise of developing a results policy after these events, it was discovered that no policy existed for the setting of referrals or tasks, and rather the centre had developed an in-house system verbally over time. The medical centre acknowledged that it was following common practice rather than best practice, and has since developed new policies (discussed in more detail in paragraph 170).
- 72. However, the medical centre told HDC that it believes it provides excellent mentorship and in-house peer support. It stated:

"We meet every Tuesday morning [at] 8am for training with the entire clinical team, and at 8.30am with all of the admin team inclusive. This would include any locum doctor(s) we have working with us at the time. Staff are encouraged to present cases



for discussion, to raise clinical topics for review and raise significant events ... [F]urthermore, there is a nurse only peer support group session every Monday at 3pm to discuss any issues."

73. The medical centre told HDC that on behalf of all the staff involved, they "unreservedly apologise for the distress caused to [Mr A]".

Medical Laboratory 2

- 74. Medical Laboratory 2 apologised to Mr A for the delays in the reporting of his tests, and stated that the issues highlighted by this case have allowed it to identify and correct small but significant issues that in combination caused Mr A not to experience the high quality of service it strives to achieve.
- 75. Medical Laboratory 2 told HDC that an audit undertaken from Month4 to Month12 recorded a total of 14 delayed reporting events. It stated that these were mainly within the anatomical pathology and molecular pathology departments, which involve particularly complex testing. However, it noted that the turnaround time data for the same period for syphilis PCR and blood tests were as follows:

	Syphilis PCR	RPR
Stated turnaround time	7 days	1–3 days
Actual mean turnaround time	3.3 days	2.7 days

85. Medical Laboratory 2 stated that it is pleased that the above data shows that it is achieving its stated turnaround times in most cases.

Responses to provisional opinion

- ^{86.} Mr A was provided with an opportunity to comment on the "information gathered" section of the provisional opinion, and had no comments to make.
- 87. RN C was provided with an opportunity to comment on the sections of the provisional opinion that relate to her. She had no comments on the opinion, but told HDC that recently she attended a New Zealand Sexual Health Society Conference.
- ^{88.} Dr B was provided with an opportunity to comment on the sections of the provisional opinion that relate to her. She told HDC that she accepts the findings of the report, and stated: "I respect [Mr A's] fortitude in coming forward with this complaint, and I am sorry my failings in this case set in motion an arduous journey for him."
- 89. DHB1 told HDC that it accepts the findings made in the provisional opinion.
- 90. RN D was provided with an opportunity to comment on the sections of the provisional opinion that relate to him. He accepts that all required tests and swabs ought to have been



undertaken when Mr A first presented to the medical centre on 19 Month4, and that he did not make appropriate arrangements for the handover of this matter when he went on annual leave. RN D said that he has reflected on his practice and has revisited the manner in which he completes documentation.

- ^{91.} In response to the provisional opinion, the medical centre acknowledged the criticisms made and stated that it believes it has made constructive changes in documentation and practice to mitigate the effects of the circumstances that occurred for Mr A. The medical centre accepted the recommendations and follow-up actions in the report and reiterated its sincere apologies for its failings during Mr A's journey.
- 92. Medical Laboratory 2 acknowledged and accepted the findings of the provisional opinion that the laboratory failed to meet the published turnaround times for Mr A's test results, on two different occasions. In addition, Medical Laboratory 2 offered to provide Mr A with a written apology for these failings.

Opinion: preliminary comment

- ^{93.} First, I wish to acknowledge the challenges faced by remote and rural practices. As noted by DHB1, the recruitment and retention of medical staff in rural locations such as this remains a significant issue and, as a result, there is significant pressure on the dedicated staff who work to provide a service to the community. My independent rural nursing advisor, RN Sharon Hansen, stated that other challenges include keeping up to date with the rest of the country, and dealing with the sheer volume of work across a wide variety of issues with sometimes non-existent or minimal support services. She noted that practices in this situation are significantly under-resourced for medical services and are supported heavily by their nurses.
- ^{94.} Throughout Mr A's sexual health journey from Month1 to Month13, he engaged with six different (rural) healthcare providers and, along the way, each provider let him down. While the individual omissions or errors in this case by each provider may seem small in isolation, they had the cumulative effect of delaying Mr A's syphilis diagnosis and treatment.
- 95. RN Hansen noted that this case highlights the vulnerability of people who navigate various healthcare services without clear communication between provider services and client, and with each other. I agree.
- ^{96.} In addition to the advice provided by RN Hansen, I obtained independent advice from rural GP Dr Liz Humm, and in-house clinical advice from GP Dr David Maplesden, to assist in my investigation of the care provided to Mr A.

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Opinion: RN C — adverse comment

- 97. On 27 Month1, Mr A presented to the sexual health clinic after having had unprotected anal sex approximately one week previously. As Dr B was on leave on this day, Mr A was seen by RN C. RN C documented Mr A's presenting problem (requesting an HIV test due to unprotected sex, and rectal pain and bleeding due to haemorrhoids), and obtained his medical and sexual history, symptoms, social history, current sexual history, and history of any high-risk activities.
- 98. RN C then took the required urine and blood samples, but omitted to undertake throat and rectal swabs at this appointment. As per the NZSHS "Sexual Health Check Management Guidelines", extragenital (throat and rectal) testing is required during sexual health checks for MSMs, irrespective of reported sexual practices or condom use.
- ^{99.} RN C reflected to HDC that Mr A's history of being MSM should have alerted her that both throat and anal swabs were needed. She believes that on this day, she was more focused on Mr A's comments regarding his rectal bleeding issue. In addition, she stated:

"Because of the anal bleeding issue, I was unsure whether an anal swab would be compromised by the bleeding and was reluctant to take the swab without advice from the doctor. I knew that [Mr A] was going to come back to see the Doctor where the throat and anal swabs would be taken."

- 100. My independent nursing advisor, RN Sharon Hansen, advised that while there is a departure from accepted standards of care in that Mr A did not undergo the site testing, clear documentation states that this was not done, and a follow-up was arranged for further examination and for it to be done at another time.
- 101. RN Hansen also considered RN C's rationale, in that she deliberated whether the anal swab would be compromised by the bleeding. RN Hansen stated:

"I wish also to acknowledge ... the limitations of [RN C's] scope of practice in providing further in-depth assessment for rectal bleeding. I believe now that her decision making on the day is entirely reasonable."

102. RN Hansen concluded that in the circumstances, the severity of the departure from accepted practice was mild, which I accept. It is acknowledged that RN C should have undertaken all the required tests and swabs for a routine sexual health check when Mr A presented. While I accept her rationale that Mr A's bleeding may have compromised the swab, and that Dr B was not available on that day for advice, this does not provide a rationale for why a throat swab was not done. A follow-up was arranged for Mr A to see Dr B, and RN C assumed that the swabs would be done then (the documentation completed by RN C showed that throat and rectum tests had not been done at this time). Unfortunately, this did not occur (discussed in more detail above), and I consider that this initial appointment was a missed opportunity to perform a full and thorough sexual health check. This was particularly important in light of the high risk of Mr A's recent sexual history.



Opinion: Dr B — adverse comment

Introduction

- ^{103.} Mr A presented to the sexual health clinic on 27 Month1, after having had unprotected anal sex approximately one week previously. Dr B, the sole GP at the clinic, was not present on this day, so Mr A was seen by RN C, who took the required urine sample and bloods for testing.
- ^{104.} On 10 Month2, Mr A presented to the clinic for his follow-up appointment with Dr B. Dr B did not examine Mr A at this appointment, or address that he had not had the full recommended STI check at his previous appointment with RN C (as the throat and rectal swabs had been omitted). In addition, Dr B did not discuss the need for Mr A to undergo repeat syphilis testing as per the NZSHS guidelines and the instructions on the laboratory form ("[I]f primary infection is suspected please repeat serology in two weeks"). She instead asked him to return in two weeks' time for repeat HIV testing, which occurred on 24 Month2, and did not see Mr A again.
- 105. My independent rural GP advisor, Dr Liz Humm, noted that the care provided by Dr B to Mr A in Month2 fell below accepted practice, because Dr B did not repeat the syphilis test, enquire about symptoms, examine Mr A, or perform rectal or throat swabbing. Dr Humm advised:

"I believe this to be a severe departure from accepted practice — particularly as his recent sexual encounter was known to be high risk ... However it seems that this departure from usual and accepted practice was an aberration rather than [Dr B's] usual practice."

- ^{106.} I accept this advice, and also note that the failures by Dr B clearly contravened the NZSHS guidelines.
- 107. Dr B's omissions in this case were significant contributing factors to Mr A not receiving care that met accepted practice. As a result, Mr A missed out on the sexual health services he required, and the opportunity to diagnose his syphilis earlier. However, I acknowledge that Dr B was going through personal issues at the time (for which I sympathise). I note that Dr B is the only GP at the sexual health clinic, and I wish to acknowledge her statement that she did not feel that there was provision for time out available to her, and she did not see any options to delegate the clinic or postpone patient contact. This is a clear example of the challenges faced by rural and remote general practices, and I allow for the possibility that had Dr B felt able to delegate or postpone Mr A's appointment owing to her personal situation, the omissions may have been less likely to occur. DHB1 has acknowledged that there is significant pressure on staff, and that the risks of such errors as occurred in this case is more likely when staff are unable to take a break from their clinical duties. For this reason, in this case I consider that the failings identified are primarily the result of a wider systemic issue.



^{108.} Dr B has shown insight into, and reflected on, the care she provided Mr A, which I and my expert advisor commend.

Opinion: DHB1

Care provided by sexual health clinic — breach

Introduction

- 109. The sexual health clinic is a GP-led clinic owned and operated by DHB1. The clinic runs for four hours per week. Dr B is the sole doctor at the clinic, and works alongside two registered nurses (one of whom is RN C), who alternate to provide leave cover for each other. At each of Mr A's presentations to the clinic, inadequate assessments and investigations were performed. He was later diagnosed with syphilis.
- ^{110.} My independent advisors identified some systemic issues with the sexual health clinic that contributed to the care Mr A received, which I will discuss below.

Lack of an electronic system

^{111.} My independent rural GP advisor, Dr Humm, noted that DHB1's service remains a paperbased service. She stated:

> "The benefits of a computerised system are manifold including screening templates and safer and more effective recall. It is likely that if this had been in place it would have provided a safety net and [Dr B's] omission would have been recognised."

- 112. DHB1 acknowledged the impact of the paper-based system on the functionality of the sexual health service, and submitted this to HDC as a relevant factor that affected the care provided by the DHB and its staff. It stated that the DHB as an organisation takes responsibility for this factor.
- ^{113.} My independent nursing advisor, RN Hansen, also commented on the lack of resources faced by DHB1 staff. Acknowledging the challenges and difficulties that rural and remote providers encounter in providing services, particularly of a more specialised nature, she stated that this makes it more important for institutional support for clinicians, in the form of adequate resourcing. RN Hansen advised:

"It seems to me that if there had been an IT system that had alerts and prompts, it would have been less likely that the initial failure to examine would have resulted in a syphilis diagnosis being missed, results would have been available and even if negative may have prompted a repeat. It would also ensure an easier recall system."

114. DHB1 recognised that an electronic system would enable best practice, and would negate the current paper-based processes that are prone to human error. Dr B also noted that an electronic system would enable screening templates and standard orders in respect of screening, diagnosis, and treatment of STIs, as well as a much safer and effective recall



system that is attached to the patient's record. However, the DHB noted that other requirements have taken priority, and its limited financial resources may mean that the DHB is unable to progress work on an electronic system in the foreseeable future.

115. RN Hansen stated that while she acknowledges this statement, "standards of care must not be compromised, patients still require adequate care".

Support and development of staff

- ^{116.} The sexual health clinic is a GP-led clinic. Dr B was the sole doctor, working alongside two registered nurses who alternate to provide leave cover for each other. At the time of these events, Dr B was facing a significant family crisis but did not feel that there was provision for time out available to her, and she did not see any options to delegate the clinic or postpone patient contact.
- DHB1 has acknowledged to HDC that the recruitment and retention of medical staff in rural locations such as this remains a significant issue and, as a result, there is significant pressure on the dedicated staff who work to provide a service to the community. The DHB stated: "[DHB1] are aware that the risk of human errors such as ... occurred in this case are more likely when staff are unable to take a break from their clinical duties."
- I am critical that the system places significant pressure on staff and does not support them adequately to take breaks from clinical practice when needed. In addition, RN Hansen was critical of the standard of performance reviews and training in place at the DHB to assist its staff in professional development, and stated that regular and senior staff attending a specialist clinic require updates and further education in this field. She noted that there was no reference to a training framework linked to a yearly performance review, or of a process where DHB1 identifies learning needs of its staff and plans to enable staff to rectify their unmet needs. She stated that this has the potential to leave both staff and the clients with whom they work vulnerable, and advised that "while it is up to the individual to maintain their practice a process of review is a safety net for the organisation and their staff and especially for the population using the service".
- ^{119.} I note that both Dr B and RN C are long-time employees of DHB1. However, considering the high level of specialised care they are providing within a rural location, without other specialised employees available for assistance, it is important that both staff members have a framework in which to identify gaps in their learning and ways to remedy the gaps.

Conclusion

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120. I acknowledge and accept the above comments from DHB1 and my experts. DHB1 did not provide adequate support for staff to take breaks from practice when required, and did not have in place an electronic system or a process to upskill and develop staff continually, and I consider that the environment and the system at DHB1 did not support Dr B and RN C sufficiently in the care they provided to Mr A. I note that DHB1 also acknowledges this. While there are challenges posed to the DHB by the overarching environment of the rural region that are outside its control, I consider that in light of these challenges, it is even more vital for DHB1 to have in place appropriate IT systems and frameworks for the development and



training of its staff. I note the consensus that had an online recall system been in place, this may have provided a safety net for RN C's and Dr B's omissions.

121. Accordingly, I find that by failing to have in place an adequate system to support its staff, DHB1 did not provide Mr A with services of an appropriate standard. It follows that I find DHB1 in breach of Right 4(1) of the Code of Health and Disability Services Consumers' Rights (the Code).¹⁶

Care provided by DHB1 Laboratories — adverse comment

- 122. On 30 Month12, Mr A presented to the medical centre to undertake an RPR test, to check whether the syphilis treatment commenced in Month5 had been successful. The sample was sent to the DHB1 laboratory and was received the same day, before being referred to Medical Laboratory 2. However, at the time of referral to Medical Laboratory 2, DHB1 used an incorrect registration code that was specific to DHB1 only and had since become redundant.
- 123. The use of an incorrect code (in conjunction with Medical Laboratory 2 not removing its own redundant codes and its subsequent actions to attempt to correct the error) contributed directly to the delay Mr A experienced in receiving his RPR test result, and therefore the knowledge of whether or not he was responding to his syphilis treatment.
- 124. While responsibility for this issue appears to be shared jointly with Medical Laboratory 2, I am critical of the fact that the wrong code was input before referring Mr A's sample to Medical Laboratory 2. I am pleased that the code has since been removed from the system, but consider the action to be reactive rather than proactive.

Opinion: RN D — breach

Care provided to Mr A

Care provided on 19 Month4

- On 19 Month4, Mr A presented to the medical centre with a recent onset of penile lesions, a rash on the palms of his hands and soles of his feet, a sore throat, and haemorrhoids. He was seen by RN D, who took Mr A's vital signs and completed a sexual health screen (which included a throat swab, genital swabs, and blood tests for hepatitis B and C, HIV, and syphilis).
- 126. As per the NZSHS guidelines for sexual health screening in MSM, a urine test for chlamydia and gonorrhoea is also recommended. In addition, the NZSHS guidelines on the management of syphilis stipulate that if there is a clinical suspicion of syphilis (as there was

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Names have been removed (except the experts who advised on this case) to protect privacy. Identifying letters are assigned in alphabetical order and bear no relationship to the person's actual name.

¹⁶ Right 4(1) states: "Every consumer has the right to have services provided with reasonable care and skill."

in this case), this should be specified on the laboratory form requesting a serology test. Neither of these things were done.

- 127. My in-house clinical advisor, GP Dr David Maplesden, was mildly critical of RN D's failure to include his suspicion of syphilis in the clinical details on the laboratory form, and I accept this advice.
- 128. Additionally, while I acknowledge that the missed urine test was eventually undertaken when Mr A re-presented to the medical centre a few days later, on 23 Month4, I believe that all the required tests and swabs for a routine sexual health check should have been performed when Mr A first presented, particularly in light of his symptoms.

Care provided after receipt of result

- 129. Mr A's positive syphilis result from his blood test was available in the medical centre's system, and able to be read by staff, from the evening of 23 Month4 onwards. The medical centre stated that as 23 Month4 was a Friday, the results would not have been seen by staff until Monday 26 Month4, as the centre is closed at weekends.
- 130. It appears that RN D checked for the blood test results, as an audit of the medical centre's database showed that RN D accessed Mr A's profile three times on 23 Month4 and twice on 27 Month4.
- 131. On 27 Month4, Mr A's throat swab results were received at the medical centre and RN D telephoned Mr A to advise him of the results. Despite the blood test results being available in the medical centre's system, RN D documented: "[P]honed with throat swab results ... still awaiting other results (due Monday 3 [Month5])."
- ^{132.} On behalf of RN D, his lawyer told HDC that there is "no reason that [RN D] would not have advised [Mr A] of the positive test result" if he had had that information available when he rang Mr A on 27 Month4, and I accept this.
- However, as noted, Mr A's blood test results were sent to the medical centre on the evening of 23 Month4, and theoretically were able to be viewed by medical centre staff then (noting, however, that this was a Friday evening). I am unsure why RN D did not see Mr A's test results when he checked on 23 and 27 Month4, but was able to see them on 30 Month4 when prompted by Mr A's telephone call. I note the medical centre's comment that Mr A's blood results were not flagged as abnormal, and therefore were not picked up by Dr E during her regular daily checks.
- 134. I consider it more likely than not that the results were able to be seen by RN D from 26 Month4, but acknowledge that they may have been overlooked by him as they were not flagged (as was the case for Dr E). I am critical regardless RN D accessed Mr A's file specifically to check for the blood test results, and these should have been picked up despite not being flagged.

Annual leave handover

- ^{135.} Mr A rang the medical centre to chase his result on 30 Month4. RN D told HDC that he then checked to see whether any new results had come in, and found that Mr A's syphilis blood test had been reported, and was reactive. RN D then went on leave and did not hand over the positive test result to Dr E, and did not make arrangements for the outstanding PCR test to be monitored. This created a risk that Mr A's syphilis result might not have been discovered or acted upon until RN D's return.
- 136. My independent nursing advisor, RN Hansen, advised:

"In this situation [RN D] had set a task and had attempted to obtain the results, however he was not successful on the 27 [Month4] and then did not review the results again until the 30 [Month4] when prompted by [Mr A]. [Dr E] did not review the results until she picked them up in a review of the EDI [(electronic data interchange)] results herself until the 3 [Month5], not through an alert or direct communication from [RN D]."

- 137. RN Hansen stated that this situation would be viewed by her peers as a moderate deviation from accepted practice, in view of poor communication to others, supported by a lack of arranged follow-up, particularly while RN D was on annual leave.
- 138. I agree and I am critical of RN D's management of Mr A's test results on this occasion. As the ordering clinician, it was RN D's responsibly to ensure that the results were communicated to Mr A promptly, and acted upon in a timely manner. First, RN D failed to obtain Mr A's abnormal blood test results from the system on 27 Month4, despite them being available. Secondly, he then checked Mr A's file for these positive results only when prompted by Mr A.
- ^{139.} Finally, RN D then went on leave, and despite being made aware of his patient's positive syphilis result, he failed to undertake a treatment plan or inform Dr E so that treatment could begin. At this time, he also omitted to make arrangements for the outstanding PCR test to be monitored.
- 140. Syphilis is an infection that is time sensitive, and can cause serious problems if not treated. I consider that going on leave without actioning or handing over this result or ensuring that there was a plan in place for Mr A's care was neglectful. Had Dr E not picked up the test result while dealing with incoming results on a day off, the delay in Mr A receiving treatment would have been even longer.

Documentation

- ^{141.} I note that RN D discussed Mr A's presentation with RN F. However, there is little detail about this discussion (documented only as "S/b Bi- ? VDRL"). No documentation was made relating to the discussion had with Mr A about the provisional diagnosis, time frames for results, or any other advice given.
- 142. In addition, when Mr A telephoned the medical centre on 30 Month4 for the results of his outstanding blood test, RN D documented that the results were given, and that he advised



Mr A to contact any sexual partners to get checked, but there is no documentation of their conversation about the next steps for treatment.

- 143. RN Hansen stated that RN D's clinical notes are "scant in detail, and do not appear to follow a framework". She stated that accepted practice would be to follow a framework such as the commonly used SOAPER¹⁷ or other similar frameworks that are taught in undergraduate programmes.
- 144. The New Zealand Nurses Organisation's guideline for documentation¹⁸ (2017) also mentions these frameworks. In addition, it states that documentation should "provide clear evidence of the care planned, the decisions made, the care delivered and the information shared, with rationale for the nursing action and/or inaction".
- ^{145.} I accept this advice. Documentation is a basic aspect of health care, and I am critical that it was not completed to the required standard in this case.

Conclusion

146. As set out above, RN D made several omissions when providing care to Mr A. The cumulative effect was a delay in Mr A receiving his positive test result, and a delay in him receiving treatment. I therefore consider that RN D did not provide Mr A with services of an appropriate standard, in breach of Right 4(1) of the Code.

Opinion: Medical centre — adverse comment

- 147. Mr A presented to the medical centre on 19 Month4 with symptoms of syphilis, a sore throat, and haemorrhoids. Tests taken by RN D included bloods to test for syphilis, which were reported by the laboratory and sent to the medical centre on 23 Month4. Mr A was not informed of the syphilis test result until 30 Month4. Further, RN D went on leave and did not hand over the positive test result to Dr E, and did not make arrangements for the outstanding PCR test to be monitored. As a result, planning for Mr A's syphilis did not start until 3 Month5, and he did not receive his first injection until 6 Month5.
- 148. At the time of these events, the medical centre did not have a formal policy or procedure for reviewing patient test results. In addition, no policy existed for the setting of referrals or tasks, and instead the centre had developed an in-house system verbally over time. The medical centre has since developed new policies. The medical centre told HDC that its practice nurses are required to create a task to check for results they have ordered by checking the inbox, and they are allocated time each day to do this. The medical centre stated that the nurses are also expected to inform the GP of any abnormal or time-critical results, or arrange for further care if the GP is not available.

 ¹⁷ S = subjective, O = objective, A = assessment, P = plan, E = evaluation, and R = review.
¹⁸ <u>https://www.nzno.org.nz/Portals/0/Files/Documents/Services/Library/2020-08-</u>24%20NZNO%20Library%20Resource%20List%20-%20Documentation.pdf



- 149. My in-house clinical advisor, GP Dr Maplesden, advised that while it cannot be established that the failure to have a written policy for management of results contributed to the oversights in this case, he believes the absence of a suitable written policy at the time of the events in question represents a "mild departure from accepted practice", and I agree. While the medical centre now has such policies in place, I believe they should have been in place at the time of the events, in order to guide its staff members.
- 150. I also agree that the absence of a written policy may not have been responsible for RN D's omission in relation to Mr A's test result. I note that in this case, RN D had set a task to track Mr A's results despite no formal policy being in place for doing so. The key issue is that he failed to inform Dr E of the result before he went on leave, which RN D accepts. In addition to this being one of the medical centre's expectations of its staff, I consider that the process of handing over important information before going on leave is a basic requirement of any healthcare provider to ensure effective communication and coordination of care. I consider that the errors made by RN D were individual ones, and are not indicative of a wider systemic issue at the medical centre.
- 151. In addition, the medical centre told HDC that it believes it provides excellent mentorship and in-house peer support. The medical centre noted that staff meet every Tuesday morning for training with the entire clinical team, and at 8.30am with all of the administrative team. The medical centre stated that at these meetings, staff are encouraged to present cases for discussion, raise clinical topics for review, and raise significant events. Furthermore, the medical centre said that there is a nurse-only peer support group session every Monday to discuss any issues.
- 152. My nursing advisor, RN Hansen, said that it is evident that the medical centre has systems in place to support its staff in their duties. She stated that "the detail offered in their reply shows excellent mentorship and in house peer group support which is not often evident in other general practices".
- ^{153.} I concur, and consider that the medical centre had taken steps that were appropriate in order to prevent the omission by RN D. As such, I consider that the medical centre is not vicariously liable for RN D's breach of the Code, as set out in section 72(2)¹⁹ of the Health and Disability Commissioner Act 1994 (the Act).
- ^{154.} Dr Maplesden has noted the number of additional remedial measures taken by the medical centre since Mr A's complaint, which should improve both general management of results and specifically the management of sexual health issues by practice staff. I commend the medical centre for this action.



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¹⁹ Section 72(2) states that an employing authority is vicariously liable for any acts or omissions of its employees. A defence is available to the employing authority of an employee under section 72(5) if it can prove that it took such steps as were reasonably practicable to prevent the acts or omissions.

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Opinion: DHB2 — breach

- 155. Medical Laboratory 2 is a division of DHB2 that provides tertiary pathology services.
- 156. The care provided to Mr A by Medical Laboratory 2 fell below accepted standards on two occasions. On the first occasion, Mr A undertook a dry swab from his penile lesion for a PCR test to be run to test for syphilis. The swab was taken on 23 Month4. Initially the swab was sent to DHB1 laboratory, before being referred to Medical Laboratory 2. The result for this swab arrived at Medical Laboratory 2 on 26 Month4. However, it was not reported until 10 Month5, far exceeding Medical Laboratory 2's standard reporting turnaround time of one week.
- 157. The error on this occasion was that the blank comment field on the form within Medical Laboratory 2's management system was not deleted, and consequently the result was not authorised for release. The error was not discovered until the next time a syphilis PCR analysis was performed, on 10 Month5.
- ^{158.} The second occasion related to Mr A's RPR test, which was taken on 30 Month12 to check whether the syphilis treatment commenced in Month5 had been successful. The sample was received by DHB1 laboratory the same day and then referred to Medical Laboratory 2. At the time of referral, DHB1 used an incorrect registration code that was an old code specific to DHB1 only and had since become redundant.
- 159. When the sample was received by Medical Laboratory 2 the next day, it was noted that the Medical Laboratory 2 transfer code was missing (as the incorrect DHB1-specific code had been used), and the correct code was added. However, as Medical Laboratory 2 told HDC, this did not correct the error, as the system required a correction of this kind to be requested by the referring laboratory in this case, DHB1. As such, Mr A's result was not processed, and the error was not picked up until Dr E rang DHB1 laboratory on 13 Month13 to chase the results. The test was then added to the worksheet ready to be performed on the next available test run, and was reported on 19 Month13.
- 160. This turnaround time of 14 working days far exceeded Medical Laboratory 2's usual turnaround time of 1–3 working days for this type of test.
- ^{161.} While I acknowledge that the responsibility for this error is shared with DHB1 (who entered the incorrect code in the first place), Medical Laboratory 2 then compounded the error by failing to fix the code correctly. In addition, Medical Laboratory 2 acknowledged that the redundant code used by DHB1 should have been removed earlier, and I consider that this responsibility was shared between the two laboratories.
- 162. Medical Laboratory 2 apologised to Mr A for the delays in the reporting of his two tests, and stated that the issues highlighted by this case have allowed it to identify and correct small but significant issues that in combination caused Mr A not to experience the high quality of service it strives to achieve.

HX

163. It is reassuring that Medical Laboratory 2's subsequent audit revealed that it had reported other syphilis PCR and blood tests in this time period within its turnaround time. However, the fact that delays in result reporting happened to the same consumer twice over a short period of time — and as a result of separate systems issues — is highly concerning. By failing to report Mr A's two test results within Medical Laboratory 2's standard turnaround time, and departing from these timeframes substantially, I consider that Medical Laboratory 2 did not provide Mr A services with reasonable care and skill. Accordingly, I find that DHB2 breached Right 4(1) of the Code.

Changes made since events

DHB1

- ^{164.} DHB1 told HDC that since receiving the complaint from Mr A, a considerable amount of work has been undertaken within its sexual health service, including:
 - a) The DHB is in the process of working in collaboration with its colleagues at DHB2 to develop an orientation plan that would support newly appointed registered nurses and medical staff who are responsible for providing cover within this service. Following development, all existing registered nurses and medical staff will complete any outstanding orientation requirements, if recognition of prior learning cannot be demonstrated.
 - b) All nurses who are currently working within the service are being supported to undertake annual performance reviews.
 - c) All policies and procedures that are specific to this service are in the process of being collaboratively updated, document controlled, and made accessible via the DHB's intranet.
 - d) It is working to ensure that the central roster for medical staff reflects who is providing cover for this service, to support identification of any gaps.
 - e) It is currently in phase one of the roll-out of its new electronic patient management system, which will help to manage recalls within the service better.
 - f) It is working with its colleagues at DHB2 to identify a person who would be able to undertake an objective review of the DHB1 sexual health services, including identifying opportunities for improvements.

Dr B

165. Since these events, Dr B has presented Mr A's case anonymously, as well as the cases of two other patients she subsequently diagnosed with syphilis, to her GP peer review group. She stated that this was an opportunity to share her omission and departure from the expected

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practice, and an opportunity to raise awareness of syphilis given the current epidemic.²⁰ At the peer review sessions, Dr B emphasised the value of the NZSHS guidelines in respect of screening, diagnosis, treatment, and management of syphilis and other STIs.

- ^{166.} Dr B told HDC that she now pays diligent attention to comprehensive STI screening, has increased attention to a proactive recall system of follow-up screening at three months, and has actively tried to build up her resilience and avoid burnout by attending workshops on these topics.
- 167. In addition, she has revised the following relevant material: The Ministry of Health's National Syphilis Action Plan, DHB1's Syphilis Reduction Action Plan, information on the Clinical Management of Syphilis sent to her by the Clinical Director of Sexual Health at DHB2, and the Best Practice Advocacy Centre (bpac^{nz}) information regarding syphilis to date.

RN C

- 168. Since these events, RN C has improved her documentation to ensure that others reading her clinical notes can clearly see that she has asked all questions required and that all responses are noted in the clinical file. In addition, she now ensures that the clinical rationale for why any tests were not taken or were delayed are written more comprehensively.
- ^{169.} RN C has also been working with DHB2 region's sexual health clinic to develop a plan for regular engagement with their peers in the region, to benefit from collaboration, learning, and support.

Medical centre

- 170. As mentioned in paragraph 71, the medical centre has now developed a test results policy that reflects the learning from this case to mitigate further regrettable incidents. The policy includes a process for the task list, laboratory investigations, and referrals.
- 171. The medical centre has also arranged for senior nurses to mentor and provide further monitoring for its staff. Additionally, the centre's on-call night nurse now second-checks the inbox for any missed or time-critical results.

RN D

172. RN D told HDC that he has revisited the manner in which he completes documentation, and has reviewed the Nursing Council's Code of Conduct about this. He stated that he has now improved the detail that he puts in his notes.

Medical Laboratory 2

173. Medical Laboratory 2 told HDC that to prevent a recurrence of the problem with the blank field (which caused the delay in reporting Mr A's PCR result in Month4–Month5), a change

²⁰ Syphilis infection rates in New Zealand and other developed countries have increased markedly in recent years. In 2017, 470 cases of syphilis were reported in New Zealand — more than double the number reported in 2015 and nearly six times the number reported in 2013. Trends for 2018/19 indicate that the number of cases is continuing to rise.



has been made to the syphilis PCR reporting format so that a blank comment box requires no further action by the scientist for the report to be authorised and released.

- 174. In addition, the laboratory has changed its "overdue parameter" (a trigger that lists overdue results when they are not reported within an expected interval), from 14 days to 7 days from receipt of the specimen, so that any errors are discovered earlier.
- 175. As discussed in paragraph 64, Medical Laboratory 2 has also removed the redundant DHB1 code (which caused the delay in Mr A receiving his 30 Month12 test results) from its registration code database, to prevent further accidental use.

Recommendations

- 176. I acknowledge the changes made by the providers in this case as a result of Mr A's complaint to HDC (outlined above). It is clear that the providers have reflected on the care they provided, identified the weaknesses in their systems and individual practices, and sought to remedy these to prevent similar events occurring again. In addition to the changes already made, I make the below recommendations for further improvement.
- 177. I recommend that DHB1:
 - a) Provide HDC with an update on the changes outlined in paragraph 164, within three months of the date of this report.
 - b) Develop a process for formalised yearly performance reviews for all staff, paying specific attention to specialised practice areas for those staff working in them. Evidence that this has been done is to be sent to HDC within three months of the date of this report.
 - c) Undertake a review of the staffing levels at the sexual health clinic, and consider the recruitment of more staff to provide leave cover for current staff when needed. The outcome of this consideration is to be sent to HDC within three months of the date of this report.
 - d) Provide Mr A with a written apology for its breach of the Code. The apology is to be sent to HDC within three weeks of the date of this report, for forwarding.
- 178. I acknowledge that Dr B provided Mr A with a written apology shortly after the events of this case. Considering negative feedback received from Mr A about this apology, I recommend that Dr B provide Mr A with an additional apology letter, for the failures outlined in this report. This apology is to be sent to HDC within three weeks of the date of this report, for forwarding.
- 179. In response to the provisional opinion, RN C provided HDC with a written apology to Mr A for the omissions outlined in this report.



- 180. In response to the provisional opinion, RN D provided HDC with a letter of apology for Mr A. In addition, I recommend that RN D organise for an experienced nurse to carry out a review of his documentation, over a three-week period, and report on the adequacy of the documentation. Evidence that this has been done, as well as the outcome of the review, is to be sent to HDC within three months of the date of this report.
- ^{181.} I recommend that the New Zealand Nursing Council consider whether a review of RN D's competence is warranted.
- 182. I recommend that the medical centre provide evidence to HDC of staff training and orientation of the new policies it has developed as a result of this complaint, within three months of the date of this report.
- ^{183.} I recommend that DHB2 undertake an audit of its test list to identify test codes not used in the past two years, and if any test codes are identified as no longer active, that these are retired. This information is to be sent to HDC within three months of the date of this report.
- ^{184.} DHB2 has offered to provide Mr A with a written apology, and this will be sent to HDC within three weeks of the date of this report, for forwarding.

Follow-up actions

- In this case, I have decided not to publish the names of the DHBs on the Health and Disability Commissioner website, noting that to do so would likely lead to the identification of the other individual providers breached or commented upon in this opinion. In this respect, the privacy interests of those individuals would be compromised in a situation where their names would ordinarily not be made public.
- 186. A copy of this report with details identifying the parties removed, except the names of the experts who advised on this case, will be sent to the Medical Council of New Zealand and the Royal New Zealand College of General Practitioners, and they will be advised of Dr B's name.
- 187. A copy of this report with details identifying the parties removed, except the names of the experts who advised on this case, will be sent to the Nursing Council of New Zealand, and it will be advised of RN C's and RN D's names.
- 188. A copy of this report with details identifying the parties removed, except the names of the experts who advised on this case, will be sent to the Ministry of Health and the New Zealand Sexual Health Society and placed on the Health and Disability Commissioner website, <u>www.hdc.org.nz</u>, for educational purposes.



Appendix A: Independent clinical advice to the Commissioner

The following expert advice was obtained from rural GP Dr Liz Humm:

"REPORT FOR HDC REF 19HDC01891

I have been asked to provide an opinion to the commissioner for the HDC. Case reference: <u>19HDC01891</u>

I have read and agree to follow the Commissioner's Guidelines for Independent Advisors. I am not aware of any conflicts of interest.

I have been a GP in New Zealand for over 27 years. I have also been the medical officer contracted to provide medical services for the Sexual Health Service run by the local District Health Board at a rural hospital in Northland for many years although I no longer do this role. My post graduate qualifications include FRNZCGP (Fellowship of the New Zealand College of General Practitioners) and FDRHMNZ (Fellowship of the Division of Rural Hospital Medicine New Zealand). I am involved in teaching and supervision of medical students, junior doctors and GP registrars on behalf of the University of Auckland and the New Zealand College of GPs. I am actively involved with patient care and on-call duties. I am PRIME (Primary Response In Medical Emergency) trained and continue to undertake MOPS (Maintenance of Professional Standards). In my time as a GP working for the Sexual Health Service I worked at a weekly half day clinic. Whilst arrangements for GPs providing care for more specialised clinics are unique to place and District Health Board I feel in a reasonably good position to comment on this case.

Before I begin my report I would like to acknowledge the distress [Mr A] has experienced.

The Commissioner has asked me specific questions which I will state now:

Please advise whether you consider the care provided met accepted standards in all the circumstances and explain your rationale.

In particular, please comment on

- 1) The adequacy of the care provided to [Mr A] by [Dr B]
- 2) The adequacy of the follow-up actions taken by [Dr B]
- 3) The adequacy of [DHB1's] Sexual Health Service policies and procedures.
- 4) Any other matters in this case that you consider warrant comment.

For each question, please advise

- a) What is the standard of care/accepted practice and what are the relevant guidelines?
- b) Has there been a departure from accepted practice? Is so to what degree: mild, moderate or severe?



³⁰ November 2021

c) What recommendations for improvement would help prevent a similar occurrence in the future.

The documents provided for me were

- a) Letter of complaint dated ... 2019
- b) [DHB1's] response letter dated ... 2019, containing [Dr B's] response
- c) Clinical records from [DHB1].
- d) [DHB1's] Sexual Health Service policies and procedures.

Brief Summary

[Mr A] presented to [DHB1's] ... Sexual Health Service on 27th [Month1] after having unprotected sex approximately one week prior. He underwent an initial screening test for sexually transmitted infections including HIV and syphilis at that time. [Mr A] returned to the clinic and was seen by [Dr B] on 10th [Month2]. At that stage [Dr B] advised [Mr A] it was too early to re-test for HIV. [Dr B] consulted the Community Microbiologist at that time and was advised that the laboratory had started using an HIV test that could test him at the six week interval. [Mr A] returned to the clinic on 24th [Month2] and at that stage was tested for HIV. A follow up syphilis test was not done. Subsequently [Mr A] was diagnosed with syphilis in [Month4].

Advice requested by the HDC

Please advise whether you consider the care provided met accepted standards in all the circumstances and explain your rationale. In particular, please comment on:

- 1) The adequacy of care provided to [Mr A] by [Dr B].
- 2) The adequacy of follow-up actions taken by [Dr B].
- 3) The adequacy of [DHB1's] Sexual Health Service policies and procedures.
- 4) Any other matters in the case that you consider warrant comment.

For each question, please advise:

- a) What is the standard of care/accepted practice and what are the relevant guidelines
- b) Has there been a departure from accepted practice? If so, to what degree: mild, moderate or severe?
- c) What recommendations for improvement would help prevent similar occurrence in future?

Question 1

The care provided by [Dr B] to [Mr A] in [Month2] fell below accepted practice inasmuch that [Dr B] did not repeat the syphilis test nor did she enquire about symptoms or examine [Mr A] or perform rectal, urethral or throat swabbing. NZSHS (New Zealand Sexual Health Society Incorporated) Best Practice Guidelines July 2017.

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a. The guidelines state that with MSM (Men who have Sex with Men) syphilis should be tested with every sexual health check.

b. I believe this to be a severe departure from accepted practice — particularly as his recent sexual encounter was known to be high risk.

c. Future recommendations I will discuss in my answer to question 4. However it seems that this departure from usual and accepted practice was an aberration rather than [Dr B's] usual practice.

Question 2

I can see no evidence that [Dr B] did not realise her omission until her attention was drawn to it by [Mr A] in [Month5]. [Dr B's] notes from 10 [Month5] document that [Mr A] was already receiving treatment. Her clinical notes document a discussion with [Mr A] on further testing every 3 months, condom use and PrEP (Pre-Exposure Prophylaxis — ie treatment to prevent infection prior to potential acquisition). [Dr B] has written unreservedly apologising for her omission. She has also reflected on her practice and studied guidelines some of which have been published after 2018. She has presented [Mr A's] case (anonymously) to her GP colleagues at peer review in [Month13] and also diagnosed and treated two further patients with syphilis as well as presenting their cases at peer review in ... 2019. She has raised awareness amongst her GP colleagues of the current syphilis resurgence. Whilst there are not to my knowledge any guidelines about follow-up actions after an omission of care, the actions of [Dr B] seem entirely appropriate and thorough.

Question 3

Regarding the adequacy of [DHB1's] Sexual Health Service policies and procedures I am unaware of guidelines advising on adequacy. Reading through the guidelines generally there is a paucity of information geared towards male patients — the documentation is predominantly towards female patients. However there is a Male STI screening specimen procedural sheet on which I notice one omission namely testing for Hepatitis A. I note also that [the service] remains a paper based service. [Dr B's] letter states that attempts have previously been made to computerise the service. The benefits of a computerised system are manifold including screening templates and safer and more effective recall. It is likely that if this had been in place it would have provided a safety net and [Dr B's] omission would have been recognised.

Question 4

[Dr B] has acknowledged her omission to re-test for syphilis has cost [Mr A] a delayed diagnosis of syphilis with accompanying distress and ill-health. This is obviously extremely regrettable that a patient who has sought medical help has not received appropriate investigation. However I feel that a doctor working for the service at a time of personal distress and distraction is in a difficult position. Safer policies and procedures including computerised recall systems with algorithms to follow would help mitigate for human vulnerability and error.

Dr Elizabeth Humm MBChB DCH DRCOG MRCGP FRNZCGP FDRHMNZ"

30 November 2021



Appendix B: Independent clinical advice to the Commissioner

The following expert advice was obtained from RN Sharon Hansen:

"Report for Complaint: Registered Nurses [RN D] and [RN C]

Ref 19HDC01891

I have read the Guidelines for Independent Advisors document (<u>www.hdc.org.nz</u>) and I agree to follow them.

My qualifications are as follows.

Sharon Hansen MN NP (rural)

I am a Registered Nurse Practitioner (Rural), having qualified in this scope of practice in 2007. I am currently working in a semi rural general practice during normal working hours, (sole practice) and undertaking after hours on call work during allocated weekends. I have also held a position, for several years, as NP in the DHB sexual health clinic, which is nurse led. I no longer hold this position.

Previous to achieving this qualification I worked as a Registered Nurse in General Practice between 1992 to 2007 in a rural sole practice. During these years I worked as 1st on call in a remote rural practice for several years as a registered nurse working under standing orders.

I have also worked as a nurse practitioner assessor for the Nursing Council, and was the chair of the Rural General Practice Network from 2014 until 2019.

I have been asked to provide expert advice to the Health and Disability Commissioner on the care provided to [Mr A] by registered nurses [RN D] and [RN C] between [Month1] and [Month2].

I do not believe that I am in a conflicted position in this case.

Care provided by [RN D]

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[Mr A] first saw [RN D] when he presented to [the medical centre] on 19 [Month4] with a recent onset penile lesion and rash on the palms and soles. He also complained of a sore throat and haemorrhoids. A full sexual health screen was performed including throat and genital swabs, test for HIV, Hep B and C and syphilis.

On 23 [Month4], the laboratory contacted [RN D] requesting a further penile swab to confirm syphilis. This was obtained from [Mr A] and sent off to the laboratory the same day. [Mr A's] HIV and syphilis results were received in [the medical centre's] system this evening (a Friday night). [The medical centre] reports that 26 [Month4] would have been the earliest date the HIV and would have been seen (the following Monday).

On 27th [Month4], [RN D] phoned [Mr A] due to the swab results being received and showing a positive Strep C result. During this phone call, [RN D] told [Mr A] that his other results were still awaiting, and were not due until 3 [Month5].

On 30 [Month4], [Mr A] rang [the medical centre] to follow up on his HIV and syphilis test result. He was then advised by [RN D] that he had a positive diagnosis of syphilis.

I have been asked to review the documentation supplied and advise whether I consider the care provided to [Mr A] by [RN D] to be reasonable and why.

The adequacy of [RN D's] task setting/tracking of [Mr A's] test results

A) What is the standard of care/accepted practice?

NZNC Registered nurse Competencies relevant in this situation. 2.3 'Ensure documentation is accurate and maintains confidentiality of information' 2.4 'Ensures the client has adequate explanation of the effects, consequences and alternatives of proposed treatment options' 2.6 'Evaluates client's progress towards expected outcomes in partnership with clients' 3.3 'Communicates effectively with clients and members of the health care team' 4.1 'collaborates and participates with other members of the health care team to coordinate care' 4.3 'Participates in quality improvement activities to monitor and improve standard of nursing'. <u>www.nursingcouncil.org.nz</u>

While registered nurses are not entirely responsible for results ordered in a standing order situation, accepted practice is that RNs would have task allocation set, supported by procedures and policy and mentored by senior staff. Nurses may access results coming into the practice EDI and may act in the capacity to highlight abnormal results and collaborate with a medical or nurse practitioner to ensure appropriate and timely treatment.

In a practice the size of [the medical centre] with only one medical practitioner, this is a practical method of ensuring results are viewed in a timely manner. Accepted practice would determine that RNs performing this work are experienced and supported with standing orders, practice policy, regular audit and peer support.

B) If there has been a departure from the standard of care or accepted practice, how significant a departure do you consider this to be? Please quantify the significance of any departures you identify by using the terms mild, moderate or severe.

I consider that in this instant there was a departure from accepted practice to a moderate degree, due to the issue of a lapse of time between results being communicated to the patient and to the medical practitioner in this case. There was an opportunity for earlier treatment and for a referral to a sexual health specialist.

C) How would it be viewed by your peers?

This situation would be viewed by peers as a moderate deviation from accepted practice in view of poor communication to others both in documentation and supported by a



lack of arranged follow up, particularly while [RN D] was on annual leave. At the time this work was done in the practice, under common agreement rather than policy or procedure. There was peer support and mentorship available however there was scant documentation on this with no forward planning or review process set up.

D) Recommendations for improvement that may help to prevent a similar occurrence in future.

I note that improvements since this situation have been initiated by the practice, including clear standing order procedure, and written policy. I would support those initiatives and add further that policy clearly links to quality framework, for example foundation standards or cornerstone accreditation, with random audit of processes, clinical notes and EDI audit.

2) The adequacy and timeliness of reporting [Mr A's] positive syphilis serology result to him.

A) What is the standard of care/accepted practice?

Standard practice is set out by the practice and the laboratory and is communicated to the practice population, appendix G, and is now set out in their laboratory results weekly audit policy dated 18/06/2020. I note [the medical centre] attempts to have all results to patients within ten working days. Urgent results within 1–3 days.

B) If there has been a departure from the standard of care or accepted practice, how significant a departure do you consider this to be? Please quantify the significance of any departures you identify by using the terms mild, moderate or severe.

In this situation I believe there was a departure from standard practice, moderate. [Mr A] was informed of the results to hand, however there was no documentation or plan communicated to [Mr A] on review to ensure further results communicated or treatment to be initiated.

C) How would it be viewed by your peers?

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In this situation [RN D] had set a task and had attempted to obtain the results, however he was not successful on the 27 [Month4] and then did not review the results again until the 30 [Month4] when prompted by [Mr A]. Dr E did not review the results until she picked them up in a review of the EDI results herself until the 3 [Month5], not through an alert or direct communication from [RN D]. This would be viewed as moderate deviation from standard practice by my peers. Although the framework for communication and triage of results was verbal at that time, there is evidence that it was discussed at the weekly practice meetings in the past.

D) Recommendations for improvement that may help to prevent a similar occurrence in future.

Future recommendation would include policy, procedure, adequate mentorship, peer support, audit. With adequate time allocation to enable work to be done.

3) The adequacy of the follow up information/advice provided to [Mr A] by [RN D] both after the testing was performed and after his positive syphilis serology was confirmed.

A) What is the standard of care/accepted practice?

While the responsibility of ensuring the test results are reviewed ultimately sits with the person who ordered the tests, it is a delegated task that is managed by registered nurses in conjunction with other team members, in many situations.

B) If there has been a departure from the standard of care or accepted practice, how significant a departure do you consider this to be? Please quantify the significance of any departures you identify by using the terms mild, moderate or severe.

There is a departure from the standard of accepted practice in that the patient was seen and examined by [RN D], supported by [RN F] who gave indication that this was likely to be a serious disease, timing of diagnosis and initiation of treatment was essential to ensure no disease progression occurred. While there is evidence of [RN D] reviewing the EDI for results on the 27 [Month4], this did not occur again until [Mr A] prompted him on the 30 [Month4]. There then appears to be a lapse on follow up as [RN D] then went on annual leave without hand over.

C) How would it be viewed by your peers?

As per the New Zealand Nursing Council Registered Nursing competencies used as a basis of standards of care. It is difficult to find evidence that the standards of care were met in the documentation, peer review would support this. Moderate.

D) Recommendations for improvement that may help to prevent a similar occurrence in future.

Recommendation is that practice policy which includes time to review results with the prescribing clinician or clinical lead, within a supportive environment which includes standing orders for results. This activity would be supported by audit.

4) The adequacy of [RN D's] clinical documentation.

A) What is the standard of care/accepted practice?

Accepted practice would normally follow an accepted framework, for example SOAPER, which is commonly used S subjective O objective A assessment P plan E evaluation R review. There are other similar frameworks which are taught in undergraduate programmes. All practitioners involved or having given an opinion in a situation should add clinical notes under their user names.

B) If there has been a departure from the standard of care or accepted practice, how significant a departure do you consider this to be? Please quantify the significance of any departures you identify by using the terms mild, moderate or severe.

There is a departure from the expected standard of care to a moderate degree as the clinical notes are scant in detail and do not appear to follow a framework.



C) How would it be viewed by your peers?

The clinical documentation would be seen as a moderate deviation from accepted standard of care.

D) Recommendations for improvement that may help to prevent a similar occurrence in future.

All health care providers are recommended to keep up to date with current best practice on documentation which enables safe practice for both their patients and themselves. [RN D] would be recommended to read the code of conduct on NZNC website.

5) The adequacy of the training given to [RN D] by [the medical centre].

A) What is the standard of care/accepted practice?

Accepted practice is to meet the requirements of professional registration as determined by the appropriate professional body. However meeting competencies is a matter of self-reflection and identification of areas of need, the process is driven by the professional. Yearly performance review is a part of this process and is usually initiated as a part of the employment contractural process.

B) If there has been a departure from the standard of care or accepted practice, how significant a departure do you consider this to be? Please quantify the significance of any departures you identify by using the terms mild, moderate or severe.

Moderate departure from the standard of care or accepted practice. There is no evidence presented for any performance review for [RN D], this would have been the opportunity for him to identify where his learning needs lay and given for any issues that may have been identified. [RN D], however, has been involved in the regular review and education offered within the practice, not all medical practices ensure an opportunity to learn within the practice environment.

C) How would it be viewed by your peers?

Education offered within a practice environment is not widespread, however the need to ensure up to date professional development is a responsibility for all health professionals. A peer review of the training opportunity offered by [the medical centre] is seen as a mild to moderate deviation of caregiver that it would be an expectation that yearly performance review would be done.

D) Recommendations for improvement that may help to prevent a similar occurrence in future.

Recommendation is for staff to have yearly performance review and to develop their own practice in a systemic manner, with an expectation that staff will have up to date professional portfolio.
6) Any other matters in this case that, in your opinion, warrant comment or amount to a departure from the standard of care/accepted practice.

Remote and rural general practice has challenges including keeping up to date, dealing with the sheer volume of work across a wide variety of issues with sometimes nonexistent or minimal support services. Practices in this situation, are significantly under resourced for medical services and are supported heavily with nurses working under standing orders.

The success of this model of care, depends on well written enacted policy, with people supported in their work. When this model doesn't work people are not provided the care and they are left vulnerable.

In this case it was confusing and difficult to see where the follow up for [Mr A] led and how communication occurred within the general practice. Also not obvious was how a plan was developed and reviewed with sexual health services and the follow on services that [Mr A] required. This case highlights how vulnerable people are in navigating various health care services without clear communication between provider services and client and with each other.

**Please note that the actual date of the notes supplied dates the consultation with [Mr A] on the 28 [Month1] not the 27 [Month1].

Care provided by [RN C]

[Mr A] presented to [the sexual health clinic] ([DHB1]) on 27 [Month1], with a recent history of unprotected receptive anal intercourse with a male partner, and requesting HIV testing. [Mr A] also said he had some anal symptoms (pain and bleeding) which he attributed to haemorrhoids. He was seen by [RN C], who performed initial screening test for STIs, including Hep B and C, HIV gonorrhoea, chlamydia and syphilis. Full 3 site testing was not done at this time. [Mr A] was advised to come back in two weeks and then three months for repeat testing of the above and a physical examination.

The adequacy of the care provided to [Mr A] by [RN C] on 27th [Month1], including the assessments carried out.

A) What is the standard of care/accepted practice?

The usual standard of accepted care is that examination and swabs are taken from three sites penile/genital, anal, and oral on MSM in accordance with management guidelines NZSHS which forms the basis of the [regional] guidelines. In addition a careful history is taken and documented.

B) If there has been a departure from the standard of care or accepted practice, how significant a departure do you consider this to be? Please quantify the significance of any departures you identify by using the terms mild, moderate or severe.

While there is a departure from accepted standards of care in that [Mr A] did not undergo the site testing, clear documentation states that this was not done and a follow



up was arranged for further examination for it to be done at another time. It is not clear why this decision was made from the documentation, for example if [Mr A] did not consent to the examination or if [RN C] felt it better for him to be examined by a doctor given his presumed haemorrhoid condition. I would consider then that this breach is moderate.

C) How would it be viewed by your peers?

The consultation would be viewed as a moderate deviation from standard care in that it was an inadequate assessment that did not follow the guidelines as set out in the NZSHS or in the 'how to guide for a sexual health check-up' as supplied. Although [RN C's] notes clearly support a discussion on follow up with expectations on a physical examination, there was no rationale why this did not occur in the context of the first consultation and how that process would be followed up. Registered Nurses are expected to take responsibility to ensure that there is an evaluation of progress towards expected outcomes in partnership with clients as a NZNO competency expectation.

D) Recommendations for improvement that may help to prevent a similar occurrence in future.

Recommendations include regular attendance or engagement in a peer group; this may occur electronically given the isolation that the RNs working in this situation experience. Isolation makes it very important to engage in regular peer support groups and in conference or education update within the specific specialty of practice.

The adequacy of the training given to [RN C] by [DHB1].

A) What is the standard of care/accepted practice?

The standard of accepted practice is that regular specific to specialty education or updates would occur with line manager yearly performance review undertaken. During this process, there is a self review done against a set of predetermined standards of practice, usually based around examples from clinical practice and linked to the nursing council competencies. Areas of need are identified and goals set with time on when those learning needs will be fulfilled. These performance reviews are a key part of maintaining an up to date portfolio that may be open to nursing council audit. To maintain registration for practice.

B) If there has been a departure from the standard of care or accepted practice, how significant a departure do you consider this to be? Please quantify the significance of any departures you identify by using the terms mild, moderate or severe.

There was no reference to training framework identified, linked to a yearly performance review or of the process that [DHB1] identified learning needs or a plan to enable staff to rectify their unmet needs. This is a moderate–serious breach and has the potential to leave both staff and the clients that they work with vulnerable. While it is up to the individual to maintain their practice a process of review is a safety net for the organisation and their staff and especially for the population using the service. It is clear however that [RN C] does participate in an educational process and much of these opportunities are provided for from [DHB1].

C) How would it be viewed by your peers?

This would be considered inadequate and a serious breach mitigated by the organised opportunity to participate in the other education sessions. In this situation regular and senior staff manning a specialist clinic require updates and further education in this field.

D) Recommendations for improvement that may help to prevent a similar occurrence in future.

The recommendation would be that a process of formalised yearly performance review be undertaken by the [DHB1] which pays specific attention to specialised practice areas for those staff working in them.

3) Any other matters in this case that, in your opinion, warrant comment or amount to a departure from the standard of care/accepted practice.

I would like to acknowledge the challenges and difficulties that rural and remote providers DHBs/PHOs and general practices encounter in providing services, particularly of a more specialised nature. Generalist health care providers are expected to work at the top of their scope of practice, across a wide range of health need and are usually compromised in doing so with lack of resources such as real time tertiary services support, IT support and remoteness from other providers.

This makes it more important for institutional support for clinicians, in the form of adequate resourcing and access to peer support and strong structures to enable professional development.

While I acknowledge the statement made that the DHB has focussed on [other requirements], standards of care must not be compromised, patients still require adequate care.

It seems to me that if there had been an IT system that had alerts and prompts it would have been less likely that the initial failure to examine would have resulted in a syphilis diagnosis being missed, results would have been available and even if negative may have prompted a repeat. It would also ensure an easier recall system.

References

Bickley, Lynn. (2003) Bates Guide to Physical Examination and History Taking. Lippincott NZSHS (2020). Syphilis Management Summary <u>www.nzshs.org/guidelines</u> New Zealand Nursing Council (2020) Competencies for Registered Nurses/Code of Conduct. <u>www.nursingcouncil.org.nz</u>.

Sharon Hansen MN NP (rural)"





The following further advice was obtained from RN Hansen:

"Thank you for the opportunity to reply to your further opinion regarding the case ref 19HDC01891/[Mr A].

I note that there are contrary statements between [RN D] who says that systems procedures and policy (paragraph 4) has changed since his time there, and [the medical centre] state that they have had support, peer group and educational systems in place while he was there.

I have not got any of the original documentation, having sent it back however I have used what you have sent back.

I hope my reply is satisfactory.

Kind Regards

Sharon Hansen NP

[RN D]:

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Whether [RN D's] explanation around the test-ordering and receiving at [the medical centre] at the time of the events changes your initial advice about the care he provided to [Mr A] in any way.

I wish to thank [RN D] for his considered reply and the opportunity to address his explanation to the events again.

[RN D's] reply states that he was part of a previous regime which has since been altered by [the medical centre] in light of this incident and that he had followed the procedures at the time of his employment there. He makes a comparison to his current practice and he highlights his responsibilities within his scope of practice for a patient presenting again with a condition that he is not able to treat under the standing orders he has available to him at the time. I would comment that it is always appropriate for the GP/NP to be informed and to be prescribing and following the care of a person with a new diagnosis of syphilis.

[RN D] states that all results went into [Dr E's] inbox and therefore he might expect that the results for syphilis would be seen by the Doctor and that he was initially responding to the strep throat results.

He did have a colleague, [RN F], who had given him information which would have highlighted the potential diagnosis of syphilis, which in this case proved to be correct.

There was a timing of results issue that was out of [RN D's] control but there was also an opportunity to ensure clear communication with his medical colleague about the situation before he went on holiday so that treatment could be initiated at the earliest opportunity. In item 8 in [RN D's] reply he states he would have given [Mr A] further information about his results and expectations of a plan for further follow up, while it is impossible to document every conversation it is important to show it has been done.

I change my opinion from severity from moderate to mild.

2) Have you any further comments to make on the care provided to [Mr A] by [RN D].

I appreciate [RN D's] apology to [Mr A] who was vulnerable and dependent on his health care providers advocating for him to provide timely and appropriate care. I can see that [RN D] has taken steps to improve the aspects of his practice that were not evident in his initial reply to [Mr A's] complaint.

I commend [RN D] in the improvements that he has made for documentation and improved practice regarding tracking of results.

[RN C]:-

Whether her explanation for not undertaking 3-site testing is reasonable, and whether it changes your initial advice in any way.

I wish to thank [RN C] for her further explanation which considerably supports her decision making at the time of the consultation.

I wish also to acknowledge the difficulties that occur in consultation with someone who is acutely distressed and anxious and the limitations of [RN C's] scope of practice in providing further in-depth assessment for rectal bleeding. I believe now that her decision making on the day is entirely reasonable.

I believe that the difficulties that [RN C] encountered at the time were enhanced by the service provision in a small provincial centre who are still developing their links to tertiary specialist services and their use of IT systems was limited.

I change my assessment of severity to mild.

2 Have you any further comments to make on the care provided to [Mr A] by [RN C].

Health Professionals do not go to work with the intent to cause or allow harm to a patient, quite the opposite, but are often compromised in their care by the environment they practise in. A rural remote environment is one of the most challenging environments which makes it important to advocate safety for the practice and patients. I commend [RN C] that she has improved her documentation, and engaging in professional development in this area.

[DHB1]

1) The adequacy of the changes made at [DHB1] since these events.

In the context of this report, I have been asked from HDC for my expert opinion from the aspect of a nurse clinician. Therefore my comments as follows are that I believe



[DHB1] have moved to identify gaps in their service which did not provide [Mr A] with adequate care at the time of his first presentation.

My first comment on reading the report from [DHB1] was 'excellent'.

I believe that [DHB1] are working to rectify the situation and have improved the services that enable the registered nurses working in [the sexual health clinic] to provide safe and supported care.

I am heartened to see that [RN C] is being supported to complete her PDRP, and to develop regular peer review with ... colleagues, along with sexual health forums/conferences etc.

2) If you have any further recommendations to make regarding [DHB1] in order to ensure a similar situation does not occur.

My recommendation is that staff are the 'basis' of a service and they should always be supported with policy and procedure which supports their work. A system that allows two way communication on the barriers that staff have to enable safe practice is also recommended. I also acknowledge the difficulty in attracting and retaining medical staff in rural areas.

[Medical centre]

1) Whether the further information provided by [the medical centre] in regards to the training, support and review they provide their staff with, changes your initial advice in any way.

I would like to comment to [the medical centre] that I am a registered Nurse Practitioner and am working within that scope of practice not an RN (registered nurse) scope of practice, as stated in their reply.

I wish to thank them for taking the time to address issues regarding accreditation and training and support that they offer their staff. It is now evident to me that they have systems in place to support their staff in their duties. The detail offered in their reply shows excellent mentorship and in house peer group support which is not often evident in other general practices.

2) If you have any comments to make on [the medical centre's] statement that sexual health services do not share patient notes or results to any GP practices and therefore the practice cannot develop a plan or review its progress

The communication between providers is difficult. All sexual health clinics ensure the privacy of their clients/patients by having a confidential system therefore communication between providers can be difficult or nonexistent. However, it can occur with the intermediary being the patient/client should they want that to occur. For example the general practice may be involved in ensuring barriers to care are addressed as appropriate.

НX

I stand by the statement 'This case highlight how vulnerable people are in navigating various health care services without clear communication between provider services ...' It is not intended as a criticism of any one service, more about the dynamics of providing services and it adds a layer of complexity, which adds to client/patient vulnerability. It is challenging for us all."



Names have been removed (except the experts who advised on this case) to protect privacy. Identifying letters are assigned in alphabetical order and bear no relationship to the person's actual name.

Appendix C: In-house clinical advice to the Commissioner

The following in-house clinical advice was obtained from GP Dr David Maplesden:

1. Thank you for the request that I provide clinical advice in relation to the complaint from [Mr A] about the care provided by to him by [DHB1] ([Dr B], [DHB1] Sexual Health Service), [DHB2] ([Medical Laboratory 2]) and [the medical centre]. In preparing the advice on this case to the best of my knowledge I have no personal or professional conflict of interest. I agree to follow the Commissioner's Guidelines for Independent Advisors. I have reviewed the documentation on file: complaint from [Mr A]; response from [the medical centre] per [manager]; [medical centre] clinical notes; response from [DHB1] including statement from [Dr B]; clinical notes [DHB1] Sexual Health Service (SHS); response and other correspondence [Medical Laboratory 2]. Original advice was provided on 2 March 2020. Additional information requested in the body of this report was reviewed on 8 April 2020 and incorporated into the original reports in bold. **Responses to my original advice were viewed on 21 September 2020 and additional comments recorded as a result of these are responses recorded in bold italics below.**

2. Complaint regarding [the medical centre]

The following issues are raised by [Mr A]:

- delays in notification of positive syphilis serology (result reported by lab 23 [Month4] but not notified to patient until he rang for results on 30 [Month4])
- delays in initiating appropriate treatment for syphilis following receipt of positive serology (treatment not commenced until 6 [Month5])
- inappropriate prescribing of oral penicillin for syphilis on 27 [Month4]
- delays in being notified of post-treatment syphilis result (test performed 30 [Month12], result notified 20 [Month13])

3. Response and notes [medical centre]

(i) [Mr A] falls into the sexual health category of man who has sex with men (MSM). He attended [the medical centre] on 19 [Month4] and was seen by practice nurse [RN D]. Presenting complaint included recent onset penile lesion and rash on the palms and soles. [Mr A] also complained of a sore throat and haemorrhoids. Vital signs were normal. Throat and penile swabs (microscopy and culture, herpes) were taken and bloods taken for sexual health check (HIV, hepatitis B/C, syphilis serology). Clinical details on the blood test form was *'unprotected sex'*. [RN D] consulted with a nursing colleague who felt [Mr A's] presentation might be consistent with syphilis infection. The Greymouth laboratory evidently contacted [the medical centre] following receipt of the samples stating a dry swab of the penile lesion was required for PCR testing if syphilis was suspected and [Mr A] was recalled for that swab which was undertaken by [RN D] on 23 [Month4] by which stage the main penile lesion was described as healed. Urine sample was also obtained for chlamydia and gonorrhoea testing on that date. On 27 [Month4] [the medical centre] received a faxed result of [Mr A's] throat swab result which was positive for strep C and [Mr A] was notified of this result the same day and



prescription provided for oral penicillin (as per sensitivities). Nurse notes on that date are: *Phoned with throat swab results. Advised genital swabs neg, still awaiting other results (due Monday 3 [Month5]).*

Comment: Best practice recommendations for sexual health screening of MSM was not followed per best practice guidelines (see [Image] 2) in that first catch urine and relevant pharyngeal and anal swabs were not taken for gonorrhoea and chlamydia testing despite [Mr A] complaining of pharyngeal and anal symptoms. However, I suspect there is some gap between common practice and best practice in this regard. [The medical centre's] response dated 30 June 2020 notes staff use local HealthPathways guidance¹ when available for specific conditions, and such advice is available for syphilis. While this advice does not specifically discuss the additional investigations referred to above, it does advise referral for acute sexual health assessment (DHB Sexual Health Service) if a penile ulcer is present, for PCR swab. I am confident the Sexual Health Service would follow the recommendations discussed or, had they been contacted for advice, such advice would have been provided. [RN D] was astute in suspecting a diagnosis of possible syphilis (presence of extremity rash and penile lesions in MSM very suspicious for this diagnosis) and discussed this with a nursing colleague ([RN F]) who concurred with the diagnosis. Recommended practice if there is a high degree of suspicion for syphilis (see [Image] 3) is to advise the patient to refrain from sexual activity until investigation results are available, and to discuss the patient with a sexual health specialist (or refer to such a specialist) particularly if there is a painless solitary penile ulcer present consistent with chancre (as may have been the case with [Mr A]). I would be mildly to moderately critical if [RN D] did not discuss the possible diagnosis of syphilis with [Mr A] on 19 [Month4] and advise him to refrain from sexual activity until his results were available. Responses from [the medical centre] and [RN D] note [RN D] sought advice from [RN F] who has experience in infectious diseases and sexual health and the likely diagnosis of syphilis was discussed between the RNs and with [Mr A]. [RN D] does not recall the details of what was discussed with [Mr A] but believes it is 'highly likely' the time frame for results and need to abstain from sexual activity in the interim was discussed. I note there was no documentation relating to discussion of the diagnosis, time frames or general advice so there was at *least a deficiency in clinical documentation (mild to moderate).* I would regard confirmation of a diagnosis of primary syphilis as a result of high significance and would therefore expect the result to have been tracked to ensure it was received and acted upon in a timely manner, and I would be mildly to moderately critical if this was not done (results were tracked — see section 3(iii)). I am mildly critical that suspicion of syphilis was not included in the clinical details of the serology request form (criticism remains). It is unclear whether [RN D] was working as a nurse practitioner (NP) and what type of clinical supervision or oversight was available at the time of the consultation of 19 [Month4] (see below). If [RN D] was not a NP and was able to speak with a GP at [the medical centre] at the time of the consultation, given the significance of the suspected diagnosis I would be mildly critical if he did not seek further clinical



Names have been removed (except the experts who advised on this case) to protect privacy. Identifying letters are assigned in alphabetical order and bear no relationship to the person's actual name.

¹ Section titled 'Syphilis'.

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advice from the GP, acknowledging he did seek advice from a nursing colleague. I believe if nursing staff who are not NPs are undertaking sexual health checks at [the medical centre], there should be relevant resources (such as the cited NZSHS primary care guidelines) available to them (see recommendations), and staff should receive appropriate sexual health training to undertake such assessments. I recommend [the medical centre] be asked to confirm the nature of training and oversight given to nursing staff performing sexual health checks at [the medical centre], and whether [RN D] was operating as a NP (and if so whether his NP scope was restricted). It has been clarified that [RN D] was not a nurse practitioner and that management of confirmed STI cases should be discussed with the GP. All nurses undergo GP-led training sessions and Family Planning training sessions including sessions on sexual health. The prescribing of oral penicillin was appropriate for [Mr A's] Strep C pharyngitis and it was not provided with the intention of treating syphilis. It would be helpful to obtain a response from [RN D] if possible, to clarify some of the uncertainties noted above and also to confirm subsequent information provided by him to [Mr A] in relation to the syphilis diagnosis and management ([RN D's] response has been incorporated).

(ii) Processing of results of samples taken at [the medical centre] or ordered by [the medical centre] staff over the period in question is summarised below as per results on file (some appear to be duplicates):

Sample	Date taken	Date reported	Comment
Syphilis ²	19 [Month4]	23 [Month4]	RPR reactive (T=64) TPHA and EIA
serology			reactive
HIV	19 [Month4]	21 [Month4]	Ag/Ab negative
Throat	19 [Month4]	23 [Month4]	Scant growth Strep C — result faxed
swab			
Hep C	19 [Month4]	21 [Month4]	Hep C ab negative
Нер В	19 [Month4]	21 [Month4]	Anti-HBs negative
Penile	19 [Month4]	23 [Month4]	Gram stain and culture negative
swab 1			
Penile	19 [Month4]	22 [Month4]	Negative for herpes
swab 2			
Penile	23 [Month4]	11 [Month5]	PCR positive for syphilis
swab 3			
Penile	23 [Month4]	10 [Month5]	PCR positive for syphilis
swab 4			
Urine	23 [Month4]	11 [Month5]	Negative for chlamydia and
			gonorrhoea
Urine	23 [Month4]	27 [Month4]	Negative for chlamydia/gonorrhoea
F/up	30	19 [Month13]	RPR reactive (T=4) TPHA and EIA
syphilis	[Month12]		reactive
serology			

² See [Image] 1. T=64 refers to the RPR titre and is a high result consistent with current active syphilis

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(iii) On 30 [Month4] [RN D] recorded a call from [Mr A]: phoned for results — given. Advised VDRL blood 'reactive'. Awaiting VDRL swab next Tuesday. Advised to contact any sexual partners to get checked. [The medical centre] response states the results were sent to [the medical centre] on Friday night 23rd [Month4]. [Medical centre] staff would not have seen these until at least Monday 26th [Month4]. [RN D] no longer works for [the medical centre] and had not provided comment as to why there was a delay in [Mr A] being given his positive syphilis serology result (apparently accessible from at least 26 [Month4]) and what actions were taken by [RN D] on receipt of the results (such as consulting with a GP or sexual health specialist).

Comment: It seems likely (per information from [Medical Laboratory 2]) that [Mr A's] positive syphilis serology was available to [medical centre] staff from the afternoon of 23 [Month4]. However, I accept the information may have arrived after staff had checked their in-boxes and after [Mr A] attended for his repeat swabs, but it was a reasonable expectation the results would be reviewed on Monday 26 [Month4] and conveyed to [Mr A] around that time. [The medical centre] response states the apparent failure by [RN D] to relay the result to [Mr A] during the phone call of 27 [Month4] as: *this is probably related to us receiving the strep information via fax on the 27th [Month4] and no results in our EDI box* implying results recorded as being reported between 21 and 23 [Month4] (see table above) were not present in the relevant PMS module at the time of the call. This seems somewhat unusual and it should be possible to audit the provider inbox to confirm when the results were received and when they were viewed by a provider (see below). I note all results recorded [Dr E] as requestor (a common situation where nursing staff are ordering tests on behalf of the GP) and the results would presumably have come to [Dr E's] electronic in-box for review and filing.

[RN D] confirms he saw [Mr A] for repeat swabs and urine tests on 23 [Month4] but 'the results had not been received by that time, so I was unable to inform him of the results'. [The medical centre's] response confirms an audit of Task Manager established [RN D] had set a task on 19 [Month4] (due date 27 [Month4]) to followup [Mr A's] results. The task was later given a due date of 3 [Month5] (normal priority). The task was finally marked as completed on 12 [Month5]. [RN D] was onleave at the time the due date of 3 [Month5] occurred and would be expected to have assigned follow-up of the results to a colleague but this did not occur. The syphilis serology result was available on 26 [Month4] but this was not conveyed to [Mr A] until he rang [the medical centre] on 30 [Month4] to query the results. [RN D] confirms he advised [Mr A] on 27 [Month4] of the throat swab result (Strep C) and 'as set out in the notes, I also advised him that his genital swab was negative, and that the results from the other tests were due on 3 [Month5] ...'. It appears [RN D] overlooked the positive syphilis serology result which was not conveyed to [Mr A], meaning there was a delay in starting definitive treatment. [RN D] did not make arrangements for a colleague to monitor return of the PCR swab results during his planned absence. I believe these are significant departures from accepted nursing practice. The departure might be best quantified by a primary care nursing expert.



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(iv) [The medical centre] response states [Dr E] attempted to contact the DHB sexual health service (SHS) on 3 [Month5] ... but was unsuccessful. She accessed on-line information (CDC) and on 4 [Month5] recorded treatment information she had obtained which was a single dose of long-acting intramuscular penicillin for primary, secondary or early latent syphilis, or three doses of long-acting intramuscular penicillin at weekly intervals for late latent syphilis or latent syphilis of unknown duration. She prescribed the longer course initially and this was ordered by the pharmacy on 5 [Month5], arriving on 6 [Month5] from [DHB2 region]. The first injection was administered by a nurse on 6 [Month5] at which stage further information was obtained that [Mr A] had been recently overseas. On 11 [Month5] [Mr A] communicated with [Dr E] via e-mail presenting his syphilis serology result from [Month1] which he had obtained from the ... SHS (negative serology) and asking if he still needed the three doses of penicillin. [Dr E] responded later that day stating she had checked with an infectious diseases specialist and confirmed a single dose of penicillin was sufficient for [Mr A's] presentation. The medical centre response confirms an appointment was made on 4 [Month5] for [Mr A] to receive his first penicillin injection on 6 [Month5] allowing time for the medication to be transported from [DHB2].

4. There may be some issues with regard to timeliness and content of communication with [Mr A] regarding his diagnosis but further information is required. I suggest further information is obtained directly from [Dr E]:

(i) please confirm the process for reviewing of results ordered on your behalf by nursing staff

All results come via EDI into [Dr E's] virtual in-box. Tests ordered by nurses are placed in nursing task list and reviewed by the nurse concerned, and brought to the attention of [Dr E] if required. [Dr E] eventually views all results and results are *filed when the investigation or treatment is complete*. I have assumed from these comments that the provider (practice nurse or GP) requesting the test is responsible for reviewing the result initially, but [Dr E] takes ultimate responsibility for ensuring appropriate management has been provided. The response notes there is no record that [RN D] set any formal tracking task for [Mr A's] swab results (since retracted, see section 3(iii)).

(ii) please audit your inbox and confirm when the results of [Mr A's] syphilis serology were received at [the medical centre] and when they were reviewed by yourself or any other provider

The auditing process with the [medical centre] PMS does not allow ready identification of when the results in question were read and filed.

(iii) please confirm when you first became aware that [RN D] had seen a patient with possible primary syphilis, and what actions you took on learning this information

[Dr E] recalls either practice nurse [RN D] or [RN F] informing her of the possible case of syphilis sometime between 20–23 [Month4]. [Dr E] initially looked for the serology result on 23 [Month4] (although she does not state if she saw it on that date).

(iv) please confirm when you first became aware of [Mr A's] positive syphilis serology (if not covered above) and what actions you took on becoming aware of this result. In particular, was there any discussion between yourself and [RN D] regarding the result and planned management before it was conveyed to [Mr A]?

[Dr E] states she became aware of the positive serology result 'when dealing with incoming results on a day off and arranged treatment the following day. I arranged for another Practice Nurse to treat [Mr A] as [RN D] was on annual leave that week and there was no discussion with [RN D] at that time'. The date [Dr E] became aware of [Mr A's] positive syphilis serology remains unstated but appears to be around Monday 3 [Month5] (... [RN D] was on leave the remainder of that week). I must assume therefore that there was no discussion between [RN D] and [Dr E] of the positive syphilis serology on 30 [Month4] when the result was conveyed to [Mr A] (by [RN D]) a week after it had been received at [the medical centre], and it was a further three days (now 10 days since receipt of the result) that the result was reviewed by [Dr E] and treatment initiated. The delays in notification of [Mr A] of his result and involvement of [Dr E] in order to initiate appropriate treatment are unacceptable and I feel represent at least a mild to moderate departure from accepted practice. I am unable to establish if the reason for the delays was a result of failure by [RN D] to follow [the medical centre] results management processes and policies, or whether the results management policy is deficient. I recommend [the medical centre] review their current results management policy and process in light of these events and provide the Commissioner with a copy of the policy (with any revisions undertaken following review) with reference to how the policy is designed to prevent incidents such as delayed receipt, review or actioning of significant results. This should include reference to how results ordered by a specific provider are reviewed in a timely manner if that provider is on leave or absent for other reasons. It is not satisfactory for an in-box to be reviewed when the provider 'has time' (ie an unstructured process) because of the risk of potentially time-critical or other significant results not being actioned in a timely manner (as has occurred in this case), particularly when such results are not tracked.

[The medical centre] response dated 30 June 2020 states the Centre did not have a written policy for management of test results at the time of the events in question. A satisfactory policy, dated 15 June 2020, has since been provided. I am unsure if [the medical centre] is Cornerstone accredited or has the more basic (but compulsory) Foundation Standard³ accreditation. Indicator 28 of the Standard notes the practice must have an effective system for the management of clinical correspondence, test results, urgent referrals and other investigations which includes (Criteria 23.1) 'There is a policy describing how laboratory results, imaging reports, investigations and clinical correspondence are managed'. While the Standard does not specify the policy must be written, in my experience it is accepted practice there is a <u>written</u> policy which is of even greater importance when there is some reliance on locum clinicians as at



³ <u>https://www.rnzcgp.org.nz/gpdocs/Foundation-Standards-Interpretation-Guide-APR-2016.pdf</u> Accessed 21 September 2020

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[the medical centre]. While I cannot establish that the failure to have a written policy for management of results contributed to the oversights in this case, I believe the absence of a suitable written policy at the time of the events in question represents a mild departure from accepted practice. The medical centre response describes the process currently used: [Dr E] reviews all results daily, prioritising those flagged by the laboratory as abnormal and actioning these as appropriate. 'Routine' results are viewed as time permits. [Mr A's] syphilis serology result was not flagged as abnormal (this issue has subsequently been brought to the attention of the laboratory but the outcome is not clear) and, in the absence of [RN D] tracking the results as he was expected to do, the abnormal result was not detected by [Dr E] until 3 [Month5] when she was reviewing 'routine' results. I would expect results which could be time critical, or where there is a high degree of suspicion for abnormality, to be tracked with high importance. All results flagged as abnormal should be promptly reviewed and actioned accordingly. I would expect 'routine' results to be reviewed by a clinician (GP or practice nurse) within a week of receipt as was done in this case. On reflection, it does appear that had [RN D] followed the accepted (verbal) [medical centre] process for tracking and reviewing of potentially significant results, and communicated with [Dr E] earlier regarding [Mr A's] likely diagnosis, the delay in [Mr A] receiving timely treatment for his syphilis would not have occurred. The 'back-up' process in place, of [Dr E] reviewing daily all results flagged as abnormal, failed on this occasion because of technical issues with the laboratory and work is being done on resolving this issue. [The medical centre] have outlined a number of additional remedial measures taken since [Mr A's] complaint which should improve both general management of results and specifically the management of sexual health issues by practice staff.

(v) are you able to confirm whether [Mr A] was contacted proactively on 30 [Month4] to convey his positive syphilis serology, or whether he called because he was concerned he had yet to be notified of the result?

[Mr A] phoned for the results on 30 [Month4]. Blood results were provided to him (swab results still awaited) and he was advised to notify any sexual partners.

(vi) please confirm that you notified the relevant public health authority of [Mr A's] diagnosis of syphilis on 27 [Month5]?

[Dr E] confirms notification was made on 27 [Month5] and responds: It took some time as there was not a clear path to do this and only became available on the 1st [Month4] via communication with [DHB2] via fax (copy provided). I have reviewed the communication from the [DHB1] community and public health service and note the process for notification (which must be anonymous) was unclear at the time of the events in question and subsequently a process facilitating notification on receipt of a relevant positive test result has been implemented.

(vii) at any stage prior to [Mr A] receiving his first dose of penicillin on 6 [Month5] did you discuss his diagnosis and planned management directly with him?

[Mr A] preferred to use [the sexual health clinic] and attended [the medical centre] only when he could not reach them. The only consultation with [Dr E] over this period was via e-mail.

(viii) please confirm when you first successfully obtained local sexual health service specialist advice regarding [Mr A's] management

There was no locally available specialist advice and [Dr E] contacted the infectious diseases department at [DHB2] on 11 [Month5].

(ix) did you formally refer [Mr A] to any specialist sexual health service in regard to treatment or monitoring of his syphilis following confirmation of his diagnosis in [Month4]? If not, what was your intended surveillance plan following his treatment on 6 [Month5] and was this communicated to him (including advice on isolation period (avoidance of sexual exposure)? Were recalls set for follow-up serology?

[Mr A] presented on 6 [Month5] for his penicillin treatment and showed the attending nurse (per mobile phone) communication he ([Mr A]) had received from the [DHB2] sexual health service with a management plan. However, this was not documented. Recalls were set up in relation to the initial treatment plan but were deleted once it was established a single dose of penicillin was to be used. Serological follow-up was to be undertaken through the [DHB2] sexual health service.

5. [The medical centre] received a request from the [DHB2] SHS on 15 Month8 for clinical notes and these were provided the same day. [The medical centre] does not receive correspondence from the SHS. On 28 [Month1] [Mr A] presented to [the medical centre] for wart cryotherapy and expressed a concern he may have re-contracted syphilis. An appointment was arranged with the SHS. The reinfection was apparently confirmed and treated and on 24 [Month12] [Mr A] e-mailed [Dr E] asking if he could have his serology rechecked sooner than the three months evidently recommended by the SHS as he was unhappy he had to be abstinent until cure was confirmed. [Dr E] provided CDC information (local recommendations are included in appendix 3) but agreed to [Mr A's] test for earlier repeat serology with the proviso the results may be inconclusive. Bloods were taken on 30 [Month12] (syphilis serology). [Mr A] phoned on 2 [Month13] seeking the result. Nursing staff could not see any result on the practice or community lab database. [Mr A] was advised by [a nurse] that the tests were done in batches and he (the RN) would monitor the results coming in. A task was set to this effect and [the nurse] states he monitored this on a semi regular basis. On the 15th [Month13] I contacted the manager of [DHB1] Laboratories as it was day 17 and still no results (there is an entry in the notes confirming this action). [The medical centre] undertakes a weekly audit of lab results to ensure timely receipt of results and I have reviewed the relevant process document which appears consistent with accepted practice. The delay in receipt of [Mr A's] results had been highlighted at the end of week one and when not received by the time of the second weekly audit (13 [Month13]) a



fax had been sent to the laboratory notifying them of the situation. The [Medical Laboratory 2] response confirms there had been an internal error which was rectified on their being notified of the delay although this was not conveyed to [the nurse] (he was just told the analysis was yet to be completed). The result was received on the evening of 19 [Month13] and conveyed to [Mr A] the next day.

Comment: I believe [Mr A's] management by [the medical centre] during 2019 was consistent with accepted practice. There was cooperation with the DHB SHS and infectious diseases service in relation to [Mr A's] management. [Dr E] provided [Mr A] with appropriate information and advice and facilitated his request for early repeat of syphilis serology following treatment. The delay in receiving the serology result was out of the control of [the medical centre], and in-house processes were followed appropriately to track the result. Consideration might have been given to notifying the laboratory after the one-week (rather than two-week) audit given [Mr A's] level of anxiety regarding the result, but the result was non-urgent/non-critical from a clinical perspective and I believe [the medical centre's] management in this regard was satisfactory.

4. Complaint regarding [Dr B] and [DHB1] Sexual Health Service

(i) [Dr B] would be regarded as a GP with special interest (GPSI) in sexual health. As such, there would be higher expectations for her to manage a sexual health check in accordance with recommended best practice (as per cited NZSHS guidance) than for a GP without a special interest or expertise in this area.

(ii) [Mr A's] clinical notes dated 27 [Month1] refer to nil past sexual history of note but recent (within a week) unprotected receptive anal intercourse with a male partner and his request for HIV testing. [Mr A] also noted he had some anal symptoms (pain and bleeding) which he attributed to haemorrhoids. There is no reference to contact with known syphilis sufferer or presence of any penile lesion suspicious for primary syphilis infection. [Mr A] was seen by a nurse on 27 [Month1] and preliminary tests undertaken. He was reviewed by [Dr B] on 10 and 24 [Month2] for follow-up. It does not appear all components of a sexual health check were undertaken as per NZSHS guidance (including no genital or anal examination to check for signs of primary syphilis infection). [Dr B] has acknowledged this in her response.

(iii) The issue of repeat serological testing is a little more complex. The pathologist comment accompanying [Mr A's] negative syphilis EIA result dated 27 [Month1] was: *No serological evidence of contact with treponemes. If primary infection is suspected please repeat serology in 2 weeks.* If there was no clinical suspicion of primary syphilis infection and no history of known contact with syphilis, recommended practice is to repeat the serology in three months (which was done but via the GP as discussed in the previous section). There was a missed opportunity to repeat syphilis serology at six weeks when HIV serology was being repeated but it cannot be stated categorically that this would have indicated [Mr A's] current syphilis infection given the variable incubation period (10–90 days but average 3 weeks) but it may well have done so, presumably leading to appropriate treatment and avoidance of progression of the



disease. In the absence of an appropriate examination it was not possible for [Dr B] to assume [Mr A] had no sign of primary syphilis (chancres are painless ulcers) although in hindsight it seems unlikely a physical examination on 10 [Month2] would have raised such suspicion.

(iv) I think it is clear there were deficiencies in [Dr B's] management of [Mr A] and her response acknowledges this and outlines a number of remedial measures which appear appropriate. However, I think any quantification of degree of departure from accepted practice, and any other recommendations regarding processes at the [DHB1] SHS, would be most appropriately made by a sexual health specialist (given this was a specialist service being provided). An appropriate specialist ... would be ...

5. Complaint [Medical Laboratory 2]

The response acknowledges there were clerical errors which resulted in delays processing [Mr A's] syphilis serology in [Month12]/[Month13], and in detection and correction of the error. It seems appropriate remedial measures have been undertaken and I am not sure the process deficiencies identified would meet the threshold for further investigation or whether any additional relevant information would be obtained from further investigation. The delay in processing of the sample was not consistent with accepted practice and proved inconvenient for [Mr A] but it did not result in any physical harm on this occasion.



Names have been removed (except the experts who advised on this case) to protect privacy. Identifying letters are assigned in alphabetical order and bear no relationship to the person's actual name.

Image 1 — Interpreting syphilis serology⁴

Interpreting syphilis serology

Syphilis serology results should be interpreted within the overall clinical picture, i.e. clinical examination, patient history and risk profile. Table 1 may be useful in aiding interpretation.

Table 1: Interpreting syphilis serology

EIA	TPPA	RPR	Interpretation
Non- Reactive	Not tested	Not tested	No evidence of syphilis, or too early, retest in one month if strong suspicion based on clinical evidence
Reactive	Non- Reactive	Non- Reactive	Possible early primary, latent or false-positive, retest in one month
Reactive	Non- Reactive	Reactive	Probable early primary, false positive possible but unlikely, retest in two weeks
Reactive	Reactive	Non- Reactive	Evidence of past infection or possible latent infection, history will help to differentiate
Reactive	Reactive	Reactive	Current syphilis

EIA, TPPA and RPR results are expressed as "reactive" or "non-reactive". RPR results also include a titre, with higher titres indicating greater disease activity. N.B. People who have had a past treponemal infection, including non-venereal infections such as yaws, will remain reactive on specific treponemal tests for their lifetime.^{7,14}

⁴ From: BPAC. Syphilis: testing for 'the great imitator'. Best Tests. June 2012. https://bpac.org.nz/BT/2012/June/06_syphilis.aspx Accessed 25 February 2020



Names have been removed (except the experts who advised on this case) to protect privacy. Identifying letters are assigned in alphabetical order and bear no relationship to the person's actual name.

Image 2⁵

Sexual Health Check

MANAGEMENT SUMMARY

Test all sexually active persons < 30 years and anyone at risk. See Express STI Testing Questionnaire <u>www.nzshs.org/guidelines</u>. Be aware of the difference between a Nucleic Acid Amplification Test (NAAT) swab (e.g. PCR) and a culture swab.

Note: Most laboratories are automatically performing multiplex NAAT testing for chlamydia & gonorrhoea (+/-trichomoniasis). False positive gonorrhoea results are possible in low prevalence populations – see NZSHS Management of Gonorrhoea 2017, and Response to the Threat of Antimicrobial Resistance <u>www.nzshs.org/guidelines</u>.

Recommended tests – Females

- Asymptomatic and/or opportunistic testing
 Offer examination including speculum.
- Vulvovaginal NAAT swab for chlamydia & gonorrhoea testing (self-collected if not
- Anorectal NAAT swab for chlamydia & gonorrhoea testing if patient has anal sex
- or anorectal symptoms (self-collected if not examined).
 Serology: Universal HIV and syphilis.
- Targeted hepatitis B and C serology if hepatitis B immune status unknown and risk factors present e.g. Maori, Pasifika, areas of high endemicity, IDU or incarceration www.hepatitisfoundation.org.nz/

Symptomatic

Examination is required for clinical assessment if symptomatic of vaginal discharge, dysuria, lower abdominal pain, abnormal bleeding, anal pain or discharge, or a contact of gonorrhoea:

- Examine the inguinal nodes, vulval and perianal skin, vestibule and introitus.
- Vulvovaginal NAAT swab for chlamydia & generiches tecting prior to chegulum insertio
- gonorrhoea testing prior to speculum insertion. Insert speculum and examine vagina and cervix.
- Endocervical culture swab for gonorrhoea (if gonorrhoea culture available).
- High vaginal culture swab for candida & BV & trichomoniasis (if NAAT for trichomoniasis not available).
- Anorectal NAAT swab for chlamydia & gonorrhoea testing if patient has anal sex or anorectal symptoms.
- Serology: Universal HIV and syphilis.
 Targeted hepatitis B and C serology if hepatitis
- B immune status unknown and risk factors present e.g. Maori, Pasifika, areas of high endemicity, IDU or incarceration www.hepatitisfoundation.org.nz/

Recommended tests – Men who have sex with women (MSW) Asymptomatic and/or opportunistic testing

- Offer examination, as below.
- First void urine for chlamydia & gonorrhoea NAAT testing (first 30ml), preferably ≥1 hour after last void.
- Serology: Universal HIV and syphilis.
- Targeted hepatitis B and C serology if hepatitis B immune status unknown and risk factors present e.g. Maori, Pasifika, areas of high endemicity, IDU or incarceration <u>www.hepatitisfoundation.org.nz/</u>

Symptomatic

Examination is required for clinical assessment if symptomatic of urethral discharge, dysuria, testicular pain or swelling, anal pain or discharge or a contact of gonorrhoea.

- Examine the genital and perianal skin, inguinal lymph nodes, penis, scrotum, and testes.
- Urethral culture swab for gonorrhoea (if gonorrhoea culture available) followed by:
- First void urine for chlamydia & gonorrhoea NAAT testing (first 30ml), preferably ≥1 hour after last void.
 Serolover Universal HV and symbilis
- Serology: Universal HIV and syphilis.
- Targeted hepatitis B and C serology if hepatitis B immune status unknown and risk factors present e.g. Maori, Pasifika, areas of high endemicity, IDU or incarceration <u>www.hepatitisfoundation.org.nz/</u>

Recommended tests – Men who have sex with men (MSM)

- All MSM should be tested at least once a year.
 Extragenital (pharyngeal and anorectal) testing is required irrespective of reported sexual practices or condom use.
- Pharyngeal NAAT swab for chlamydia & gonorrhoea testing.
- Anorectal NAAT swab for chlamydia & gonorrhoea testing (self-collected if not examined).
- First void urine for chlamydia & gonorrhoea NAAT testing (first 30ml), preferably ≥1 hour after last void.
- If anorectal symptoms refer or discuss with a sexual health specialist
 Combined by the section of P (if board in a section of P)
- Serology: Universal HIV, syphilis, hepatitis A and B (if hepatitis A and B immune status unknown).

Targeted hepatitis C if HIV positive, IDU or incarceration.

MSM who fall into one or more categories below require testing up to 4 times a year:

- Any unprotected anal sex
- More than 10 sexual contacts in 6 months
- Participate in group sex
- Are HIV positive
 Use of PrEP or PEP
- Use recreational drugs during sex.

30 November 2021



Names have been removed (except the experts who advised on this case) to protect privacy. Identifying letters are assigned in alphabetical order and bear no relationship to the person's actual name.

⁵ From: NZSHS STI Management Guidelines for use in primary care 2017. <u>https://www.nzshs.org/guidelines</u> <u>Accessed 19 February 2020</u>

Image 3⁶

Syphilis

MANAGEMENT SUMMARY

TEST IF

- · MSM (at least annually, but ideally with every sexual health check)
- · HIV positive (at least annually, but ideally with every sexual health check)
- Routine antenatal screen; consider rescreening in later pregnancy if partner change
- Routine immigration screen
- · A sexual contact of a person with syphilis
- · Routine sexual health check

Signs or symptoms of infectious syphilis:

- Genital ulcers (see Genital Ulcer Disease summary <u>www.nzshs.org/guidelines</u>)
- MSM with any genital symptoms or rash
- Any rash affecting the palms of the hands or soles of the feet, or that is persistent or unexplained
- Pyrexia of unknown origin, unexplained persistent lymphadenopathy, unexplained liver function disturbance, alopecia

RECOMMENDED TESTS

- Syphilis serology if clinical suspicion of infectious syphilis specify on laboratory form
- HIV serology
- Routine STI tests (see Sexual Health Check guideline <u>www.nzshs.org/guidelines</u>)
- In MSM also request hepatitis A and B serology, unless known to be immune
- · In persons with a history of IDU, incarceration, or who use recreational drugs during sex, request hepatitis C serology

Refer or discuss with a sexual health specialist if high index of suspicion of infectious syphilis (e.g. symptoms and/or signs, or contact of index case), or if pregnant. It is recommended to discuss all positive syphilis serology with a sexual health specialist.

MANAGEMENT

- Advise to refrain from any sexual activity until assessed or discussed with a specialist service
- Do not use/prescribe any topical agents or oral antibiotics for genital ulcers
- Patients being treated for infectious syphilis should have syphilis serology repeated on the day treatment is commenced to provide an accurate baseline for monitoring treatment
- It is important that any intramuscular penicillin formulation used should be long-acting Bicillin LA (benzathine penicillin) 1.8g, as short-acting formulations are insufficient for syphilis treatment. Treatment should ideally be given at a sexual health service.

PARTNER NOTIFICATION AND MANAGEMENT OF SEXUAL CONTACTS

- Referral or discussion with a sexual health specialist or service is strongly recommended
- Be clear about language: 'partner' implies relationship
- All sexual contacts within the intervals below should be dinically and serologically evaluated

Infectious syphilis

- Primary syphilis: 3 months plus duration of symptoms. Empiric treatment for syphilis is recommended, as serology may be negative
- Secondary syphilis: 6 months plus duration of symptoms
- Early latent syphilis and syphilis of unknown duration where RPR ≥ 1:32: 12 months
- Late latent syphilis, syphilis of unknown duration with low RPR and tertiary syphilis
- Serologic evaluation of current or last sexual contact and/or serologic evaluation of children if index case is female

FOLLOW-UP

- Infectious syphilis
 Repeat serology at 3, 6 and 12 months
- Serological cure is defined by consistent four-fold (2 dilutions) drop in RPR titre
- Failure of RPR titre to decrease fourfold (2 dilutions) within 12 months indicates treatment failure re-evaluation is necessary
- A subsequent four-fold (2 dilution) rise in RPR titre is an indication of re-infection re-evaluation is necessary

Late latent syphilis and tertiary syphilis (excluding neurosyphilis)

- Repeat serology at 6 and 12 months to ensure remains serofast
- · Fourfold (2 dilutions) increase in titre indicates either treatment failure or re-infection re-evaluation is necessary

HX

Appendix D: Relevant standards

The NZSHS's "Sexual Health Check Management Guidelines" (September 2017) stipulate:

"Recommended tests — Men who have sex with men (MSM)

- Extragenital (pharyngeal and anorectal) testing is required irrespective of reported sexual practices or condom use.
- Pharyngeal NAAT swab for chlamydia & gonorrhoea testing.
- Anorectal NAAT swab for chlamydia & gonorrhoea testing (self-collected if not examined).
- First void urine for chlamydia & gonorrhoea NAAT testing (first 30ml), preferably >1 hour after last void.
- If anorectal symptoms refer or discuss with a sexual health specialist.
- Serology: Universal HIV, syphilis, hepatitis A and B (if hepatitis A and B immune status unknown).

...

...

Note: If person is asymptomatic and is concerned about a specific recent sexual event — the recommended testing interval is 2 weeks from time of last sexual intercourse."

The NZSHS guidelines on the management of syphilis (September 2017) stipulate:

"TEST IF

- MSM (at least annually, but ideally with every sexual health check)
- HIV positive (at least annually, but ideally with every sexual health check)
- Routine antenatal screen; consider rescreening in later pregnancy if partner change
- Routine immigration screen
- A sexual contact of a person with syphilis
- Routine sexual health check

Signs or symptoms of infectious syphilis:

- Genital ulcers (see Genital Ulcer Disease summary www.nzshs.org/guidelines)
- MSM with any genital symptoms or rash
- Any rash affecting the palms of the hands or soles of the feet, or that is persistent or unexplained

•••

RECOMMENDED TESTS

• Syphilis serology — if clinical suspicion of infectious syphilis specify on laboratory form



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⁶ From: NZSHS STI Management Guidelines for use in primary care 2017. <u>https://www.nzshs.org/guidelines</u> <u>Accessed 25 February 2020</u>

- HIV serology
- Routine STI tests (see Sexual Health Check guideline www.nzshs.org/guidelines)
- In MSM also request hepatitis A and B serology, unless known to be immune

•••

Refer or discuss with a sexual health specialist if high index of suspicion of infectious syphilis (e.g. symptoms and/or signs, or contact of index case), or if pregnant. It is recommended to discuss all positive syphilis serology with a sexual health specialist.

MANAGEMENT

- Advise to refrain from any sexual activity until assessed or discussed with a specialist service
- Do not use/prescribe any topical agents or oral antibiotics for genital ulcers
- Patients being treated for infectious syphilis should have syphilis serology repeated on the day treatment is commenced to provide an accurate baseline for monitoring treatment
- It is important that any intramuscular penicillin formulation used should be longacting Bicillin LA (benzathine penicillin) 1.8g, as short-acting formulations are insufficient for syphilis treatment. Treatment should ideally be given at a sexual health service.

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FOLLOW-UP

Infectious [early stage] syphilis

- Repeat serology at 3, 6 and 12 months
- Serological cure is defined by consistent four-fold (2 dilutions) drop in RPR titre
- Failure of RPR titre to decrease fourfold (2 dilutions) within 12 months indicates treatment failure re-evaluation is necessary
- A subsequent four-fold (2 dilution) rise in RPR titre is an indication of re-infection re-evaluation is necessary"

