Medical Centre

General Practitioner, Dr B

A Report by the

Health and Disability Commissioner

(Case 18HDC00918)

Health and Disability Commissioner

Te Toihau Hauora, Hauātanga

Contents

Executive summary

1. On 8 May 2018, Mrs A presented to a medical centre for an appointment with general practitioner (GP) Dr B, to receive the flu vaccine.

2. When Dr B took the vaccine from the practice's vaccine fridge, he did not check the contents of the syringe visually, or ensure that the plunger was not already decompressed. He proceeded to administer the vaccine to Mrs A.

3. After administering the vaccine, Dr B realised that the syringe he had used was already empty and had no label, and that the plunger was fully decompressed prior to administration. He explained to Mrs A that either the injection may have been faulty, or it had already been used on an earlier patient.

4. Mrs A then asked Dr B to continue with the appointment, and a second successful flu vaccine was administered. However, there is no record of either vaccine in Mrs A's PMS immunisation module or clinical records.

5. The failed vaccine was treated as a needle-stick injury, and Mrs A underwent serological testing for transmissible diseases.

Findings

6. The Commissioner found that by failing to check the flu vaccine visually before it was administered to Mrs A, Dr B did not provide Mrs A services with reasonable care and skill, and breached Right 4(1) of the Code of Health and Disability Services Consumers' Rights (the Code). In addition, by failing to document the required information for both flu vaccines, Dr B did not provide services to Mrs A that complied with relevant standards, and breached Right 4(2) of the Code.

7. The Commissioner found that the medical centre did not breach the Code.

Recommendations

8. The Commissioner recommended that Dr B:

   a) Provide a written letter of apology to Mrs A;

   b) Provide HDC with an audit of his clinical documentation, to check whether consent for vaccination is being recorded appropriately; and

   c) Undertake training on vaccine administration, and provide HDC with his reflections and learnings from the training.

Complaint and investigation

9. The Health and Disability Commissioner (HDC) received a complaint from Mrs A about the services provided by Dr B and the medical centre. The following issues were identified for investigation:

- *Whether Dr B provided Mrs A with an appropriate standard of care in May 2018.*
- *Whether the medical centre provided Mrs A with an appropriate standard of care in May 2018.*

10. The parties directly involved in the investigation were:

Mrs A	Consumer
Dr B	Provider/general practitioner (GP)
Medical centre	Provider

Also mentioned in this report:

Dr C	Medical centre director
Ms D	Medical centre practice manager

11. In-house clinical advice was obtained from Dr David Maplesden, general practitioner, and is included as Appendix A.

Information gathered during investigation

Introduction

12. On 8 May 2018, Mrs A presented to the medical centre for an appointment to receive cryotherapy[1] of solar keratosis[2] on her top lip, and a routine flu vaccine. Mrs A's appointment was booked with General Practitioner (GP) Dr B.[3]

13. This report concerns the administration of the flu vaccine to Mrs A by Dr B.

Administration of flu vaccine

14. On arrival, Mrs A had a discussion with a staff member who advised that the flu vaccine injection would be administered prior to the cryotherapy, to account for the 20-minute waiting time after the vaccine. Dr B obtained the vaccine from the practice's vaccine fridge, and then returned to the consultation room and administered the vaccine into Mrs A's right deltoid.[4]

[1] The use of extreme cold produced by liquid nitrogen to destroy abnormal tissue.
[2] A rough, scaly patch on the skin caused by years of sun exposure.
[3] Dr B is a general practitioner with an annual practising certificate from the Medical Council of New Zealand.
[4] A large muscle located at the uppermost part of the arm, at the shoulder.

15. Mrs A stated that after the vaccine had been administered, she heard Dr B say, "Oh it's empty! Oh God," before leaving the room. After checking the packet from which the vaccine had been taken, Dr B returned to the consultation room and explained that the syringe he had used had been empty and had no label on it. He informed Mrs A that either the injection may have been faulty, or it had already been used on an earlier patient.

16. Dr B told HDC that he discovered his error after the needle had been inserted, when he noticed that the plunger of the syringe may have already been fully depressed, and the syringe was already empty prior to administration. Dr B stated that his usual practice is to check a vaccine visually before administering it, but he acknowledged that at the time of this event he was in a rush and omitted to double-check the syringe.

Second flu vaccine

17. Mrs A asked Dr B to continue with the consultation she had come for, and informed HDC that she received a second, successful vaccine from Dr B.

18. Dr B agrees that Mrs A asked that he continue with the consultation, but "cannot recall" whether a second flu vaccine was administered to Mrs A. He informed HDC that his usual practice is to record the administration of a flu vaccine in both the clinical documentation and the PMS[5] immunisation module. As there is no documentation, Dr B thinks it unlikely that Mrs A was given a second vaccine, but he cannot be certain.

19. There is no documentation in Mrs A's clinical record or PMS immunisation module of consent having been obtained, the date on which the vaccine was administered, the vaccine type and number, the batch number and expiry date, the needle length, or patient observations for a flu vaccine being administered on this day.

The medical centre's Flu Vaccine Practice Guideline

20. At the time of events, the medical centre had a Flu Vaccine Practice Guideline in place, which outlined the process of checking the integrity of the vaccine prior to administration. The guideline stated:

> "Check the integrity of the vaccine/syringe before using including but not limited to:
>
> - Amount and [clarity] of vaccine in the barrel
> - Needle cap fully intact
> - Plunger not depressed
> - Within expiry date
>
> …
>
> Procedure:
>
> …
>
> - If no consent form is used, record consent in the notes
> - Once removed <u>do not</u> return a flu vaccine to a box

[5] Practice Management System.

…

- Position the sharps container near the patient so that the syringe may be disposed of immediately after use.

…

Any discrepancy with a vaccine:

- Immediately report to Practice Manager

…

- 'if in doubt do not use'
- Follow health pathways 'needle stick injury' extra information regarding blood or body fluid exposures, chronic Hep C, PPE, using sharps safely and waste management."

21. The medical centre's director, Dr C, informed HDC that this guideline is specific to the practice, and that all employees are given a copy to ensure that they are aware of the guideline.

22. Dr B informed HDC that he was aware of the medical centre's Flu Vaccine Practice Guidelines at the time of the incident.

Follow-up actions

23. As it could not be determined whether the vaccine had been used previously, or if it was faulty, Dr B managed the incident as a needle-stick injury.[6] As such, he followed the "Blood or body fluid exposure" Health Pathway as stipulated in the Flu Vaccine Practice Guidelines.

24. Upon discovery of his error, Dr B apologised to Mrs A and informed her that he would telephone the on-call infectious diseases consultant for guidance on the next steps.

25. On the advice of the on-call infectious diseases consultant, serological testing for blood transmissible diseases such as Hepatitis B, Hepatitis C, and HIV was requested that day, and a Hepatitis B vaccine was administered three days later. An ACC form was completed on Mrs A's behalf, along with an Occupational Health and Safety accident form.

26. The medical centre's practice manager, Ms D, told HDC that ongoing support was provided to Mrs A subsequent to this incident, and that a meeting was held on 16 May 2018 as part of the support and resolution process.

Further information

Dr B

27. Dr B told HDC that he "deeply regrets" that during his care of Mrs A he did not meet the high standard of care toward which he strives. He apologised unreservedly for not double-checking the vaccine prior to using it, and for the upset and distress that Mrs A suffered as a result.

[6] A wound caused by a needle that accidentally punctures the skin.

28. Dr B said that following the incident he spent considerable time familiarising himself with the Flu Vaccine Practice Guidelines and procedures for administrating vaccines. He now ensures that he follows the guidelines strictly, including checking the vaccine prior to administering it.

29. Dr C told HDC that normally the details of the relevant vaccine would be documented in the patient's clinical notes, but that on this occasion it was not done, as Dr B did not believe that he had administered the empty vaccine successfully.

The medical centre

30. Ms D informed HDC that the incident was discussed at a clinical meeting the following day. The meeting minutes record: "[I]t was clear from the responses from the Doctors/Nurses that no one would return a used needle into the immunisation fridge." The Flu Vaccine Practice Guidelines state that once removed, a vaccine is not to be returned to the box. The Guidelines also stipulate that syringes are to be disposed of in a sharps container "immediately" after use.

31. The medical centre subsequently contacted its vaccine supplier and provided it with the empty/used syringes. The supplier sent the syringes to its manufacturer for investigation. The manufacturer reviewed all of the batch documentation, and confirmed that aside from an issue with the labels not adhering completely to individual syringes, the batch complied with all of the relevant specifications. The manufacturer explained that a camera system in place rejects any faulty syringes, and that the system is inspected regularly to ensure that such defects are detected. The manufacturer was unable to identify a manufacturing-related cause for the incident.

32. Ms D stated that the medical centre reviewed its practice guidelines in response to the incident, to minimise the risk of such an event happening again. She noted that the matter has been discussed across the practice, and that if any staff were to come across a faulty syringe again, they would recognise it. Further education was also provided to the medical centre employees, to ensure that vaccine barrels are double checked. Dr C told HDC that it is common practice at the medical centre for GPs to administer flu vaccines, and that the practice administers approximately 1100 flu vaccines a year. He stated that in his 30 years at the practice, he cannot recall another incident such as this ever occurring.

33. Dr C acknowledged that Dr B was remiss in not double-checking the vaccine prior to use. However, Dr C believes that subsequent to the incident, the medical centre acted in a responsible manner.

Responses to provisional opinion

34. Mrs A was provided with an opportunity to comment on the "information gathered" section of the provisional opinion, and stated:

> "The only comment is that I am very disappointed with how I was treated as a person. The practice addressed their practice standards but as a patient, nothing was done to address my anxiety/stress caused by the needle stick injury in the first instance."

35. The medical centre was also provided with an opportunity to comment on the provisional opinion, and stated that the findings of no systems or organisational issues were "very reassuring". Dr C reiterated how regretful the practice is for this incident, and sincerely apologised again "for any upset and distress this caused to [Mrs A]".

36. Dr B was also provided with an opportunity to comment on the relevant sections of the provisional opinion. He accepts that there were deficiencies in the care that he provided to Mrs A on 8 May 2018, and stated that he remains very sorry for these deficiencies. He also accepts the criticisms of my expert advisor, Dr Maplesden, and advised that he has amended his practice accordingly.

Relevant standards

37. The Ministry of Health's "Immunisation Standards for Vaccinators" section of the *Immunisation Handbook 2017* (Immunisation standards) sets the quality levels that all vaccinators should achieve to ensure that they can deliver safe and effective immunisation services competently. The standards apply to all vaccinators, and the term "vaccinator" applies to *any* health professional who offers a vaccinator service. The standards include the following:

> "**Standard 2: The vaccinator obtains informed consent to immunise.**
> …
> 2.5 Consent does not need to be given in writing … but the vaccinator must document in the clinical notes a summary of the discussion and note that verbal consent was obtained.
> …
>
> **Standard 3: The vaccinator provides safe immunisation**
> …
> 3.8 The vaccinator uses clean techniques in the preparation and administration of all vaccines, visually checks the vaccine, checks expiry date, prepares vaccine as appropriate and uses vaccines within the recommended period after preparation.
>
> **Standard 4: The vaccinator documents information on the vaccine(s) administered, and maintains patient confidentiality**
> …
> 4.3 Having chosen the appropriate immunisation schedule, the vaccinator documents the following details:
>
> - consent obtained
> - date vaccine administered
> - vaccine type and number in the series
> - batch number and expiry date
> - injection site (eg, 'right deltoid' not 'upper arm')

- needle length
- that the patient was observed for 20 minutes post-vaccine …"

Opinion: Dr B — breach

Introduction

38. As a health professional, it was Dr B's responsibility to ensure that the care he provided to Mrs A met acceptable standards. GPs are required to administer all medications in compliance with legislation, guidelines, and codes.

Failure to check vaccine visually

39. On 8 May 2018, Mrs A presented to the medical centre for an appointment with Dr B for the administration of a flu vaccine. Dr B did not check the vaccine syringe visually prior to administering the vaccine, and has acknowledged that he was required to do so.

40. Dr B acknowledged that at the time of the event he was aware of the medical centre's internal Flu Vaccine Practice Guideline. The Guideline specifies that the integrity of the vaccine must be checked prior to use, which includes checking the amount and clarity of the vaccine in the barrel, as well as making sure that the plunger of the syringe is not already depressed. The Guideline also states that if no consent form is used for the vaccination, the consent must instead be documented in the patient's clinical notes.

41. In addition, pursuant to standard 3, subsection 3.8 of the Ministry of Health's Immunisation standards, a vaccinator must check the vaccine visually before it is administered.

42. My expert advisor, Dr Maplesden, advised that Dr B's failure to check the vaccine visually before attempting its administration was a "potentially dangerous omission and represents a moderate departure from accepted practice".

43. In my view, there has been a clear (and acknowledged) departure from the accepted standard of care.

Documentation

44. I acknowledge that there are differing accounts about whether or not a second flu vaccine was administered on 8 May 2018. Mrs A told HDC that after the first unsuccessful flu vaccine attempt, she asked Dr B to continue with the consultation and was successfully administered a flu vaccine on the second attempt. However, Dr B stated that he cannot recall whether or not he gave Mrs A a second vaccine on this day. Dr B did not document anything about the administration of a flu vaccine in Mrs A's clinical notes, or in the PMS immunisation module. He stated that because of the lack of documentation, he thinks it unlikely that a second vaccine was administered; however, he cannot be certain. I have considered both Mrs A's and Dr B's accounts — Mrs A has a specific memory of the vaccine

being administered, and Dr B cannot recall whether or not he administered a second vaccine. I consider it more likely than not that a second, successful vaccine was administered to Mrs A on 8 May 2018.

45. Standard 4, subsection 4.3 of the Ministry of Health's Immunisation standards for vaccinators details the expected documentation that should accompany any administration of a vaccine. Documentation should include the consent obtained, the date on which the vaccine was administered, the vaccine type and number in the series, the batch number and expiry date, the injection site, the needle length, and that the patient was observed for 20 minutes post-vaccine.

46. Dr B did not document any of the vaccine details for either vaccine in Mrs A's clinical notes, or in the PMS immunisation module. Whilst I accept Dr C's explanation that Dr B did not document the first vaccine because he did not believe that it had been administered successfully, I would still expect the consent for this vaccine to have been documented as per the medical centre's Flu Vaccine Practice Guideline. Dr Maplesden regards the failure to record verbal consent to immunisation as a mild departure from best practice. He advised that if a flu vaccine was administered to Mrs A successfully on 8 May 2018, but was not documented in either the patient's clinical documentation or in the "immunisation" module of PMS, he would be moderately critical of Dr B's documentation. I accept Dr Maplesden's advice.

47. Dr B's documentation did not meet the requirements stipulated in the Ministry of Health's Immunisation standards, and I am critical of Dr B's lack of documentation for both vaccines.

Conclusion

48. In my view, Dr B failed to provide services to Mrs A with reasonable care and skill, by failing to check the flu vaccine visually before it was administered to Mrs A. As such, I find that Dr B breached Right 4(1) of the Code.[7]

49. Dr B failed to provide services to Mrs A that complied with relevant standards by failing to document that consent was obtained for both vaccines, as well as all other required documentation for the second vaccine. Accordingly, I find that Dr B also breached Right 4(2) of the Code.[8]

Opinion: medical centre — no breach

50. As a healthcare provider, the medical centre is responsible for providing services in accordance with the Code.

[7] Right 4(1) states: "Every consumer has the right to have services provided with reasonable care and skill."
[8] Right 4(2) states: "Every consumer has the right to have services provided that comply with legal, professional, ethical, and other relevant standards."

51. I am unable to determine whether the empty vaccine syringe was the result of a manufacturer error, or whether a staff member had returned a used syringe to the vaccine container. If the latter, I would be extremely concerned. I note that at the clinical meeting subsequent to the event, it was clear to Ms D that staff would not consider returning a used syringe to the immunisation fridge. The medical centre's Flu Vaccine Practice Guideline states that once removed, a vaccine is not to be returned to the box.

52. The Practice Guideline in place at the time of the incident also clearly required the integrity of the vaccine to be checked prior to administration, and for consent to be documented. Dr C informed HDC that each employee is given, and made aware of, these guidelines, and Dr B acknowledged that he was aware of the guidelines prior to the event. Dr Maplesden advised that the practice's guidelines appear to be consistent with accepted practice, and include requirements that would have prevented such an incident from occurring.

53. In addition, Dr C informed HDC that approximately 1100 flu vaccines are administered by the medical centre each year, and that this is the first incident of this sort in his 30 years at the practice.

54. In my view, the above factors indicate that the events of 8 May 2018 were due to an individual failure, and that no systems or organisational issues contributed. I consider that the medical centre did not breach the Code directly.

Recommendations

55. In accordance with the recommendations made in my provisional opinion, Dr B provided this Office with a written letter of apology to Mrs A for his breach of the Code.

56. Additionally, I recommend that Dr B:

a) Provide HDC with an audit of his clinical documentation, to check whether consent for vaccination is being recorded appropriately, within three months of the date of this report.

b) Participate in a course/training relevant to the issues raised in this case (vaccine administration), and provide HDC with his reflections and learnings from the course/training, within three months of the date of this report.

Follow-up actions

57. A copy of this report with details identifying the parties removed, except the expert 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.

58. A copy of this report with details identifying the parties removed, except the expert who advised on this case, will be placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

Appendix A: Independent advice to the Commissioner

The following expert advice was obtained from Dr David Maplesden, general practitioner:

"1. Thank you for providing this file for advice. To the best of my knowledge I have no conflict of interest in providing this advice. I have reviewed the available information: complaint from [Mrs A]; response from [Dr B]; response from practice manager [the medical centre]; clinical notes; minutes from meeting with practice staff and [Mrs A] on 16 May 2018; Flu Vaccine Practice Guidelines for [the medical centre]; response from [the vaccine supplier].

2. [Mrs A] states that on 8 May 2018 she attended [Dr B] at [the medical centre] to get a flu vaccination and cryotherapy to some lip lesions. [Dr B] went out of the consultation room and returned with a vaccine which he administered. [Mrs A] states that after inserting the needle into her skin, [Dr B] expressed concern the vaccine syringe was actually empty. He left the room to check the packet from which the vaccine had been taken. [Dr B] explained he would seek specialist advice regarding the possibility the vaccine he had administered had been used on another person although there may have been a manufacturing fault leading to the empty syringe. [Mrs A] was subsequently contacted by the practice and had blood tests and a hepatitis-B vaccination performed as a precaution. She has been in close contact with a nurse at the practice regarding her follow-up. [Mrs A] states in her complaint that prior to leaving the practice on 8 May 2018 she requested the vaccine she had actually come for. I am unable to establish if the flu vaccine was actually administered successfully on that date.

3. [Dr B] includes the following points in his response:

(i) Verbal consent was gained for the vaccination but [Dr B] did not double check the flu vaccine before administering it.

(ii) He openly disclosed the error to [Mrs A] and explained he would contact an infectious diseases specialist to get follow-up advice.

(iii) [Mrs A] was followed-up as per the advice received.

(iv) On checking the vaccination packages following the incident, it was noted there were two empty syringes in a partially used package and another empty syringe in an unused package (10 syringes per package). This led [Dr B] to consider a manufacturing error as the most likely cause of the empty syringe.

4. The practice manager response reiterates the actions taken by [Dr B] and practice staff since the incident and notes there has been a practice meeting regarding the incident and advice sought from the vaccine manufacturer. No staff member recalls placing an empty vaccine syringe back into the vaccine packet and their practice is always to dispose of the syringe and needle into a sharps container after the vaccination as per normal and expected process. [Mrs A] met with practice staff on 16 May 2018 as part of the support and resolution process.

5. Clinical notes for the consultation of 8 May 2018 refer to cryotherapy to lip lesions and discussion regarding lipid-lowering therapy. There is reference to right deltoid needlestick with a flu jab which I have reason to believe had been used on another patient. ACC forms were completed regarding the incident. Additional correspondence records confirm appropriate reporting of the incident, contact with the infectious diseases specialist and ongoing contact with [Mrs A]. I do not have a copy of the immunisation module records to confirm whether, if a flu vaccine was successfully administered on 8 May 2018, there was appropriate recording of vaccine details (site, batch number etc) and it is not apparent from the clinical notes supplied that a flu vaccine was successfully administered on that date.

6. The report from [the vaccine supplier] acknowledges there is an issue with vaccine labels not adhering completely to the individual syringe which might result in the label adhering to an adjacent syringe. However, they report the vaccine manufacturer has strict quality control procedures and the manufacturer is unable to determine how empty syringes might have been part of a supplied vaccine package.

7. The practice Flu Vaccine Practice Guidelines appear consistent with accepted practice and include the requirement to check the integrity of the vaccine before use including expiry date, contents, plunger not depressed and needle cap intact, and disposal of the vaccine into a sharps container once used.

8. Comments

(i) I do not think it is possible to determine unequivocally if the empty vaccine syringe was the result of a manufacturer error or if a staff member (unidentified) had returned a used syringe to the vaccine fridge/container. If it was the latter, this would be regarded as a significant departure from accepted practice.

(ii) The steps taken by [Dr B] and practice staff immediately following the incident and in the longer term are appropriate and consistent with accepted practice.

(iii) Any vaccinator is expected to comply with Ministry of Health immunisation standards for vaccinators (Appendix 3 of the New Zealand Immunisation Handbook 2017[1]). Section 3.3 (Standard 3, subsection 3.8) of the Appendix states: The vaccinator uses clean techniques in the preparation and administration of all vaccines, visually checks the vaccine, checks expiry date, prepares vaccine as appropriate and uses vaccines within the recommended period after preparation. It is apparent [Dr B] did not visually check the vaccine before attempting its administration and this oversight is admitted. This is a potentially dangerous omission and represents a moderate departure from accepted practice.

(iv) Standard 4, subsection 4.3 of the cited standards outlines the expected documentation accompanying administration of a vaccination. This includes: Having

[1] Ministry of Health. 2018. Immunisation Handbook 2017 (2nd edn). Wellington: Ministry of Health. https://www.health.govt.nz/system/files/documents/publications/immunisation-handbook-2017-2nd-ed-mar18-v2_0.html#Appendix3 Accessed 15 August 2018

chosen the appropriate immunisation schedule, the vaccinator documents the following details:

- consent obtained
- date vaccine administered
- vaccine type and number in the series
- batch number and expiry date
- injection site (eg, 'right deltoid' not 'upper arm')
- needle length
- that the patient was observed for 20 minutes post-vaccination

If a flu vaccine was successfully administered to [Mrs A] on 8 May 2018 I would be mildly critical that this is not apparent in the clinical documentation presented. If a flu vaccine was successfully administered to [Mrs A] on 8 May 2018, I would expect the information noted above to be present in the 'Immunisation' module of the PMS and I would be moderately critical if this was not done.

(v) It appears the practice has managed this incident with appropriate consideration. GPs may be less familiar with immunisation standards than nurses who are administering vaccines on a more regular basis and further in-house education in this regard might be considered. I have no further comments or recommendations."

Additional comment received from Dr Maplesden:

"I think it was appropriate not to document details of the failed administration of flu vaccine in the Immunisation module of the PMS. However, details of the 'failed' vaccine (Batch number, expiry etc) should have been recorded in a retrievable place (and may have been) to enable appropriate review of the incident. I think recording of details in the clinical notes (daily record) would have been most appropriate but if the details were recorded in an incident form or similar that would be acceptable. Basically, the vaccine details need to be available in order to report the failure to the manufacturer and/or identify patients who received vaccines from the same batch in case it was accidental needle re-use.

Best practice is to record consent gained (verbal or written) for any procedure including immunisation. It may be this was the GP's intention but when the vaccination did not proceed effectively, consent was not recorded. I would regard the failure to record verbal consent to immunisation as a mild departure from best practice but in my experience of reviewing GP notes when the GP has administered the vaccine (as opposed to the practice nurse which is a more common scenario), omission of recording verbal consent is common. This is most likely because the vaccine is being given by the GP opportunistically on top of the 'normal' consultation whereas nurse administration is usually done as a specific single immunisation task."