Canopy Cancer Care (Canopy Cancer Care Ltd) Registered Nurse RN B Oncologist, Dr C

A Report by the Deputy Health and Disability Commissioner

(Case 19HDC01148)

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# **Executive summary**

1. This report concerns the care provided to a man by Canopy Cancer Care Ltd, including by two oncologists and a registered nurse. The man became unwell on day three of the first round of chemotherapy treatment provided to him by Canopy. After contacting the triage line for advice, the man presented at the clinic for acute assessment. He was discharged several hours later after receiving IV fluids and anti-emetics. Sadly, the man subsequently collapsed and died from a cardiac event later that evening.

# Findings

- 2. The Deputy Commissioner found Canopy Cancer Care Ltd in breach of Rights 4(1), 4(2), and 4(5) of the Code of Health and Disability Services Consumers' Rights (the Code) for failing to have a clear process in place for managing acute patients, including timely blood screening, appropriate patient assessment and record-keeping tools, clear staff roles and responsibilities, and appropriate administration of IV prescription medicine. While not a breach of the Code, the Deputy Commissioner was also critical of Canopy Cancer Care Ltd's complaint handling.
- 3. The nurse was found in breach of Right 4(2) of the Code for administering IV prescription medicine contrary to legislation, and for keeping inadequate records.
- 4. An oncologist was found to have breached Rights 4(1) and 4(2) of the Code for failing to conduct timely blood testing and retrospectively prescribing IV medicine contrary to legislation. The Deputy Commissioner was also critical of the oncologist's documentation and communication but did not consider that he had breached the Code in those respects.
- 5. The Deputy Commissioner was also critical of the second oncologist's documentation but did not find him in breach of the Code.

# Recommendations

- 6. The Deputy Commissioner recommended that Canopy Cancer Care Ltd provide a written apology to the man's family; audit staff clinical records and Clinical Nurse Educator training; review and update specific aspects of its Management of Acute Patient Guidelines; review its blood screening and referral processes to ensure that urgent screening is available; and review its prescribing processes and related charts to ensure that they comply with legislation and accepted practice.
- 7. The Deputy Commissioner recommended that the nurse provide a written apology to the man's family and complete appropriate nursing documentation and administration of prescription medicine refresher courses.
- 8. The Deputy Commissioner recommended that the oncologist provide a written apology to the family and complete appropriate clinical documentation and prescribing refresher courses.



<sup>13</sup> October 2023

# **Complaint and investigation**

- 9. The Health and Disability Commissioner (HDC) received a complaint from Mrs A about the services provided to her late husband, Mr A, by Canopy Cancer Care Limited (Canopy Cancer Care/Canopy). The following issues were identified for investigation:
  - Whether Canopy Cancer Care provided Mr A with the appropriate standard of care in and about Month3<sup>1</sup> 2018.
  - Whether RN B provided Mr A with the appropriate standard of care on 9 Month3 2018.
  - Whether Dr C provided Mr A with the appropriate standard of care in and about Month3 2018.
- 10. This report is the opinion of Deborah James, Deputy Health and Disability Commissioner.
- 11. The parties directly involved in the investigation were:

Mrs A	Complainant/consumer's wife
Canopy Cancer Care	Provider/oncology practice
RN B	Provider/oncology nurse
Dr C	Provider/oncologist

12. Further information was received from:

Dr D	Oncologist
Dr E	Cardiologist
Dr F	Oncologist
Dr G	Cardiologist
Dr H	Cardiologist
Dr I	Clinical pharmacologist
RN J	Oncology nurse
RN K	Oncology nurse
District health board	
Accident Compensation Corporation (ACC)	

13. Independent advice was obtained from an oncology specialist, Dr Richard Isaacs (Appendix A) and an oncology nurse practitioner, NP Sarah Ellery (Appendix B).

<sup>&</sup>lt;sup>1</sup> Relevant months are referred to as Months 1–3 to protect privacy.



Names have been removed (except Canopy Cancer Care Limited and the advisors) to protect privacy. Identifying letters are assigned in alphabetical order and bear no relationship to the person's actual name.

# Information gathered during investigation

#### Background

- 14. This report concerns the care provided to Mr A during chemotherapy treatment at Canopy Cancer Care Ltd, a private outpatient oncology clinic. Mr A became unwell on day three of his first cycle of FOLFOX6<sup>2</sup> chemotherapy and presented acutely<sup>3</sup> to Canopy on the morning of 9 Month3.
- 15. Sadly, later that day Mr A collapsed at home from an unsurvivable cardiac event. A post mortem identified a right coronary artery anomaly<sup>4</sup> that can cause reduced blood flow to the heart and sudden death during stress.
- <sup>16.</sup> Mrs A complained to HDC that Mr A was not adequately informed of the risk of fatal cardiotoxicity from FOLFOX chemotherapy, and not assessed properly when he became unwell on 9 Month3.
- 17. For clarity, the Deputy Health and Disability Commissioner's role is to review the standard of care provided to Mr A, not to make a finding as to the cause of Mr A's death, which is the responsibility of the Coroner. The standard of care is assessed on the basis of the information that was known at the time of events, rather than information that has come to light with the benefit of hindsight.
- 18. I take this opportunity to express my deepest sympathies to Mr A's family for their loss.

#### **Care provided**

### FOLFOX chemotherapy

- 19. On 20 Month1, Mr A, aged in his forties, underwent a colonoscopy and was diagnosed with a cancerous rectal tumour. It had invaded the colonic wall and was removed surgically on 9 Month2. Cancer was present in two local lymph nodes, but had not metastasised.<sup>5</sup> On 24 Month2, Mr A was referred to Canopy's oncologist, Dr D, for consideration of adjuvant chemotherapy.<sup>6</sup>
- <sup>20.</sup> Mr A's recent medical history included paroxysmal supraventricular tachycardia (PSVT),<sup>7</sup> which had been treated with cardiac ablation<sup>8</sup> by cardiologist Dr E in June 2017. A functionally normal heart was shown in a follow-up echocardiogram<sup>9</sup> in July 2017. Mr A had



<sup>&</sup>lt;sup>2</sup> <u>https://www.eviq.org.au/medical-oncology/colorectal/adjuvant-and-neoadjuvant/637-colorectal-adjuvant-folfox6-modified-fluoro.</u>

<sup>&</sup>lt;sup>3</sup> With sudden onset illness.

<sup>&</sup>lt;sup>4</sup> Abnormality.

<sup>&</sup>lt;sup>5</sup> Spread to other parts of the body.

<sup>&</sup>lt;sup>6</sup> Treatment to destroy any remaining cancer cells.

<sup>&</sup>lt;sup>7</sup> Episodes of rapid heart rate caused by abnormal electrical conduction in the upper chamber of the heart.

<sup>&</sup>lt;sup>8</sup> A procedure that scars tissue in the heart to block irregular electrical signals.

<sup>&</sup>lt;sup>9</sup> An ultrasound test to check the structure and function of the heart.

no history of ischaemic<sup>10</sup> heart disease and was on a diuretic<sup>11</sup> but no other cardiac medication.

- Dr D met with Mr and Mrs A on 26 Month2 and discussed chemotherapy options, including the eviQ<sup>12</sup> FOLFOX6 protocol.<sup>13</sup> This is a combination chemotherapy regimen for metastatic colorectal cancer, consisting of oxaliplatin, calcium folinate (Leucovorin), and fluorouracil (also called 5FU). Fluorouracil and oxaliplatin have a known risk of adverse cardiac effects.<sup>14</sup> Dr D's clinical notes record 'prior cardiac conduction disorder' and 'cardiac ablation (Dr E) ?PAT<sup>15</sup>'.
- 22. Dr E later informed Mrs A that Dr D spoke to him about Mr A beginning chemotherapy treatment. Dr E said that he advised Dr D that there was no cause for further cardiac investigation. This discussion was not recorded in any clinical notes.
- <sup>23.</sup> On 1 Month3, Mr A attended an orientation meeting with a Canopy nurse to review the selected FOLFOX treatment, explain side-effects, and take baseline assessments, including an electrocardiogram (ECG), <sup>16</sup> blood testing, and a thymine trial to rule out dihydropyrimidine dehydrogenase (DPD) deficiency. <sup>17</sup> The ECG and DPD results were normal. The blood screen was normal, apart from an elevated liver enzyme.<sup>18</sup>
- <sup>24.</sup> The orientation was followed by a video link discussion with Dr D, who was overseas at the time. Dr D told HDC that he discussed three key life-threatening side effects 'severe diarrhoea and dehydration; high temperature with a low white blood cell count; and angina<sup>19</sup> or "heart pain", which can lead to a heart attack'. This discussion is not explicitly recorded in the clinical notes. Mr A then signed a general consent form, which stated:

'I have had the opportunity of discussing the benefits and possible immediate and long term side effects of this treatment ... I understand that the use of this medicine may carry an unknown risk of side effects and adverse reactions ... By signing this form, I acknowledge that I have understood the risks and have had the opportunity to ask questions and I have had those questions satisfactorily answered.'

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<sup>18</sup> Gamma-glutamyl transferase (GGT). High levels of GGT in the blood may be a sign of liver disease.

<sup>19</sup> A type of chest pain caused by reduced blood flow to the heart.

<sup>&</sup>lt;sup>10</sup> Decreased blood flow and oxygen to the heart muscle.

<sup>&</sup>lt;sup>11</sup> Drugs that remove extra fluid or salt water from the body by helping the kidneys to produce more urine.

<sup>&</sup>lt;sup>12</sup> eviQ is an Australian Government freely available online resource of cancer treatment protocols developed by multidisciplinary teams of cancer specialists.

<sup>&</sup>lt;sup>13</sup> <u>https://www.eviq.org.au/medical-oncology/colorectal/adjuvant-and-neoadjuvant/637-colorectal-adjuvant-folfox6-modified-fluoro</u>.

<sup>&</sup>lt;sup>14</sup> <u>https://www.medsafe.govt.nz/profs/Datasheet/f/FluorouracilEbeweinj.pdf</u> and <u>https://www.medsafe.govt.nz/profs/Datasheet/o/oxaliplatininf.pdf</u>.

<sup>&</sup>lt;sup>15</sup> Paroxysmal atrial tachycardia — a sudden irregular rapid heartbeat.

<sup>&</sup>lt;sup>16</sup> To measure the electrical activity of the heart.

<sup>&</sup>lt;sup>17</sup> DPD deficiency prevents the breakdown of 5FU, leading to a higher risk of toxicity. DPD is not routinely tested for in New Zealand, but it is overseas; instead, NZ patients are monitored closely for toxic reactions. See: <u>https://www.cancertrialsnz.ac.nz/thymine/</u>.

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- <sup>25.</sup> Canopy told HDC that an orientation folder was provided, which included contact numbers for Dr D and on-call Canopy staff. The eviQ patient information provided by Canopy included 'heart problems' as an adverse effect, including 'chest pain or tightness, shortness of breath and an abnormal heartbeat'. It states to tell your doctor or nurse immediately or go to the nearest hospital emergency department for symptoms of heart problems, or uncontrolled vomiting. The patient handout does not specifically mention 'cardiotoxicity'.<sup>20</sup>
- 26. Mrs A told HDC that they had been unaware that the appointment was an orientation, otherwise she would have attended with her husband. She feels that they were not informed adequately of the fatal risk from chemotherapy treatment, including the potential for cardiotoxicity from fluorouracil. She said that they were informed that angina might occur, and to expect vomiting and nausea, 'neither of which are usually fatal to a patient'. Mrs A stated that this information would have affected Mr A's decision to proceed with chemotherapy and, as the main caregiver, would have made her more aware of what signs to look out for when he became unwell.
- 27. On 5 Month3, Mr A had a portacath<sup>21</sup> inserted. On 7 Month3, Mr and Mrs A attended Canopy, where Mr A began the FOLFOX protocol. This consisted of initial in-clinic intravenous (IV) doses of oxaliplatin, Leucovorin (calcium folinate) and fluorouracil, followed by discharge home with fluorouracil continuing by infusion pump. This cycle of treatment was to be for 48 hours and was due to finish at 10am on 9 Month3. Mr A was prescribed, in tablet form, the antiemetics<sup>22</sup> domperidone and ondansetron, and the corticosteroid<sup>23</sup> dexamethasone.
- 28. Mrs A told HDC that when they left Canopy that day, they were not briefed at all on possible side-effects, but were told to call the clinic if Mr A was unwell.

### Assessment on 9 Month3

- 29. Overnight on 8–9 Month3, Mr A became very unwell, with sweating, agitation, nausea, and about eight episodes of vomiting. He was unable to hold down any medication or fluids. Mrs A had observed some shortness of breath. At around 9am, Mrs A telephoned Canopy for advice, as she was concerned that Mr A was so unwell that she would be unable to bring him into the clinic.
- 30. Canopy told HDC that it has a dedicated triage telephone staffed by a nurse specialist<sup>24</sup> from 8am until 6pm. Canopy said that it does not provide formal training for the triage phone, but staff are expected to 'gather information and apply critical thinking skills'.



<sup>&</sup>lt;sup>20</sup> <u>https://www.eviq.org.au/medical-oncology/colorectal/metastatic/114-colorectal-metastatic-folfox6-modified-fluo/patient-information</u>.

<sup>&</sup>lt;sup>21</sup> A device inserted into a vein to provide access for regular long-term administration of medication.

<sup>&</sup>lt;sup>22</sup> Medication to prevent vomiting and nausea.

<sup>&</sup>lt;sup>23</sup> Medication used to reduce inflammation.

<sup>&</sup>lt;sup>24</sup> Canopy has both oncology nurse specialists and general oncology nurses. Nurse specialists (advanced nursing practice) were allocated to patients through the course of their treatment, while general oncology nurses would administer treatment and be available for acute presentations.

- <sup>31.</sup> When Mrs A called, the triage nurse had not yet started, so a general oncology nurse, RN K, took the call. RN K told HDC that she could see on the Canopy system that Mr A was due in that day for pump removal, but 'seeing as [Mrs A] sounded so worried on the phone and he had vomited so many times over night [she] felt that he should come into the clinic as soon as possible so that [they] could try to manage his nausea and vomiting'. RN K stated that she should have asked further questions, but she felt that the symptoms described were reason enough to come in and a 'full and more thorough assessment would take place by the nurse seeing him in the clinic'.
- <sup>32.</sup> Mr and Mrs A arrived at Canopy just after 9am, and RN B,<sup>25</sup> a general oncology nurse, was allocated by the nurse team leader to provide care. RN B told HDC that Canopy did not have an assessment tool or procedure for acute presentations. She stated:

'[P]hone calls were triaged according to the nature and severity of complaint/ symptoms. Very unwell patients were advised to present at nearest hospital emergency centre or call emergency for ambulance services ... When [Mr A] presented on 9 [Month3], this was for symptom or side effect management.'

- <sup>33.</sup> RN B said that she did not know Mr A, but she reviewed his notes and 'discussed with the team leader and some of the other nurses that he would likely need his chemotherapy pump disconnected, oncologist review and symptom management'. She stated that she assessed him visually as he walked into the clinic, and she described him as 'visibly dehydrated and weak' and looking 'exhausted<sup>26'</sup>.
- 34. RN B told HDC that she took Mr A and his wife into a treatment room, where she took a verbal history, clamped and disconnected the fluorouracil infusion pump, and took Mr A's vital signs. His heart rate was later recorded in the clinical notes as 125 beats per minute, his blood pressure as 115/78mmHg, a temperature of 37.4°C, and oxygen saturation<sup>27</sup> of 100%.
- <sup>35.</sup> Mrs A described Mr A as being pale, sweating, with 'poor perfusion<sup>28</sup> to lower legs', and what Mr A described as 'heartburn'.
- <sup>36.</sup> RN B said that she questioned Mr A, and no chest pain, shortness of breath, sweating, poor leg perfusion, skin discolouration, reflux or heartburn was described or observed. She stated: 'On assessment, [Mr A] was dehydrated. His mouth was dry.' Canopy told HDC that RN B 'felt that he did not require immediate medical assessment'.
- <sup>37.</sup> At 9.21am, an ECG conducted by RN B reported 'HR [Heart rate] 126, Extreme Tachycardia,<sup>29</sup> Intraventricular Conduction Block,<sup>30</sup> Poor R Wave Progression (V2, V3),<sup>31</sup> and ST Elevation

<sup>&</sup>lt;sup>31</sup> A common finding on ECG that has unclear clinical significance.



<sup>&</sup>lt;sup>25</sup> Registered as a nurse overseas. Not currently on the NZ register. An employee of Canopy.

<sup>&</sup>lt;sup>26</sup> Exhaustion or fatigue is a symptom listed on the UKONS and eviQ triage assessment tool.

<sup>&</sup>lt;sup>27</sup> Percentage of oxygen in a person's blood.

<sup>&</sup>lt;sup>28</sup> Circulation.

<sup>&</sup>lt;sup>29</sup> A fast resting heart rate (more than 100 beats per minute).

 $<sup>^{\</sup>rm 30}$  A heart conduction disorder that can cause abnormal activation of the ventricles.

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(V5)<sup>32</sup>'. RN B told HDC that she then 'discussed Mr A's case with some of the other nurses and agreed to administer antiemetic medication intravenously'. This is recorded in the medication chart as being ondansetron and Maxolon (metoclopramide) administered via IV at 9.35am.

- <sup>38.</sup> In response to the provisional opinion, RN B told HDC that the IV medication was physically checked by another oncology nurse prior to administration, but the check was not recorded in the medication chart or clinical notes. The second nurse was not identified.
- <sup>39.</sup> At 9.40am, RN B commenced a saline drip at 200ml/hour, 'pending the doctor's assessment and plan'. She told HDC that she observed Mr A closely, completing 15-minute observations<sup>33</sup> for the first hour, followed by 30-minute observations. These were recorded on a piece of paper, as Canopy 'did not use paper charts and notes were recorded on a computer in the office'. RN B said that her usual practice was to record observations on paper and to transcribe these into the workspace computer file later.
- 40. In response to the provisional opinion, Canopy told HDC that Mr A was treated in a side room that had desktop computers where clinical notes and vital signs can be entered. All staff members can log on to the desktop computers to access the patient's medical records and enter notes. RN B confirmed that there was a computer in Mr A's treatment room, but she did not think it had a scanner. She stated:

'I personally prefer the old-fashioned way of taking notes on a notepad in the patient's room, instead of sitting down to type on a PC as it can inhibit authentic engagement and eye contact with the patient ... [U]sing the office computer [at the nurses' station] also allowed me to discuss [Mr A's] condition with my senior colleagues ... [I]t is common practice for nurses to do their paperwork at the nurses' station.'

- 41. Oncologist Dr C<sup>34</sup> stated that on the morning of 9 Month3 he was running a fully booked clinic (9.30am–12.30pm), when he was asked by a nurse to review an acute patient who had been vomiting for hours overnight. Canopy's subsequent Root Cause Analysis noted that eventually Dr C had two acute patients on top of a full clinic of one new patient and three reviews.
- 42. Dr C reviewed Mr A just after 10am. He told HDC that 'antiemetic drugs had been administered', and he viewed the initial observations and the ECG report, then met Mr and Mrs A in a side room. The exact time at which the ECG was viewed by Dr C has not been recorded on the ECG report, and it has not been recorded whether the ECG result was communicated to Mr A.



<sup>&</sup>lt;sup>32</sup> An abnormal finding on an ECG.

<sup>&</sup>lt;sup>33</sup> Vital signs, including heart rate, blood pressure, and temperature.

<sup>&</sup>lt;sup>34</sup> Registered with the Medical Council of New Zealand in a general scope; a contractor of Canopy.

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43. Dr C stated that his assessment lasted about 10 minutes, and he considered it to be an initial assessment. He said that as there were no symptoms he would have described as angina, he excluded a cardiac cause. He told HDC:

'[Mr A's] JVP<sup>35</sup> was low at -1cm, his pulse was rapid and thready, heart sounds were dual with no added sound and the anterior chest was clear ... There was no shortness of breath, no concerning chest pain, although he had a taste of acid in his mouth and a retrosternal<sup>36</sup> burning sensation that I took to be from vomiting ... [T]here was an intraventricular conduction abnormality which was similar to appearances on his baseline ECG ... I had no definite evidence of cardiac ischaemia<sup>37</sup> so troponin<sup>38</sup> levels were not planned at this time.'

- <sup>44.</sup> Dr C told HDC that he ordered a further two litres of saline to be administered over the next two to three hours (three litres in total), and he expected to complete a later review. He said that although he did not instruct RN B directly that he would complete a later review, it 'would be standard practice with the level of intervention required up to that point'.
- In response to the provisional opinion, Dr C stated that he was 'not directly involved' in Mr A's care and 'in conjunction with a fully booked practice, was focused on making [Mr A] comfortable and assisting with his nausea and fatigue'. Dr C accepts that he could have communicated his intention for a second clinical review better, 'particularly to staff that he has not worked with previously'.
- <sup>46.</sup> Dr C stated that initial blood testing was not ordered, as first he wanted to rehydrate Mr A. He told HDC that at the time, it was not standard practice at Canopy to take bloods on all patients who presented with chemotherapy-induced nausea and vomiting (CINV). Urgent community blood testing took around six hours to turn around,<sup>39</sup> so results would not have been available prior to rehydrating Mr A. Dr C said that he discussed the possibility of hospital admission should Mr A not improve. Dr C stated that the decision to do blood testing would have been done at review, as 'having had 3 litres of fluid, blood testing for electrolytes<sup>40</sup> (esp[ecially] potassium) would be important'.
- 47. In response to the provisional opinion, Dr C stated:

'[A]t the very least, electrolytes and cardiac enzymes should have been sampled. However, there was no indication that [Mr A] was suffering from anything other than standard side-effects of chemotherapy and as such, bloods were not the priority. Even if bloods had been completed, the outcome would have likely been the same. The results would not have been available at the time of the second review and therefore

<sup>&</sup>lt;sup>35</sup> Jugular venous pressure — an indirect measure of central venous pressure.

<sup>&</sup>lt;sup>36</sup> Behind the breastbone (sternum).

<sup>&</sup>lt;sup>37</sup> Decreased blood flow and oxygen to the heart muscle.

 $<sup>^{\</sup>mbox{\tiny 38}}$  A protein released in the blood when the heart muscle has been damaged.

<sup>&</sup>lt;sup>39</sup> The time taken for a result to be returned if requested urgently.

<sup>&</sup>lt;sup>40</sup> Minerals in the blood, for example, sodium and potassium. An imbalance of electrolytes can affect the electrical signals in the heart.

[he] would have been relying on clinical factors such as intensity and type of symptoms to make a decision regarding either discharge or hospitalisation.'

48. Dr C further responded:

'There was no indication that [Mr A] was at risk [of] suffering from a cardiac event. In the normal course of events, while bloods are helpful, they are not urgent and can be taken at a follow-up assessment.'

49. RN B told HDC that she was present for only parts of Dr C's assessment, but she recalls that he did ask about chest pain and shortness of breath. She stated:

'He said the patient was dehydrated, prescribed antinausea medication and fluids retrospectively. He ordered the fluid rate of current bag increased immediately and that a further two litres should follow (making three litres in total). The doctor sighted my observations and the ECG results and no further intervention or tests were ordered.'

- 50. Mrs A told HDC that Dr C's assessment lasted only a few minutes and appeared rushed, and she was not consulted about Mr A's signs and symptoms. She said that she was surprised when Dr C told them that Mr A was dehydrated, as he had been eating and drinking the day before and had vomited only small amounts.
- 51. Mr A received a further 1000ml of saline over an hour. RN B told HDC that he seemed to 'perk up' and began to tolerate oral fluids. She said that after the second bag of saline finished at 11.50am, he declined the third bag of saline, and expressed a strong desire to return home.

#### Discharge

- <sup>52.</sup> There are differing accounts of Mr A's discharge. Mrs A described Mr A as being confused, as 'he wanted to go home with the IV running'. She stated: 'I told the nurse he was confused; she did not comment.' RN B denies that Mr A was confused, as he was able to explain that he wanted to leave 'because he was feeling better, able to drink fluids, and that he did not want to wait for reassessment'. She stated that if Mr A had been 'sweaty and confused when he called Canopy, it is likely he would have been advised to go to the emergency department rather than coming to Canopy for symptom management'.
- <sup>53.</sup> Mrs A recalled that after the saline had finished, RN B advised them that Mr A could leave if he drank a glass of water. Mrs A stated:

'[Mr A] was sent home; he did not discharge himself ... [W]e were told he needed 3L of fluid and if he drank the last glass of water he could go. We were never informed about a re-assessment from the Oncologist.'

- 54. Mrs A said that Mr A drank the water and they left at around 12pm.
- 55. RN B told HDC that she expressly advised Mr and Mrs A not to leave until Mr A had been reviewed by Dr C. She said that when she went to see if Dr C was free, he was still in a consultation, and Mr A did not want to wait. She stated: 'I was reluctant to interrupt the



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doctor but I really did not have any other choice.' She said that eventually she interrupted Dr C and informed him that Mr A wished to leave. RN B stated that Dr C asked about Mr A's heart rate, and when she said that it had improved, he advised that if Mr A wished to leave, he could do so. No blood testing or a repeat ECG was ordered. Dr C stated that he cannot recall this discussion.

- <sup>56.</sup> RN B entered her clinical notes into the office computer at 12.31pm. She did not scan in the observations she had written on a piece of paper and said that normally she would transcribe them. She said she understood that this was common practice at Canopy at the time. Only the first set of observations were entered. RN B told HDC that she accepts that not every aspect of her assessment is recorded in her notes, but she believes her notes were appropriate in the circumstances. She stated: 'If [Mr A] was being transferred to hospital I very likely would have made a more detailed note of my assessments.'
- 57. RN B's clinical notes state:

'Presented in clinic acutely following phone call advice with [RN K]. Miserable, dry retching ++, dry mouth, exhausted and generally unwell. Pump discontinued 45min early, nearly empty. Low grade temp 37.4, HR 125, bp 115/78 sats 100%. S/B Dr [C], IV Zofran<sup>41</sup> and Maxolon given. Comm saline stat. ECG — Tachy. Dehydrated. 2 litres Saline administered stat. Nausea settled, tolerating PO fluids. Declined to have 3rd litre of Saline, now quite determined to drink PO fluids. Has tolerated 750mls water and 1 cup of coffee in clinic. HR imp. Feeling much better. POC flushed and locked with heparin 500iu/5mls and deaccessed. Given script for ammend. Enc po fluids, reg antiemetics, small frequent meals and monitor temp. May need another script for pre-next cycle. Rushing to get home. Left clinic with wife.'

- <sup>58.</sup> Dr C's account is that when his clinic finished at 12.45pm, the nursing team informed him that Mr A's heart rate had dropped back to 90 beats per minute, he had declined the third bag of saline, and he had left. Dr C stated that he did not sanction the early departure.
- <sup>59.</sup> In response to the provisional opinion, Dr C told HDC:

'[Mr A's] symptoms improved following the IV medication and so it is possible that he would have also been sent home following a second review with the same medical plan — to call the Emergency Department if he began vomiting again.'

Follow-up

60. RN B told HDC that before Mr and Mrs A left, she gave advice encouraging oral fluids, regular antiemetics, small and frequent meals, to monitor Mr A's temperature, and to call the clinic again if things changed. She said that after Dr C had finished his consultation, she spoke with him about Mr A's new prescription for antiemetic medication for subsequent rounds of chemotherapy.



<sup>&</sup>lt;sup>41</sup> Brand of ondansetron.

- 61. At around 1.30pm, RN B rang Mrs A and asked how Mr A was doing and where his prescription should be faxed for dispensing. Mrs A told RN B that 'he was okay and that he was going to have a sleep as he was still tired'. RN B told HDC that she expected that Mr A would be reviewed by his allocated nurse specialist in the next few days.
- <sup>62.</sup> RN B's clinical notes entered at 1.36pm state: 'I have contacted [Mrs A], [Mr A's] wife, after further discussion with [Dr C]. re: Ammend.<sup>42</sup> Special authority will be done later today and the ammend is for pre next cycle.' RN B's shift finished at 2pm. There is no record that Canopy staff contacted Mr A's primary oncologist (Dr D) or nurse specialist.
- <sup>63.</sup> Dr C told HDC that no follow-up was completed with Mr A because of his existing afternoon commitments. Dr C said that he had planned to contact Dr D to explain what had happened. Dr C stated:

'[Mr A] needed to be contacted to make sure things had definitely settled, he had medicine for nausea and that blood tests were done ... Sadly, before any of this was arranged I received shattering news a few hours later that he had arrested and could not be resuscitated.'

<sup>64.</sup> Dr C told HDC that he had intended to refer Mr A for a community blood test but 'it was not actioned'. He said that he expected a member of the nursing team to follow up, and he understood from RN B's telephone call at 1.30pm that '[Mr A] was feeling better and had not experienced any further nausea and vomiting'.

#### Subsequent events

- <sup>65.</sup> Just before 5pm, Mrs A rang the Canopy triage line concerned for her husband. Mrs A told HDC: '[I] was informed that I must call an ambulance if [Mr A] was unwell as it was a Friday evening and "not much can be done at Canopy now".'
- 66. The triage nurse, RN J, told HDC that she was the nurse specialist rostered to cover the triage phone. She recalled that Mrs A sounded anxious, and '[s]he was not able to be clear about what she wanted or to identify a specific concern or change in her husband's condition'. RN J stated that there was no indication of any new symptoms or 'anything that would have raised concern for toxicity, other than nausea and vomiting'.
- 67. RN J's notes at 4.54pm state:

'Call from [Mrs A] — very concerned about [Mr A]. Has not been home long after being seen here for re-hydration and antiemetics. Tolerating sips of water but [Mrs A] afraid he will not keep antiemetics down. Advised had IV Ondansetron and Maxolon whilst here which will still be active. Needed clear instruction so advised that if [Mr A] is tolerating sips of fluid regularly [without] retching or vomiting then hopefully he will [settle] over the next 24 hours — not to worry about food at this stage but if he is vomiting he needs to go to hospital.'



<sup>&</sup>lt;sup>42</sup> Aprepitant, sold under the brand name Emend, is another antiemetic.

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- <sup>68.</sup> At 5.40pm, Mr A asked for an ambulance. Mrs A told HDC that the ambulance service emergency call centre felt that there was no immediate danger so did not intend to respond.
- <sup>69.</sup> While Mrs A was on the telephone, Mr A collapsed. The ambulance service initiated a callout at 5.48pm. However, despite immediate cardiopulmonary resuscitation (CPR) and transport to hospital, sadly Mr A was unable to be revived. His time of death was recorded as 7.13pm.
- 70. Dr C's clinical notes, entered at 9pm, state:

'Asked to see this morning — came in early with his wife, For de-access pump day 3 cycle 1 folfox regimen. Intensely nauseated and vomiting over last 12 hours, unable to keep antiemetic down. HR rapid, ECG done — rate 129/min with intraventricular conduction abnormality, poor R wave progression. Similar appearances with baseline, ST elevation commented on by automated report — possibly related to tachycardia, no chest pain, SOB. Extremely dry — had 1000ml normal saline by the time of my review — HR approx 120, reg, dry mucous membranes. I[V] ondansetron 8mg, given 2000ml normal saline over 2hours.

Not reviewed by me before leaving clinic — tolerated oral fluid, and less nausea, Tachycardia had settled to approx 90/min. Script for aprepitant for cycle 2. Presumed oxaliplatin-induced emesis<sup>43</sup> with dehydration.'

- 71. These notes appear to have been entered after Dr C was informed of Mr A's death.
- 72. In response to the provisional opinion, Dr C stated:

'I accept that in a perfect world, notes are written at the time, or shortly after the assessment of the patient. However, the delay needs to be considered against the real-world practicalities of a fully booked and busy practice. The time to make detailed notes needs to be managed with other competing tasks and the care of other patients.

On initial assessment, [Mr A] presented in an uncomfortable but not life-threatening state. I had no reason to prioritise my note writing over the clinical care of other patients. I consider that if I had prioritised [Mr A's] notes, I would not have been providing my other patients with reasonable and timely care.'

<sup>73.</sup> The post mortem identified a right coronary artery anomaly. Dr E advised Mrs A that this defect would not have been identified by the 2017 echocardiogram or baseline ECG, and that there was nothing from Mr A's previous history that suggested he had an underlying coronary artery anomaly. Dr E said that a CT coronary angiogram<sup>44</sup> would have been required to identify the anomaly.

<sup>&</sup>lt;sup>43</sup> Vomiting.

<sup>&</sup>lt;sup>44</sup> An imaging test that looks at the arteries that supply blood to the heart.

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# Further information

# Mrs A

74. Mrs A is concerned that on 9 Month3 Mr A did not receive a thorough medical assessment, and instead it was presumed that he required treatment only for nausea and dehydration. She feels that cardiac symptoms caused by fluorouracil were not adequately ruled out. She also feels that the clinic was not helpful when she called again seeking advice just before Mr A collapsed.

# Additional advice

75. In support of her complaint, Mrs A sought medical opinions from Dr E, cardiologist Dr H, and clinical pharmacologist Dr I. This was provided to HDC and shared with all providers for comment. I have taken this advice into account for the purpose of assessing the standard of care provided.

# <u>Dr E</u>

<sup>76.</sup> Dr E's view is that Mr A's symptoms on 9 Month3 were possibly related to myocardial ischaemia,<sup>45</sup> rather than the effect of chemotherapy. Dr E said that the ECG changes 'could have been consistent with cardiac ischaemia but this was not definitive'. He noted that the ECG traces recorded by the paramedics showed more prominent ischaemic changes.

# <u>Dr H</u>

- 77. Dr H's opinion is that neither the pre-existing cardiac history nor the artery abnormality were relevant to the outcome, but that acute myocarditis,<sup>46</sup> combined with the possible disequilibrium of serum electrolytes through dehydration then rapid rehydration led to fatal arrhythmia. His view is that tachycardia could have caused the mild ST elevation rather than cardiac pathology. He noted that blood tests were not performed, and there was early patient departure prior to review.
- 78. Canopy commented that Dr H's view of the abnormal ECG is consistent with its own finding of tachycardia.

<u>Dr I</u>

- 79. Dr I noted that the echocardiogram was not repeated prior to starting treatment, and that the cardiac anomaly may have prevented effective CPR. His view is that tachycardia alone did not cause the ECG changes, and that Mr A developed cardiotoxicity, which was compounded by severe dehydration. Dr I suggested that if Mr A had been admitted to hospital and had had cardiac enzymes<sup>47</sup> measured prior to discharge, it may have allowed closer observation and a more favourable outcome.
- <sup>80.</sup> It is noted that Dr I interpreted 'no chest pain, SOB' in Dr C's notes as meaning that shortness of breath was present. However, Canopy responded that this interpretation is incorrect, and



<sup>&</sup>lt;sup>45</sup> A lack of blood flow to the heart muscle.

<sup>&</sup>lt;sup>46</sup> Inflammation of the heart muscle.

<sup>&</sup>lt;sup>47</sup> Troponin.

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it meant that Mr A did not present with shortness of breath or chest pain. Canopy also noted that Mr A's condition had improved prior to his departure at 12pm.

## FOLFOX chemotherapy

- 81. The eviQ FOLFOX clinical information for fluorouracil lists cardiotoxicity as being an immediate (hours to days) side-effect. It notes that patients treated with fluorouracil, 'especially those with a prior history of cardiac disease or other risk factors, should be carefully monitored during therapy'.<sup>48</sup> The reported incidence of cardiotoxicity ranges from 1–18% of patients, and can be asymptomatic.<sup>49</sup>
- <sup>82.</sup> The eviQ clinical guidance on cardiotoxicity management states that it can present:<sup>50</sup>

'Acutely — during or shortly after treatment, presenting as ventricular dysfunction, ECG abnormalities, arrhythmias, or pericarditis-myocarditis syndrome.

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Baseline measurement (ECHO<sup>51</sup>) should be considered in all patients and especially in those with pre-existing risk factors of developing cardiac disease or in patients receiving potentially cardiotoxic agents.'

- <sup>83.</sup> The Medicines and Medical Devices Safety Authority (Medsafe) data sheet for oxaliplatin<sup>52</sup> lists risks of cardiac disorders, including Torsade de Pointes,<sup>53</sup> acute coronary syndrome, arrhythmia, tachycardia, and cardiac arrest.
- <sup>84.</sup> The 2017 Medsafe<sup>54</sup> fluorouracil data sheet<sup>55</sup> advises that due to the possibility of severe toxic reactions, 'all patients should be hospitalised, at least during the initial course of therapy and appropriate facilities should be available for adequate management of complications should they arise'.<sup>56</sup> Undesirable cardiovascular effects include chest pain, tachycardia, and ECG changes.

<sup>51</sup> Echocardiogram (an ultrasound examination of the structure and functioning of the heart).

<sup>&</sup>lt;sup>48</sup> <u>https://www.eviq.org.au/medical-oncology/colorectal/adjuvant-and-neoadjuvant/637-colorectal-adjuvant-folfox6-modified-fluoro#clinical-information</u>. Accessed 19 April 2022.

<sup>&</sup>lt;sup>49</sup> Yuan, C, Parekh, H, Allegra, C et al. 5-FU induced cardiotoxicity: case series and review of the literature. Cardio-Oncology 5, 13 (2019). <u>https://doi.org/10.1186/s40959-019-0048-3</u>.

<sup>&</sup>lt;sup>50</sup> <u>https://www.eviq.org.au/clinical-resources/side-effect-and-toxicity-management/cardiovascular/1851-</u> cardiac-toxicity-associated-with-antineoplast##assessment-and-management.

<sup>&</sup>lt;sup>52</sup> https://www.medsafe.govt.nz/profs/datasheet/o/oxaliccordinf.pdf.

<sup>&</sup>lt;sup>53</sup> A very fast heart rate (tachycardia) that starts in the lower chambers (ventricles) of the heart.

<sup>&</sup>lt;sup>54</sup> The New Zealand Medicines and Medical Devices Safety Authority.

<sup>&</sup>lt;sup>55</sup> The 2021 version of the patient handout has an expanded description of cardiovascular effects:

https://www.medsafe.govt.nz/profs/Datasheet/f/FluorouracilEbeweinj.pdf. Accessed 22 April 2022.

<sup>&</sup>lt;sup>56</sup> <u>https://www.medsafe.govt.nz/profs/Datasheet/f/FluorouracilEbeweinj.pdf</u>. Accessed 22 April 2022, p3. This information is the same in both the 2017 and 2021 versions.

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#### 85. Dr C told HDC:

'I know of no oncology units that administer the first dose of infusional 5FU<sup>57</sup> as an inpatient with cardiac monitoring over this 72-hour period. It is universally given in an outpatient setting.'

### Canopy Root Cause Analysis (RCA)

- <sup>86.</sup> Following Mrs A's complaint, Canopy conducted an internal RCA to review what occurred, identify any failings in care, and seek possible improvements in practice. I have considered the RCA and the changes made as a result, as part of my own investigation, opinion, and recommendations.
- <sup>87.</sup> The RCA timeline of events notes that Dr C was consulted by RN B after the ECG and just prior to antiemetics being administered, and that Dr C subsequently assessed Mr A '45 minutes after arriving at the clinic'. The RCA states that Mr A self-discharged against RN B's advice to stay for a medical review, and that Dr C was informed of the departure after Mr and Mrs A had left. The RCA noted that Dr C had felt reassured by RN B's report that Mr A's heart rate and condition had improved, and therefore he did not follow up further.
- <sup>88.</sup> The RCA included internal advice by Canopy's oncologist Dr F, and external advice by a cardiologist, Dr G. Dr F advised that the clinical decision-making, choice of chemotherapy, and documentation by Dr D was appropriate, and that Mr A had been provided with appropriate information for informed consent. In Dr F's view, the previous PSVT did not exclude the use of fluorouracil or oxaliplatin chemotherapy.
- <sup>89.</sup> However, Dr F also noted that the specific information provided to Mr A is not stated, and that there is a theoretical risk of torsades de pointes<sup>58</sup> with ondansetron, specifically in the setting of hypokalaemia<sup>59</sup> caused by bendrofluazide,<sup>60</sup> and that a baseline blood screen showed an elevated liver enzyme.<sup>61</sup>
- <sup>90.</sup> The RCA states that Canopy refers to the 'European Society of Medical Oncology (ESMO) Cardiovascular toxicity induced by chemotherapy practice guidelines (2012)' recommendations for the pre-treatment/work-up of patients with potential cardiotoxic agents. However, the RCA is silent on the specific recommendations and whether they were complied with.
- <sup>91.</sup> Dr G considered it reasonable to interpret the ECG changes as attributable to dehydration, and that on the information provided by Canopy,<sup>62</sup> no further cardiac investigations were warranted. Dr G noted that angina can also present as nausea and vomiting, and a troponin blood test may have been helpful.



<sup>&</sup>lt;sup>57</sup> Fluorouracil.

<sup>&</sup>lt;sup>58</sup> A very fast heart rhythm that starts in the heart's lower chambers (ventricles). It has a specific ECG pattern.

<sup>&</sup>lt;sup>59</sup> Low potassium level in the blood. Potassium helps to carry electrical signals and is critical for heart cells.

<sup>&</sup>lt;sup>60</sup> Bendrofluazide is a diuretic that Mr A had already been taking prior to starting FOLFOX.

<sup>&</sup>lt;sup>61</sup> Liver function can affect drug metabolism.

<sup>&</sup>lt;sup>62</sup> Dr G was provided the baseline ECG, new patient letter, 9 Month3 ECG, and 9 Month3 clinical notes.

- 92. The RCA team found the following:
  - There was no concerning cardiac history that would have excluded the use of fluorouracil.
  - The initial diagnosis of dehydration secondary to chemotherapy-induced nausea and vomiting (CINV) was reasonable.
  - Mr A's condition had improved, which was evidence that the diagnosis was correct.
  - There was a missed opportunity for a medical review prior to discharge, which would have allowed an ECG and blood tests to be performed.
  - There had been 'premature closure',<sup>63</sup> where other alternatives were not explored after an initial diagnosis of dehydration.
  - Mr A's self-discharge had prevented any further care.
  - The communication between doctor and nurse was not clear.
  - There were omissions in clinical documentation.
  - Blood tests may not have been helpful due to the six-hour community laboratory test turnaround.
  - Staff numbers on the day were acceptable.
  - Due to the undiagnosed right coronary anomaly, the physiological distress from the CINV precipitated the tragic cardiac event.
- 93. Canopy offered to meet with Mrs A to discuss the draft report, but this was declined. Mrs A told HDC that she strongly disagrees with the finding that Mr A self-discharged against medical advice, and instead they left when RN B told them they were free to go. Mrs A feels that all her 'questions and complaints' regarding the lack of acute patient protocol and poor record-keeping were addressed as recommendations in the report without taking adequate responsibility for the events.
- 94. The report included Canopy's sincere condolences to the family.

#### Changes made since events

- 95. Canopy told HDC that it takes the safety of patients very seriously, and it participates in external audits to ensure compliance with the Code of Health and Disability Services Consumers' Rights (the Code). Canopy said that as a result of the RCA, it implemented the following:
  - Developed the management of acute patient guidelines.
  - All patients on fluorouracil presenting with CINV are to have an ECG and troponin test.
  - All patients presenting with CINV will have routine bloods taken.

<sup>&</sup>lt;sup>63</sup> The acceptance of a diagnosis before it has been established objectively and alternative diagnoses have been investigated fully.

- Refresher training on documentation.
- Improved communication between staff with the management of acute patients.
- The introduction of a self-discharge form.
- <sup>96.</sup> Since the event, the nurse team leader has been made responsible for accepting and assessing acute patients and notifying the doctor. A nurse educator has also been employed to improve patient care, safety, and satisfaction across all sites.

#### Staff allocation and training

- <sup>97.</sup> Canopy told HDC that it refers to multiple overseas clinical guidelines for staff, including eviQ, ESMO<sup>64</sup> and UKONS.<sup>65</sup> A copy of the nausea guideline from the UKONS acute oncology guidelines was provided to HDC.<sup>66</sup> All clinical staff who administer cytotoxic medicines<sup>67</sup> are required to complete the eviQ online Antineoplastic Drug Administration Course (ADAC) training.
- 98. RN B told HDC that nursing work was divided between nurse specialists and oncology nurses. The nurse specialist was allocated for the course of the patient's treatment. The oncology nurses would administer treatment and be available for acute presentations and general tasks. If a patient presented acutely, ordinarily the nurse specialist would then follow up with their patient.
- <sup>99.</sup> Mr A had been allocated a nurse specialist, who had taken him through the detailed orientation. Canopy told HDC that it encourages patients to bring a support person to the orientation appointment.
- 100. Canopy told HDC that RN B was an oncology nurse with 20 years' experience in haematology and oncology settings. RN B had completed the eviQ ADAC reassessment of clinical competence on 13 June 2018. <sup>68</sup> This training includes an anti-cancer drug patient assessment tool<sup>69</sup> and a patient and care education checklist.<sup>70</sup> RN B had also completed the Canopy medication management assessment on 8 June 2018.
- <sup>101.</sup> Canopy stated that while there were learnings in the care provided to Mr A, the acute management met acceptable standards, and the 'red flags'<sup>71</sup> for chemotherapy-related



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<sup>&</sup>lt;sup>64</sup> European Society for Medical Oncology.

<sup>&</sup>lt;sup>65</sup> United Kingdom Oncology Nursing Society <u>https://www.ukons.org/</u>. Accessed 23 May 2022.

<sup>&</sup>lt;sup>66</sup> <u>https://www.ukons.org/site/assets/files/1134/acute\_oncology\_initial\_management\_guidelines.pdf</u>, p18. Accessed 9 May 2022.

<sup>&</sup>lt;sup>67</sup> A group of medicines that are toxic to cells, preventing their replication or growth, and so are used to treat cancer.

<sup>&</sup>lt;sup>68</sup> <u>https://education.eviq.org.au/courses/antineoplastic-drug-administration-course-adac/adac-reassessment-of-clinical-competency</u>. Accessed 24 May 2022.

<sup>&</sup>lt;sup>69</sup> <u>https://www.eviq.org.au/clinical-resources/assessment-tools/4-anti-cancer-drug-patient-assessment-tool</u>. Accessed 17 May 2022.

<sup>&</sup>lt;sup>70</sup> <u>https://www.eviq.org.au/clinical-resources/assessment-tools/550-anti-cancer-drug-patient-education-checklist</u>. Accessed 17 May 2022.

<sup>&</sup>lt;sup>71</sup> Canopy listed 'red flags' as being gastrointestinal, haematological, cardiac, neurological and skin toxicities.

toxicity were assessed appropriately. Canopy stated: 'There was no report of chest pain or shortness of breath or other symptoms that in retrospect would indicate [Mr A] was experiencing a cardiac event.'

#### Relevant policies

- <sup>102.</sup> Canopy's Administration of Intravenous Medication Policy (Appendix C) states that verbal orders<sup>72</sup> may be made only where it is impossible to obtain a written prescription but the administration of a drug is necessary to prevent deterioration in a patient's condition. The instruction should be confirmed by two nurses, and the dose, dose method, and rationale recorded in the notes. It states that 'all medico-legal requirements pertaining to the prescribing and administration of fluids and medications must be followed. IV medication 'needs to be checked by two people. Any drug calculations should be undertaken by both nurses involved in administration/checking.' The policy does not specify how checks by a second person are to be recorded.
- 103. Canopy's Medication Management Policy (Appendix C) includes a standing order<sup>73</sup> for 1000ml 0.9% sodium chloride IV in the event of a chemotherapy reaction. There are no standing orders for IV antiemetics. Prescriptions are to conform to the Code of Practice of the New Zealand Medical Council and comply with the laws pertaining to the prescribing of medicines.
- 104. Canopy acknowledged to HDC that RN B's administration of antiemetics via IV without a prescription was a deviation from its organisational policy and accepted standard of care. Canopy stated: 'It is not standard practice at Canopy Cancer Care for nurses to administer unprescribed medications.' However, Canopy told HDC that the administration of the existing oral prescription was reasonable in the circumstances and consistent with RN B's knowledge and experience.
- <sup>105.</sup> Mr A had been initially prescribed ondansetron tablets, but there was no prior prescription for metoclopramide. The Medsafe data sheet for metoclopramide states:

'The effects of metoclopramide may mask symptoms and delay the recognition of a serious disease. It should not be prescribed until diagnosis has been established and should not be substituted for appropriate investigation of the patient's symptoms.'<sup>74</sup>

106. Canopy told HDC that all clinical note-taking met the minimum Nursing Council of New Zealand and Medical Council of New Zealand standards (see Appendix D). Canopy said that its Documentation/Clinical Records Policy (Appendix C) provides expectations for staff consistent with the standards, including prompt record-keeping that supports communication, the planning of care, and evidence of any discussions or decisions.

<sup>&</sup>lt;sup>74</sup> https://www.medsafe.govt.nz/profs/datasheet/m/Metoclopramidepfizerinj.pdf.



<sup>&</sup>lt;sup>72</sup> A prescription ordered verbally by an authorised prescriber. Acceptance of verbal orders is not specifically provided for under legislation.

<sup>&</sup>lt;sup>73</sup> A standing order is a written instruction issued by a medical practitioner authorising specified person(s) to administer specified prescription medicines.

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107. At the time of the event, Canopy did not have a policy or guidelines in place for the assessment and management of acute patients, or patient self-discharge.

### Responses to provisional opinion

Mrs A

<sup>108.</sup> Mrs A was given an opportunity to respond to the 'information gathered' sections of the provisional opinion. She did not provide any comment in response.

#### Canopy

- 109. Canopy was given the opportunity to respond to the provisional opinion, and its comments have been incorporated in this opinion where relevant and appropriate.
- 110. Canopy submitted:

'[Mr A's] symptoms on the morning of 9 [Month3] (nauseous, dehydrated, exhausted and weak), need to be considered against the fact that he was undergoing chemotherapy at the time, and nausea, fatigue, and vomiting are common side-effects of chemotherapy. There was no reason to believe that [Mr A] was experiencing anything other than the common side-effects of chemotherapy.'

- 111. Canopy accepted that there were shortcomings in the care provided to Mr A but asserted that a breach finding is disproportionate, and a critical comment is more appropriate. Canopy said that it 'has made several improvements to its practice' since Mr A's case.
- 112. Canopy suggested that HDC's independent advisors were unnecessarily made aware of Mr A's death. It said that this knowledge 'likely biased [the advisors'] opinions and impacted on the severity of their criticisms (as opposed to if their opinions were based solely on the care delivered to a patient who presented with nausea and vomiting following the start of chemotherapy).' Canopy said that HDC should therefore consider the potential for hindsight bias when considering the independent advice obtained.
- 113. Canopy accepted the recommendations made by the Deputy Commissioner.

### RN B

- 114. RN B was given the opportunity to respond to the sections of the provisional opinion that relate to the care she provided, and her comments have been incorporated into this opinion where relevant and appropriate.
- 115. RN B accepted that her documentation was lacking and agreed to abide by the recommendations made by the Commissioner.

### Dr C

<sup>116.</sup> Dr C was given the opportunity to respond to the sections of the provisional opinion that relate to the care he provided, and his comments have been included in this opinion where relevant and appropriate.



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- 117. Dr C accepted that Mr A should have been referred for bloods; that the intended medical plan could have been communicated better; that retrospectively authorising the prescription of IV medication is against Canopy's internal policy and against legislation; and that 'in a perfect world' notes are written at the time, or shortly after the assessment of the patient.
- 118. However, Dr C considered that these aspects of his care warranted a critical comment, rather than a breach of the Code. He believes that a breach finding is disproportionate to his involvement in Mr A's care as, 'in conjunction with a fully booked practice, [Dr C] was focused on making [Mr A] comfortable and assisting with his nausea and fatigue'.
- <sup>119.</sup> Dr C accepted the recommendations made by the Deputy Commissioner.

# RN K, RN J, and Dr D

120. RN K and RN J read the provisional report and had no comment to make. Dr D read the report and accepted the findings and recommendations in respect of his conduct.

# **Opinion: Initial comment**

- 121. I wish to acknowledge Mr A and his family and offer my sincerest condolences. It is clear that this tragic event has prompted each provider, both group and individual, to reflect on the care they provided.
- 122. I reiterate that my role is to determine the standard of care Mr A was provided, rather than how he died. I note that there are several opinions on the cause of, or potential factors in, Mr A's death, many of which have benefited from information that has come to light following reflection and review of the events. While I acknowledge and respect Mrs A's concerns regarding the cause of Mr A's death, the purpose of this report is not to comment on those opinions. When assessing the standard of care provided to Mr A, I must consider whether appropriate care was provided based on the information known to the providers at the relevant time.
- In that respect, I note that Canopy raised concerns that my independent advisors were provided with information they did not require, such as Mr A's outcome (his death after leaving Canopy). Canopy suggested that this information may have given my advisors the benefit of hindsight when advising on the quality of Mr A's care, which 'likely biased' their advice and the severity of their criticisms. Having considered Canopy's comments, I do not believe hindsight bias was a factor in the advice provided in this case. The advisors were sent the information I would expect them to receive in order to advise me about Mr A's care. Further, HDC's independent advisors are routinely advised to be alert to hindsight bias, and to be aware that the outcome of care or treatment should not influence an advisor's

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view on the quality of that care and treatment, based on the information available to the health provider at the time.<sup>75</sup> Both the advisors in this case received that information.

124. This report highlights the importance of good systems for identifying and managing unwell oncology patients who present acutely to outpatient clinics, including clear processes for assessment, blood testing, the administration of prescription medicines, communication between staff, and the transfer or discharge of patients. It also demonstrates the importance of timely and accurate clinical notetaking.

#### **Chemotherapy guidelines**

- 125. Currently there are no national practice standards for general chemotherapy care in New Zealand,<sup>76</sup> despite the increasing administration of chemotherapy in the community setting.<sup>77</sup> Due to the narrow threshold between the therapeutic window and the development of serious complications,<sup>78</sup> it is important that community chemotherapy providers have good processes in place to identify, assess and respond to adverse reactions. New Zealand providers rely on quality evidence-based overseas guidelines such as eviQ, ESMO, and UKONS. The Knowledge and Skills Framework for Cancer Nursing (KSFCN) has also been developed to provide a New Zealand framework of learning for cancer nurses in a variety of clinical settings.
- 126. In forming my opinion, I have taken into account international guidelines, the differing accounts of events from those involved, and a range of medical opinions, including my independent advisors, Canopy advisors, and opinions provided by Mrs A.
- 127. I sought independent advice from an oncology specialist, Dr Richard Isaacs (Appendix A) and from an oncology nurse, NP Sarah Ellery (Appendix B). Their advice identified concerns at both the system and individual level, many of which complement the findings and recommendations in Canopy's RCA. I acknowledge the steps Canopy has taken to introduce changes since this event, and I emphasise the importance of responding well to concerns as part of the promotion of safe practice and ongoing system improvement.

### **Disputed facts**

- 128. First, I will address the disputed and unclear facts around Mr A's presenting symptoms, the administration of antiemetics, and his early departure, having carefully considered the parties' statements and the clinical notes.
- 129. From the statements and clinical notes, I accept that RN B and Dr C conducted an initial assessment of Mr A, and that Dr C considered and excluded chest pain and shortness of breath. I also accept that Dr C intended to conduct a review of Mr A after he had been hydrated, which is supported by RN B's response that she sought out Dr C when Mr A wanted to leave. However, there is no timely record in the notes of this assessment and plan, or



<sup>&</sup>lt;sup>75</sup> https://www.hdc.org.nz/media/fa1pl1dk/hdc-guideline-for-independent-advisors.pdf.

<sup>&</sup>lt;sup>76</sup> Clinical standards for advanced breast cancer were recently released in October 2022.

<sup>&</sup>lt;sup>77</sup> <u>https://bpac.org.nz/bpj/2015/october/chemotherapy.aspx</u>.

<sup>&</sup>lt;sup>78</sup> <u>https://bpac.org.nz/bpj/2015/october/chemotherapy.aspx</u>.

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whether it was made clear to Mr and Mrs A that it had been an initial assessment with a need for review. This may have influenced Mrs A's perception that the assessment was fleeting and deficient.

- 130. From Mrs A's and Dr C's statements, I accept that Mr A described a feeling of burning in his chest. Mrs A described this as 'heartburn', whereas Dr C understood Mr A to be describing retrosternal burning as a consequence of vomiting. This symptom was not recorded in the clinical notes, but it was accepted in the RCA timeline.
- 131. From RN B's and Dr C's statements, I find that the antiemetics were administered by IV at 9.35am prior to Dr C's medical assessment at around 10am. RN B said that she 'discussed Mr A's case with some of the other nurses and agreed to administer antiemetic medication intravenously'. I note that this differs from the RCA, which reports that Dr C reviewed the ECG results before prescribing the antiemetics, and then later returned to conduct the physical assessment.
- 132. It is also accepted that following the administration of fluids and antiemetics, Mr A felt better, prompting him to decline the third bag of saline, start drinking his own fluids, and express the wish to leave. Mrs A's recollection is that Mr A was confused. I am unable to make a finding about whether he was confused but note that Dr C's and RN B's impression was that Mr A was able to account for himself. It is not disputed that Mr A wanted to go home.
- 133. I accept both RN B's and Mrs A's recollection that Mr A was advised by RN B that he was able to leave. RN B told HDC: '[A]fter speaking with [Dr C], I then went back to the patient and told him the doctor had said he could go.' The nursing clinical notes simply record, 'rushing to get home'. Dr C later notes, retrospectively, 'not reviewed by me before leaving'. As the intended medical review by Dr C and any subsequent discussion around departure was not recorded at the time, I consider that contrary to the Canopy RCA, Mr A did not knowingly self-discharge against medical advice but instead departed when told he was free to go.
- <sup>134.</sup> I am unable to determine from RN B's and Dr C's statements whether Dr C was interrupted and then verbally advised RN B that Mr A could leave, as nothing to this effect is recorded in the clinical notes.

# **Opinion: Canopy Cancer Care** — breach

22

135. Group providers are responsible for the overall operation of their clinical services, and it is incumbent on Canopy to support its staff with systems and resources that guide thorough and coordinated clinical assessment, communication, note-taking and decision-making. As detailed below, I am concerned about aspects of Mr A's care. In my view, while there is individual accountability for the failures (which I discuss below), I consider that several systemic issues contributed to the standard of care provided.



- <sup>136.</sup> For the reasons discussed below, I find that Canopy Cancer Care Limited breached Right 4(1),<sup>79</sup> Right 4(2),<sup>80</sup> and Right 4(5)<sup>81</sup> of the Code, for failing to ensure:
  - A clear process for assessing and managing unwell chemotherapy patients;
  - That staff are equipped with accessible assessment and record-keeping tools;
  - That staff are available and have clear roles and responsibilities;
  - Timely blood screening of unwell patients; and
  - That IV prescription medicine was prescribed and administered in compliance with relevant legislation.
- 137. I note that the Canopy RCA identified gaps in the service provided, and that subsequently Canopy developed the Management of Acute Patient Guidelines, with clearer roles, responsibilities, and process for patient care. This report seeks to build on the RCA report and recommendations.

## Management of acute patients — breach

138. At the time of the event, Canopy did not have a formal management strategy for managing chemotherapy patients who became unwell and presented acutely to their clinics. Instead, there was heavy reliance on decision-making and coordination by individual clinicians. I am critical that this reliance, without the support of a formal strategy for the management of acute patients, led to gaps in the care provided, which were exacerbated by the use of both hard copy and electronic records, the absence of acute patient assessment tools, staff availability, unclear roles and responsibilities, and poor record-keeping and prescribing practices.

### Accessible assessment and record-keeping tools — breach

- 139. I am concerned at the poor level of documentation evident in this case, and that Canopy did not provide its staff with assessment tools and charts to record patient symptoms, clinical observations, key discussions, and medical plans promptly and accurately.
- <sup>140.</sup> The poor documentation has meant that there are significant gaps in the timeline of care, disjointed records of communication between nursing and medical staff, and few records of objectively verifiable data on Mr A's condition.
- 141. RN B told HDC that Canopy did not have an 'assessment tool or procedure for acute presentations', and, as there were no 'paper charts', her bedside observations were recorded on a piece of paper to be transcribed into an office computer later. She understood that this was standard practice at the time.



<sup>&</sup>lt;sup>79</sup> Right 4(1) states: 'Every consumer has the right to have services provided with reasonable care and skill.'

<sup>&</sup>lt;sup>80</sup> Right 4(2) states: 'Every consumer has the right to have services provided that comply with legal, professional, ethical, and other relevant standards.'

<sup>&</sup>lt;sup>81</sup> Right 4(5) states: 'Every consumer has the right to cooperation among providers to ensure quality and continuity of services.'

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- 142. RN B entered portions of her handwritten notes into the Canopy computer system at 12.31pm, after Mr A's departure. Only initial vital signs and observations were transcribed, and there is no record of tracked clinical data to show an improvement (ie, consecutive heart rate measurements) or any of the discussion with Dr C about Mr A's early departure.
- <sup>143.</sup> RN B did not record any of the discussions with Mr A regarding his 'self-discharge'. Canopy did not have a self-discharge form or process to prompt good documentation of the risk discussions, relevant decisions, and associated follow-up advice.
- 144. Dr C was called to assess Mr A between seeing patients in a fully scheduled clinic. Dr C told HDC that at around 12.30pm, he was advised that Mr A had already departed. Dr C was then off site for the remainder of the afternoon and did not enter notes from his assessment into the Canopy computer system until 9.05pm, 11 hours later, and after Mr A's death.
- <sup>145.</sup> No timely or accurate record was made of Mr A's assessment, plan of care, or that he had departed without a medical review. This would have informed and guided subsequent staff.
- 146. NP Ellery advised:

'The brevity of documentation of all the health professionals is below the expected standard of documentation. It has failed to include comprehensive assessment, ruling in or out of differential diagnoses, or a comprehensive plan for the patient.

•••

I believe the minimal documentation in the assessment of, and advice provided to, [Mr A] has led to a lack of visibility of the actions of RN B and therefore subsequently a lack of visibility to the care [Mr A] likely received.

•••

Minimal documentation standards in this case are attributable to both the system and the individual, both have responsibility to ensure minimum standards are maintained.'

- 147. Canopy told HDC that clinical note-taking met minimum standards. I disagree.
- <sup>148.</sup> I accept NP Ellery's advice that the clinical note-taking is below the expected standard, and am critical that while Canopy did have a records management policy and a computer available for entering clinical notes in the treatment room, the use of both paper and electronic systems and the absence of acute patient assessment tools failed to equip staff appropriately. Clear, structured bedside charts and notes could have been readily scanned into the Canopy electronic system prior to staff departure.
- <sup>149.</sup> While individual staff members hold some degree of responsibility for their failings (discussed below), I consider that the deficiencies outlined above indicate a service level departure, for which Canopy bears responsibility at an organisational level.

- 150. I note that the RCA recognised that there were omissions in the clinical assessment records, and while this prompted staff refresher training, there was no review of the bedside assessment tools or charts staff were to use.
- <sup>151.</sup> The RCA also did not identify the significant delay in Dr C's documentation entry. Timely records of Mr A's symptom of retrosternal burning, and premature departure prior to medical review (without a repeat ECG or blood testing) would have been informative for the triage nurse who answered Mrs A's call of concern just prior to 5pm.
- 152. I am also critical that although Canopy subsequently conducted refresher training on documentation on 6 December 2018, this was not attended by three key staff involved: Dr D, Dr C, and RN B.
- <sup>153.</sup> In response to the provisional opinion, Canopy told HDC that training was offered to every staff member, but Canopy does 'not have control over who attended'. Canopy submitted that it is not reasonable for HDC to be critical of it for the failure of those individuals to attend.
- <sup>154.</sup> In my view, however, it is incumbent on providers to ensure that their clinical staff have the appropriate training to maintain the required standard of documentation. This suggests that it should be considered mandatory for relevant staff to attend such training periodically.
- 155. In her advice, NP Ellery recommended the UKONS triage toolkit. She stated:<sup>82</sup>

'This document provides an alert card, algorithm for assessment, triage assessment process and log sheet for documentation along with training and competency education to "credential" staff in triage in this setting.

...

The algorithm is extremely valuable and undertaken on initial presentation (including phone triage) — covers the range of toxicities, scores them and provides level of urgency and actions needed. Completion of this tool would have led to greater visibility of assessment undertaken in the care of [Mr A] as one of the parameters is chest pain.

I would recommend its implementation at Canopy Cancer Care Centre to support the oncology nurses' practice in triaging unwell patients.'

<sup>156.</sup> Canopy has referred to the UKONS nausea algorithm from the UKONS Acute Oncology Initial Management Guidelines<sup>83</sup> and to eviQ and UKONS guidelines in its expectations for staff in its responses to this Office, but this information was not referred to in the Canopy Management of Acute Patient Guidelines. Instead, staff are referred only to broad eviQ online symptom summaries.<sup>84</sup> While the UKONS assessment algorithms may be considered



<sup>&</sup>lt;sup>82</sup> <u>https://www.ukons.org/site/assets/files/1134/oncology\_haematology\_24\_hour\_triage.pdf</u>.

<sup>&</sup>lt;sup>83</sup> <u>https://www.ukons.org/site/assets/files/1134/acute\_oncology\_initial\_management\_guidelines.pdf</u>.

<sup>&</sup>lt;sup>84</sup> <u>https://www.eviq.org.au/clinical-resources/oncological-emergencies</u> and <u>https://www.eviq.org.au/clinical-resources/side-effect-and-toxicity-management</u>.

'gold standard', Canopy failed to have any organisational assessment tools or charts in place for staff at the time, thereby increasing the risk of human error.

- 157. I note that the Canopy Acute Patient Guidelines have focused on the management of patients unwell with chemotherapy toxicities. Where triage staff 'suspect' a patient is 'clinically unstable' then they are to arrange immediate urgent admission to the nearest appropriate hospital. There is no clear objective guidance for telephone triage staff on what would be considered clinical instability.
- 158. For patients advised to attend the clinic, the Canopy Acute Patient Guidelines include the completion of a patient Early Warning Score (EWS), but it is not clear how the vital signs for this calculation will be tracked and recorded. Te Tāhū Hauora|Health Quality & Safety Commission (HQSC) has had a national vital signs and EWS chart available for patients since 2017. I am critical that there is no reference to a similar bedside chart in the Guidelines.
- In response to the provisional opinion, Canopy told HDC that the eviQ and UKONS guidelines do not apply to New Zealand and so Canopy cannot be found in breach of them. This contradicts the references Canopy has made to the same guidelines in its responses, including the provision of eviQ FOLFOX information to Mr A. I am satisfied that the quality evidence-based eviQ and UKONS guidelines apply to chemotherapy care in New Zealand, and I intend to inform Te Ahu o te Kahu | Cancer Control Agency of my decision.
- <sup>160.</sup> Canopy also told HDC that it had applied the New Zealand Early Warning Score Vital Sign Chart<sup>85</sup> (NZEWS) to Mr A's recorded vital signs.<sup>86</sup> Canopy stated:

'[T]he only vital sign that was not within the normal range on the morning of 9 [Month3] was a slightly elevated heart rate. Because of this, he would have received an EWS score of 2<sup>87</sup> [which] does not meet the need for increased clinical monitoring.'

- 161. I consider this to be speculative at best, given that Canopy did not have an appropriate EWS chart in place at the time and Mr A's respiratory rate and ongoing vital signs were not recorded in the notes. It also does not account for the entirety of Mr A's symptoms, such as retrosternal burning and the abnormal ECG result.
- 162. With this in mind, I recommend a review of the Acute Patient Guidelines to ensure that they include assessment algorithms, log sheets, and vital signs charts to prompt staff to record all a patient's symptoms and plan of care accurately from the moment of initial contact with triage, including broader clinical indicators, not just vital signs.

<sup>&</sup>lt;sup>85</sup> https://www.hqsc.govt.nz/assets/Our-work/Improved-service-delivery/Patient-deterioration/Publicationsresources/Vital\_sign\_chart\_user\_guide\_July\_2017\_.pdf.

<sup>&</sup>lt;sup>86</sup> Defined in the chart as respiratory rate, oxygen supplementation, oxygen saturation, heart rate, blood pressure, temperature, and level of consciousness.

<sup>&</sup>lt;sup>87</sup> Providers are to establish their own escalation pathways relevant to their circumstances. The HQSC example for escalation of EWS 1–5 is: '[C]onsider increased vital sign frequency, discuss with senior nurse, manage pain, fever and distress.'

Names have been removed (except Canopy Cancer Care Limited and the advisors) to protect privacy. Identifying letters are assigned in alphabetical order and bear no relationship to the person's actual name.

<sup>163.</sup> I have also made recommendations for an audit of clinical note-taking, and refresher note-taking training for Dr C and Dr D.

#### Staff availability and responsibilities - breach

- <sup>164.</sup> I am critical that the unavailability of staff and unclear roles and responsibilities led to disjointed clinical assessment and misunderstandings around Mr A's plan of care.
- 165. The triage nurse was not available to receive Mrs A's initial telephone call so it was answered by RN K, a general nurse, who asked Mr A to come into the clinic 'for IV fluids and possible IV antiemetics'. There is no record of a full telephone triage assessment. RN K told HDC that a 'full and more thorough assessment would take place by the nurse seeing him in the clinic'. RN B told HDC that Mr A presented 'for symptom and side effect management', because if he had been 'sweaty and confused when he called Canopy, it is likely he would have been advised to go to the emergency department rather than coming to Canopy for symptom management'.
- 166. RN B described receiving her initial directions from the nursing team, while waiting for Dr C to become available from his fully booked clinic to conduct a medical assessment.
- 167. Mrs A's impression was that Dr C's assessment was rushed. The discussions, assessment, and plan of care were not recorded. RN B stated that she was not present for all of the medical assessment, then later had difficulty accessing Dr C to review Mr A, eventually interrupting Dr C's clinic appointment to seek his advice. Dr C cannot recall this event and told HDC that he was only informed of Mr A's departure after Mr A had left.
- 168. Canopy stated that Dr C did not contact Mr A after discharge as he had been reassured by RN B that Mr A had improved. However, Dr C told HDC that there had been an intention for subsequent follow-up and community blood testing after discharge, but this was not actioned.
- <sup>169.</sup> While RN B telephoned Mr A at 1.30pm to relay a prescription, she told HDC that she expected Mr A's allocated nurse specialist to conduct further follow-up. It is not clear who was responsible for initiating this. By 2pm, both Dr C and RN B had left Canopy for the day, and there were no clinical notes on the system recording Dr C's initial assessment and plan, or Mr A's premature departure prior to medical review, including the intended repeat ECG and blood testing for electrolytes after rehydration.
- 170. When Mrs A contacted the triage nurse just before 5pm, critical information was missing from the notes and a further detailed assessment was not recorded. Mrs A was told that Canopy was closing and to take Mr A to hospital 'if he is vomiting'.
- 171. I sought independent advice from oncology specialist Dr Richard Isaacs, who advised:

'It is my opinion that there should have been a clearer understanding of the need for clinical review prior to discharge.

...



Failure of clinical review to occur would have been avoided by having clear practice guidelines in place, to ensure clinician review when this degree of intervention has occurred. Again these are process issues, influenced by factors involving the patient, nurse and clinician in this particular instance.'

- 172. Canopy accepted that the lack of medical review was a process issue and told HDC that there were 'different recollections of the communication between RN B and Dr C prior to Mr A leaving the clinic'. Canopy accepted that the failing was due to there being 'no clearly documented process for managing patients wishing to self-discharge against medical advice'.
- 173. There is no evidence in the clinical notes that Mr A knowingly self-discharged against medical advice. I accept Dr Isaacs' advice and consider that the absence of guidelines for the management of acute patients, with clear roles and responsibilities for staff, contributed to the failure to conduct a thorough medical review prior to discharge, and any subsequent follow-up by the relevant staff. I agree that a formal self-discharge process would have also ensured that Mr A was aware of the intended medical plan, the risks associated with departing prior to its completion, and the next steps should his condition deteriorate.
- 174. In response to the provisional opinion, Canopy accepted that the communication between relevant staff members caring for Mr A was 'not at an acceptable level' and there should have been a clinical review before Mr A was discharged. However, Canopy suggested that the description of 'disjointed clinical assessment and misunderstandings around Mr A's plan of care' is misleading. Canopy stated that there was no misunderstanding of Mr A's care as 'on Mr A's discharge, he was advised to call or attend the Emergency Department if he began vomiting again. It was intended that blood samples would be taken in the community setting.'
- 175. Furthermore, Canopy accepted that 'it would have been helpful if the referral for bloods (the plan of care) was referenced in Mr A's notes'. However, it does not consider that the failure to do so amounts to a misunderstanding of Mr A's care, and it considers that the failure to refer for bloods was unrelated to staffing roles and responsibilities.
- 176. I have considered this response and remain critical that the lack of clear processes and roles and responsibilities (including notifying Mr A's primary staff for further follow-up), and the unavailability of staff (including a triage nurse for the triage line, and Dr C due to his other commitments) led to disjointed assessment and misunderstandings around the plan of care, both before and after Mr A's discharge. I note that no blood testing was in fact arranged despite Dr C's acceptance that assessing electrolytes after rehydration would have been important. Nor was Mr A's primary oncologist and nurse specialist informed of his presentation.
- 177. I remain satisfied that the failure to have a clear process in place is a departure from the expected standard of care for unwell chemotherapy patients.
- 178. In response to the provisional opinion, Dr C told HDC that Mr A 'presented in an uncomfortable but not life-threatening state' and he had to prioritise the clinical care of his

other patients over note writing. Dr C considered that if he had prioritised Mr A's notes, he would not have been providing his other patients with reasonable and timely care.

- 179. I remain critical that Canopy had not managed the clinic workstreams appropriately to allow time for an oncologist to complete timely and accurate records for acute patients. This is reinforced by Mrs A's statement that Dr C's assessment appeared rushed, the ECG report was not signed, and RN B was not present for all of the medical assessment, then subsequently had difficulty accessing (and was reluctant to interrupt) Dr C when she needed to seek advice. I remain of the view that knowledge of Mr A's 'premature departure' (as accepted by Canopy) without further medical review and objective testing, was important information for the triage nurse at 5pm.
- 180. Canopy's Acute Patients Guideline now provides clear roles and responsibilities, and a pathway for patient assessment, treatment, review, discharge, referral to hospital, and follow-up.
- 181. NP Ellery commented on the adequacy of the new guidelines:

'The acute patient management policy subsequently implemented appears adequate and I commend Canopy Cancer Care Centre for implementation. However, it should be recognised that a policy is not a comprehensive document to cover patient management for clinical staff. Guidelines or pathways aid in clinical management and as above I would recommend the implementation of the UKONS triage toolkit to support nursing practice with additional educational support from the nurse educator on relevant topics to maintain nursing knowledge and skills in this area.'

<sup>182.</sup> I accept this advice. As a result, I recommend a review of triage assessment tools and an audit of the training provided by the Canopy nurse educator over the last 12 months.

# Blood screening — breach

- 183. I am concerned that there were no policies or procedures in place to provide Canopy staff with guidance around the necessity for timely blood testing in acute patients to inform patient medical care.
- 184. RN B told HDC that blood tests were not taken, as usually they were ordered by a doctor. Dr C told HDC that he intended to conduct a blood test and a repeat ECG when he returned to review Mr A after fluids had been administered. Dr C said that on learning that Mr A had departed, he had intended to arrange community blood testing. However, this plan was not recorded or actioned before Mr A died.
- 185. Dr Isaacs advised:

'It is my opinion that the initial assessment of [Mr A] was appropriate, with the exception of the patient not having a biochemistry screen, which I would consider as a moderate departure from the standard of care in this setting, given the assessed degree of dehydration and the potential for electrolyte disturbance, renal impairment and the potential need for hospitalization.

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[Dr C] acknowledges that blood testing would be important in this setting and indicated he would have expected bloods to be performed subsequently. I see the apparent failure to take blood tests as a process issue, rather than an individual failing.'

- <sup>186.</sup> Dr Isaacs advised that it would have been appropriate to undertake an urgent biochemistry screen, with a result available within two hours.
- <sup>187.</sup> The failure to conduct timely blood tests was also noted by Dr G, Dr H, and Dr I. In accordance with the UKONS guidelines for nausea and vomiting,<sup>88</sup> as subsequently provided to HDC by Canopy, Mr A would have required urgent blood screening,<sup>89</sup> including electrolytes.
- In response to Dr Isaac's advice, Canopy told HDC that it considers that the failure to take blood tests is a process issue and not an individual failing. The subsequent Acute Patient Guidelines includes for nursing staff to consider blood screening<sup>90</sup> within 30 minutes of acute patient arrival, and for medical staff to consider cardiac screening, including troponin.
- 189. Canopy responded that as a community clinic, urgent blood testing has a six-hour turnaround, and so would not have been available until after Mr A had been discharged. In my view, the timing for the turnaround of results is immaterial, as the providers did not know at the time that Mr A would leave earlier than anticipated. It is clear that the standard of care in these circumstances was to arrange timely blood tests to provide necessary information to direct Mr A's care.
- 190. I am mindful that the Medsafe datasheet for fluorouracil states:

'Because of the possibility of severe toxic reactions, all patients should be hospitalised, at least during the initial course of therapy, and appropriate facilities should be available for adequate management of complications should they arise.'

- <sup>191.</sup> It follows that it is important for community chemotherapy providers to have good processes in place where urgent blood testing (under two hours) is required.
- <sup>192.</sup> In response to the provisional opinion, Canopy submitted that as the failure to refer for blood testing did not impact on the care provided to Mr A, he received services of reasonable skill and care. Furthermore, Canopy said that a referral for bloods was not the priority as there was no indication that Mr A was suffering from anything other than the standard side-effects of chemotherapy. Canopy stated that any blood testing would have been completed in a community setting, and patients who require urgent testing, based on clinical assessment, are referred to hospital.

<sup>&</sup>lt;sup>90</sup> Full blood count, liver function tests, and urea and electrolytes.



<sup>&</sup>lt;sup>88</sup> <u>https://www.ukons.org/site/assets/files/1134/acute\_oncology\_initial\_management\_guidelines.pdf</u>, p18, p26.

<sup>&</sup>lt;sup>89</sup> Urgent full blood count, urea and electrolytes, liver function test, blood cultures, calcium and C-reactive protein.

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- As detailed above, both Dr Isaacs and other doctors, as well as the guidelines (referred to by Canopy in its previous responses) have identified that conducting urgent blood screening is the appropriate standard of care for unwell chemotherapy patients. It is a critical step in objective information gathering for patients who become very unwell while receiving cytotoxic drugs.
- <sup>194.</sup> I accept Dr Isaacs' advice that the failure to undertake blood testing was a moderate departure from the expected standard of care, and I consider that the lack of a formal process for management of acute patients was a contributing factor to this departure. There is also some individual responsibility on medical practitioners (which I discuss further separately).
- 195. I note that the Acute Patient Guidelines now include blood testing 'to be considered' by nursing and medical staff. They are, however, silent in relation to urgency and the necessary transfer to hospital for time-sensitive tests like troponin and electrolyte screening. This does not appear to align with Canopy's responses throughout this investigation. I suggest that Canopy review its guidelines to include referral to hospital services if urgent testing is indicated or consider point-of-care testing if test result turnaround times from its community laboratory provider are not sufficiently prompt to guide timely clinical decisionmaking.

## Administration of prescription medicine — breach

- <sup>196.</sup> I am concerned that IV prescription-only medicine was administered prior to a medical assessment and without a prescription, contrary to relevant legislation and standards.
- 197. At 9.35am, RN B administered ondansetron and metoclopramide intravenously, upon instruction by the nursing team and 'pending the Dr's assessment and plan'. This discussion is not recorded, and instead RN B stated that Dr C 'retrospectively' signed the chart when he became available to conduct Mr A's medical assessment.
- <sup>198.</sup> The Canopy Intravenous Medication Policy requires that '[a]II medico-legal requirements pertaining to the prescribing and administration of fluids and medications must be followed', and pre-administration checks include that the 'medication needs to be checked by two people'. The policy is silent in relation to recording the check on the medication chart. The Medication Management Policy requires prescriptions to comply with the Code of Practice of the New Zealand Medical Council and to comply with the laws pertaining to the prescribing of medicines. Canopy had no standing orders for antiemetics.
- In response to the provisional opinion, RN B told HDC that the medication was checked by another nurse prior to administration, but the check was not recorded on the chart. Canopy's medication chart did not have a dedicated space for medication checks to be recorded, and the chart lacks detail; notably, it is unclear where the prescriber and administrator of each medication are expected to sign.

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200. Under the Medicines Act 1981:

'19 Administering prescription medicines:

- (1) A prescription medicine may be administered to any person only in accordance with—
  - (a) the directions of the authorised prescriber or delegated prescriber who prescribed the medicine; or
  - (b) a standing order.'
- 201. Canopy acknowledged to HDC that the administration of prescription medicine without a prescription was contrary to organisational policies, but considered that it was reasonable in the circumstances, consistent with RN B's knowledge and experience, and because the medications had been prescribed in tablet form already and were just administered by a different route.
- 202. Canopy did not initially provide Mr A's original prescription records to HDC with the clinical notes. When the records were provided, Dr D had prescribed ondansetron in tablet form for Mr A's first round of treatment, but there was no prior prescription for metoclopramide. I note that Medsafe advises that 'the effects of metoclopramide may mask symptoms and delay the recognition of a serious disease. It should not be prescribed until diagnosis has been established.'<sup>91</sup>
- 203. NP Ellery advised:

'If [RN B] administered IV antiemetic medication prior to it being prescribed she has departed moderately from the expected standard of practice against policy, scope of practice and legislation. This departure is attributable to both the individual and the system, as this was [RN B's] decision which may have been influenced by her extensive oncology experience and also by time/resource constraints on the medical staff attending in a timely manner and the lack of standing orders in place.

•••

Consideration could be given to the development of standing orders by Canopy Cancer Care for the administration of antiemetics in the oncology triage setting. My own practice setting has these in place to support timely patient treatment.'

I accept this advice. It appears that because of the unavailability of an oncologist, prescriber, or standing order, the nursing team had developed an accepted practice of proceeding to administer IV antiemetics to patients experiencing CINV to provide immediate patient comfort while they waited for an oncologist's assessment. Regarding ondansetron, there were no standing orders in place for nursing staff to change the route of administration should the patient be unable to swallow tablets. Metoclopramide was administered without any evidence of either a verbal order or an existing prescription, and prior to a medical

<sup>&</sup>lt;sup>91</sup> https://www.medsafe.govt.nz/profs/datasheet/m/Metoclopramidepfizerinj.pdf.



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assessment.<sup>92</sup> I consider that Canopy must take responsibility for that practice, which did not comply with appropriate standards, at a service level.

- <sup>205.</sup> I note that the Canopy Management of Acute Patients Guideline is silent on the administration of antiemetics or other prescription medicine by staff.
- <sup>206.</sup> With this in mind, I recommend that Canopy review its prescription medicine practices and related charts to ensure that they comply with the Medicines Act and accepted practice, either by improving timely access to a medical assessment, the verbal order process through a prescriber, or through appropriate standing orders.
- 207. I recommend that the Acute Patients Guideline is updated to reflect this review, ensuring that there are clear roles and responsibilities for the administration of IV antiemetics to acute patients.
- <sup>208.</sup> In response to the provisional opinion, Canopy stated that '[d]octors are available in Canopy to complete the prescriptions and it does not condone a practice of regularly retrospectively prescribing medication'.
- 209. Canopy acknowledged that RN B's actions demonstrate gaps in Canopy's training, and all nurses have been reminded that prescription medication is not to be administered without a prescription.

#### Conclusion

- 210. Right 4(1) of the Code states that every consumer has the right to have services provided with reasonable care and skill. For failing to have in place guidelines for the assessment and management of unwell chemotherapy patients, including timely blood screening, I find Canopy Cancer Care Ltd in breach of Right 4(1) of the Code.
- 211. Right 4(2) of the Code states that every consumer has the right to have services provided that comply with legal, professional, ethical, and other relevant standards. For having a system that allowed for the administration of IV prescription medicine contrary to legislation, I find Canopy Cancer Care Ltd in breach of Right 4(2) of the Code.
- 212. Right 4(5) states that every consumer has the right to co-operation among providers to ensure quality and continuity of services. For the failure to have in place clear roles and responsibilities, and accessible assessment and record-keeping tools to ensure continuity of care between Canopy staff, I find Canopy Cancer Care Ltd in breach of Right 4(5) of the Code.

### **Complaint handling — adverse comment**

213. I acknowledge that Canopy promptly completed an RCA into the event and subsequently implemented significant changes as a result. I have identified discrepancies in the findings of the RCA above. I remind Canopy to ensure that it cross-references statements by staff



<sup>&</sup>lt;sup>92</sup> The Medsafe data sheet states: 'The effects of metoclopramide may mask symptoms and delay the recognition of a serious disease. It should not be prescribed until diagnosis has been established, and should not be substituted for appropriate investigation of the patient's symptoms.'

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with evidence from the complainant during the process. There was potentially a missed opportunity to bring earlier resolution to Mrs A and her family, at their time of immense distress.

# **Opinion: RN B** — breach

- 214. A description of the care provided by RN B is detailed in paragraphs 32–62 above. While I have taken into account significant systemic issues that affected the care provided by RN B, there are still some aspects of relevant individual responsibility.
- <sup>215.</sup> I acknowledge RN B's honesty in her statements to my Office. Her actions appear to have been well intentioned, with Mr A's comfort and wishes at the forefront. This decision reflects the important role of nurses in upholding individual practice standards despite challenging healthcare environments.

### Administration of prescription medicines — breach

- I am concerned that RN B administered IV prescription medicines<sup>93</sup> to Mr A without these having been charted by an authorised prescriber.<sup>94</sup> On 1 Month3, Mr A was prescribed the antiemetics domperidone and ondansetron as oral tablets. RN B told HDC that at Mr A's acute presentation on 9 Month3, she 'discussed Mr A's case with some of the other nurses and agreed to administer antiemetic medication intravenously' pending Dr C's assessment.
- 217. RN B recorded the administration of the antiemetics in the medication chart as Maxolon (metoclopramide) and ondansetron by IV at 9.35am. The clinical notes and medication chart do not record a verbal order or standing order, or that the medication was checked by two people prior to administration, as required by the guidelines and policies stipulated below.
- <sup>218.</sup> In response to the provisional opinion, RN B advised that the medication was checked by another nurse, but the check was not recorded. The name of the other nurse has not been provided.
- 219. RN B told HDC that Dr C then 'prescribed anti-nausea medication and fluids retrospectively' when he assessed Mr A physically at around 10am.
- 220. The Canopy Medication Management and Administration of Intravenous Medication policies (Appendix C) are described in paragraphs 102 and 103. Relevant standards are provided at Appendix D. The law and professional standards are clear that prescriptions can be issued only by authorised prescribers, of which RN B was not one. The Canopy Intravenous Medication Policy also required IV medication and verbal orders to be checked

<sup>&</sup>lt;sup>93</sup> Prescription medicines are medicines that can only be administered pursuant to a prescription by a person authorised to prescribe medicines (s3(3) of the Medicines Act 1981).

<sup>&</sup>lt;sup>94</sup> The Medicines Act 1981 states: '(2) authorised prescriber means — a nurse practitioner, optometrist, practitioners, registered midwife or designated prescriber.'
by two nurses prior to administration, and for verbal orders to be noted in the patient's notes.

221. NP Ellery advised:

'I acknowledge the 20 years of experience in cancer care outlined by [RN B] and therefore she will have significant knowledge and experience in the use of antiemetics in chemotherapy induced nausea and vomiting and acted to provide the patient with appropriate medication to relieve symptoms with the best interest of the patient at the centre of her decision making.

•••

If [RN B] administered IV antiemetic medication prior to it being prescribed she has departed moderately from the expected standard of practice against policy, scope of practice and legislation. This departure is attributable to both the individual and the system, as this was [RN B's] decision which may have been influenced by her extensive oncology experience and also by time/resource constraints on the medical staff attending in a timely manner and the lack of standing orders in place.

•••

[RN B] is bound by the Registered Nurse Scope of Practice and Competency 2.1 Provides planned nursing care to achieve identified outcomes. Indicator: Administers interventions, treatments and medications, (for example: intravenous therapy, calming and restraint), within legislation, codes and scope of practice; and according to authorised prescription, established policy and guidelines.<sup>95</sup>

...

[I]n most health settings [two] nurses are required to check IV medications prior to administration. It is not clear from the medication chart that [two] nurses checked this IV medication.'

- 222. RN B completed training in the administration of intravenous medication in July 2017, and in the Canopy medication policy in June 2018. There were no standing orders for ondansetron or metoclopramide.
- <sup>223.</sup> I have considered NP Ellery's advice, and, while I accept that RN B's decisions were affected by the lack of acute patient guidelines, verbal instructions by the broader nursing team, and the unavailability of Dr C for an assessment and prescription, this does not override individual professional responsibility to comply with relevant legislation. As a registered nurse, a basic requirement was to ensure that appropriate prescriptions were in place before administering medication.



Names have been removed (except Canopy Cancer Care Limited and the advisors) to protect privacy. Identifying letters are assigned in alphabetical order and bear no relationship to the person's actual name.

<sup>&</sup>lt;sup>95</sup> <u>https://www.nursingcouncil.org.nz/Public/Nursing/Standards\_and\_guidelines/NCNZ/nursing-</u> section/Standards\_and\_guidelines\_for\_nurses.aspx. Competencies for Registered Nurses page 7.

<sup>13</sup> October 2023

#### Clinical note-taking — breach

- 224. NP Ellery initially identified major departures in care for failing to document a comprehensive assessment of Mr A and the safety-netting advice provided. However, following RN B's responses, NP Ellery accepted that more assessment and safety-netting advice was provided than was recorded in the clinical notes.
- 225. NP Ellery advised:

'I believe the minimal documentation in the assessment of, and advice provided to, [Mr A] has led to a lack of visibility of the actions of [RN B] and therefore subsequently a lack of visibility to the care [Mr A] likely received.

•••

36

In my opinion [RN B's] documentation did not fully meet the expected standard. However, considering the use of multiple systems (electronic and paper) and potential workflow issues that may have been encountered this is a mild departure from expected standard of practice.'

- 226. The NCNZ Code of Conduct 4.8 (Appendix D) requires nurses to keep clear and accurate records, including any discussions, the assessments made, care and medicines given, and how effective these have been. Records are to be completed as soon as possible after an event has occurred.
- 227. Canopy's Clinical Records Management Policy (Appendix C) states:

'The record of care will include evidence of decisions made by clinicians, and discussions with any health care professional involved in the patient's care. Any entries into the clinical notes will be clear, structured and detailed. The record will identify any problems which have arisen and the action taken to rectify them, including discussions with the family, friends or carers of the patient.'

- I am concerned that the clinical note-taking does not record a complete set of clinical observation records, discussions with Mr and Mrs A around their departure (including the risks of leaving prior to medical review), or the discussion with Dr C advising that Mr A could leave. While there is evidence of some advice upon discharge, there is no evidence of contact with the nurse specialist who would provide the intended follow-up care and further safety-netting advice.
- <sup>229.</sup> The failure to record critical information around Mr A's departure then affected the advice provided by the triage nurse when Mrs A called at 5pm.
- I note that RN B has accepted that her notes were not detailed enough and told my Office that she has made an effort to improve her practice. However, RN B did not participate in Canopy's refresher training in clinical note-taking conducted in December 2018, and has not provided evidence of voluntarily completing any refresher training. She is now practising overseas.

I accept NP Ellery's advice that the note-taking did not provide good visibility of the care provided to Mr A, but while there were contributing systemic factors, in my view the poor record-keeping does not meet the required NCNZ standards.

# Conclusion

Right 4(2) of the Code states that every consumer has the right to have services provided that comply with legal, professional, ethical, and other relevant standards. For administering medication without a prescription, and failing to meet the relevant record-keeping standard, I find RN B in breach of Right 4(2) of the Code.

# **Opinion:** Dr C — breach

232. A description of Dr C's care is described in paragraphs 41 to 6472 above. I have accepted Dr C's response that he conducted an initial assessment of Mr A and intended to review him again after rehydration, with a view to blood testing and a repeat ECG.

## Blood testing — breach

- <sup>233.</sup> Oncology specialist Dr Isaacs advised that the initial assessment of Mr A was appropriate, but the failure to conduct a biochemistry screen, given the assessed degree of dehydration, and the potential for electrolyte disturbance, renal impairment, and the potential need for hospitalisation, was a moderate departure from expected standards. However, Dr Isaacs considered this to be a process issue rather than an individual failing, and he noted that Dr C 'acknowledges that blood testing would be important in this setting and indicated he would have expected bloods to be performed subsequently'.
- 234. Canopy accepted that this was a process issue, and that an acute patient management policy would have provided guidance for all clinical staff. However, in response to the provisional opinion, Canopy told HDC that the guidelines 'are not designed to replace standard clinical decision making. Assessing a patient (whether acute or not) relies on a clinical assessment of the presenting symptoms.'
- I have considered Dr Isaacs' advice and accept that there were contributing systemic issues, such as the lack of an acute patient policy, and an expectation to see acute patients on top of a full schedule. However, I note that MCNZ's 'Safe practice in an environment of resource limitation standards' (see Appendix D) states:

'While a service or team making a decision about the management of a patient is responsible for the effects of that decision, as a doctor, you are still accountable for your actions within the team.'

In my view, despite Dr C's heavy workload and the systemic issues identified, it would have been reasonable for Dr C to have arranged for timely blood screening, either at the initial assessment, following rehydration, or once he was aware that Mr A had departed prior to medical review.

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- <sup>237.</sup> I agree with Dr Isaacs' advice that the situation could have been mitigated to an extent by having an acute patient policy in place. However, applying MCNZ's standards, individual clinician responsibility remains for decisions and actions taken or not taken.
- <sup>238.</sup> In response to the provisional opinion, Dr C stated:

'There was no indication that [Mr A] was at risk from suffering a cardiac event. In the normal course of events, while bloods are helpful, they are not urgent and can be taken at a follow-up assessment. When [Mr A] first presented to Canopy, the focus was to make him comfortable.'

I note, however, that on Mr A's presenting symptoms Dr C would now refer for urgent blood testing, which is consistent with Dr Isaacs' advice. Dr C told HDC that his current practice for 'patients receiving chemotherapy (with low incidence cardiac toxicity) that experience the nonspecific symptoms and signs that Mr A presented with on that morning ... is to send them to the Emergency Department for cardiac enzymes and serial ECG assessments (which provide faster laboratory turnaround times)'.

#### Retrospective authorisation of IV prescription medications - breach

- 240. RN B told HDC that at 9.30am, after consulting the nursing team and while waiting for Dr C to conduct a medical review, she administered fluids and the prescription antiemetics metoclopramide and ondansetron by IV. During his medical assessment at about 10am, Dr C then signed the prescription 'retrospectively'.
- <sup>241.</sup> The Canopy Medication Management Policy states (see Appendix C):

'[Medical staff are] responsible for the prescribing and administration of drugs. Prescriptions should conform to the Code of Practice of the New Zealand Medical Council and in compliance with the laws pertaining to the prescribing of medicines.'

- <sup>242.</sup> Canopy did have a standing order for IV 0.9% sodium chloride, but there was no standing order for antiemetics.
- 243. MCNZ's 'Good Prescribing Practice' guidelines (see Appendix D) state:

'You should only prescribe medicines or treatment when you have adequately assessed the patient's condition, and/or have adequate knowledge of the patient's condition and are therefore satisfied that the medicines or treatment are in the patient's best interests.

•••

Never prescribe indiscriminately, excessively or recklessly.

•••

Prescribe in accordance with accepted practice and any relevant best practice guidelines. Prescribing outside of accepted norms should only occur in special circumstances with the patient's informed consent.

•••

If you are the doctor signing and issuing the prescription you bear responsibility for that treatment; it is therefore important that, as the prescriber, you understand the patient's condition as well as the treatment prescribed and can monitor any adverse effects of the medicine should they occur.'

- I am concerned that as the prescribing doctor, Dr C did not question the prior administration of IV prescription medicines without his authorisation and before a full medical assessment. The practice is not supported by Canopy policy and outside legislation. Furthermore, knowing that this had occurred did not prompt clearer communication around the need for a subsequent medical review at a scheduled time, or further follow-up once informed that Mr A had gone home without the intended blood test or repeat ECG.
- <sup>245.</sup> In response to the provisional opinion, Dr C told HDC:

'[R]etrospectively authorising the prescription of IV medication is against Canopy's internal policy and against legislation. However, the drugs had already been administered by the time I was consulted, and it is medication that I would have prescribed. I understand why [RN B] decided to administer the medication quickly as any delay would have led to unnecessary discomfort and suffering. The improvement in [Mr A's] symptoms suggests that this medication was needed as quickly as possible.'

- <sup>246.</sup> Dr C submitted that in light of this, his conduct in this respect is worthy of criticism but falls short of a breach of the Code.
- <sup>247.</sup> I have considered this response, particularly against the Medsafe data sheet, which states that metoclopramide should not be administered prior to a full medical assessment, and against the requirement in the MCNZ guidelines that medicines are to be prescribed only after the prescriber has adequately assessed the patient's condition. I remain satisfied that Dr C's actions in retrospectively completing the prescription were a departure from the expected professional standards.

#### Conclusion

<sup>248.</sup> While acknowledging the mitigating factors in relation to the systems at Canopy, I nevertheless consider that Dr C's failure to conduct timely blood screening of an unwell chemotherapy patient was a departure from Mr A's right to be provided with services of an appropriate standard. It follows that I find Dr C in breach of Right 4(1) of the Code. In addition, Dr C's retrospective authorisation of IV prescription medicine was a departure from expected MCNZ professional standards. Accordingly, I also find Dr C in breach of Right 4(2) of the Code.



<sup>13</sup> October 2023

#### Clinical note-taking and communication — adverse comment

- 249. MCNZ's guidance (see Appendix D) is that patient records must be clear and accurate, completed at the time of the events or as soon as possible afterwards, and must record decisions made and the reasons for them, and the proposed management plan, including any follow-up. This is consistent with Canopy's Clinical Records Policy (see Appendix C). While I note Dr Isaacs' and NP Ellery's advice about the lack of an acute patient management policy, the lack of bedside record-keeping tools, and workload constraints, there is still an expectation for individual clinicians to meet their own professional standards.
- <sup>250.</sup> Dr C's clinical notes were entered at 9pm, almost 11 hours after the initial medical assessment. They are significantly lacking in detail, including the symptoms of heartburn and low TVP, clinical reasoning, and the plan to review Mr A after rehydration. The comment of 'no chest pain, SOB' was ambiguous as to whether shortness of breath was present or absent, and the entry of '[t]achycardia had settled to approx 90/min' appears to be verbal information provided by the nursing team.
- 251. Accurate notes of the assessment and plan of care at the time would have communicated the intended medical plan to RN B and the other nursing staff. The failure to write timely notes contributed to Mr A's early departure prior to a full medical review, and his subsequent follow-up care. Knowing that Mr A had left prematurely would have provided the triage nurse important information when she later answered Mrs A's call.
- <sup>252.</sup> In response to the provisional opinion, Dr C considered this 'to be speculative' and he does 'not consider it justifies a speculative finding to support a breach of the Code'.
- I have considered this submission and note that RN B was not present throughout Dr C's assessment, and no plan of care was written for her to follow in relation to the need for a medical review, repeat ECG, and blood testing. Nor was a record made that Mr A's departure was without Dr C's sanction, in order to inform triage and other staff of Mr A's ongoing care. The ECG report was not signed as having been reviewed. Dr C's notes were eventually written in retrospect at 9pm, after Mr A's death, but did not include any acknowledgement that they were made retrospectively.
- It is not speculative to consider the impact of Dr C's missing records on Mr A's standard of care. RN B's and RN J's subsequent actions and inactions must be viewed based on the information they had available to them at the time, which was the complete absence of any notes by Dr C. This case illustrates the importance of upholding MCNZ professional standards for timely and accurate clinical record-keeping.
- 255. Dr C advised HDC that he has reflected on his practice and ensures that he records clear descriptions of treatment and review plans so that there is no ambiguity around reassessment, including firm timings for review so that it is also clear to the patient.
- <sup>256.</sup> I acknowledge Dr C's reflection on his practice. I note, however, that Dr C did not participate in Canopy's refresher training in clinical note-taking conducted in December 2018, nor has he provided evidence of other re-training in the intervening period. With this in mind, I make

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the recommendation (outlined below) that Dr C attend a refresher course in clinical notetaking.

<sup>257.</sup> In connection with Dr C's failure to make timely notes of Mr A's assessment, plan of care, and premature departure, I am also critical that Dr C did not verbally communicate his intended medical plan. RN B and Mr and Mrs A were not directly made aware that Dr C intended to conduct a later review after Mr A had received rehydration, with a repeat ECG and blood testing. Dr Isaacs considered the failure to communicate the need to conduct a further review of Mr A to be a mild departure from the accepted standard. I accept Dr Isaacs' advice that the confusion about this matter could have been avoided if there had been clear practice guidelines in place stating that a medical review was necessary with the degree of intervention that occurred in Mr A's case.

# **Opinion: Dr D — adverse comment**

- Dr D was Mr A's primary oncologist and conducted an initial interview with Mr and Mrs A on 26 Month2 outlining possible chemotherapy options. During Mr A's orientation at Canopy on 1 Month3, Dr D had a video conference with Mr A to discuss the selected FOLFOX treatment regimen. Following this, Mr A signed a general consent document acknowledging an unknown risk of side effects and adverse reactions.
- <sup>259.</sup> Mrs A raised concerns that insufficient information had been provided around the risk of cardiac events and cardiotoxicity. Dr D told HDC that during the video call he explicitly covered 'angina or "heart pain" which can lead to a heart attack and that heart attacks are sometimes fatal'. Mr A was then provided with the eviQ patient FOLFOX patient handout, which details the risk of 'heart problems'.
- 260. Both Dr F (for Canopy) and my independent advisor, Dr Isaacs, reviewed the clinical decisionmaking, choice of chemotherapy, and information provided to Mr A by Dr D, and found no departure in care.
- <sup>261.</sup> I accept this advice regarding the choice of chemotherapy.
- 262. However, I note that while there is a general signed consent form, there are no clinical records detailing the information on specific risks provided to Mr A by Dr D verbally. Furthermore, there is no record of a telephone call to Dr E regarding Mr A's previous cardiac history and Dr E's advice that there was no reason to exclude Mr A from a FOLFOX regimen.
- <sup>263.</sup> In Dr I's advice, provided by Mrs A, Dr I noted that a baseline ECHO had not been conducted. The eviQ clinical guidelines for cardiotoxicity state:

'Baseline measurement (ECHO) should be considered in all patients and especially in those with pre-existing risk factors of developing cardiac disease or in patients receiving potentially cardiotoxic agents.'

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- <sup>264.</sup> While Dr E advised that ECHO would not have identified Mr A's heart anomaly, I suggest that Dr D proactively consider baseline ECHO in the future, or fully document any reasoning for not conducting an ECHO prior to starting cardiotoxic chemotherapy.
- <sup>265.</sup> I remind Dr D of the importance of accurately recording the risks about which a patient is informed, and the cardiologist advice sought regarding patients with a cardiac history.
- <sup>266.</sup> I note that Dr D did not attend the Canopy refresher training in clinical note-taking conducted in December 2018. In light of this, and the comments above, I recommend that Dr D complete a clinical note-taking refresher course.

# Recommendations

#### **Canopy Cancer Care Ltd**

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- <sup>267.</sup> I recommend that Canopy Cancer Care Ltd:
  - a) Conduct a spot audit of clinical note-taking over the last 12 months to ensure that it complies with relevant standards.
  - b) Review its Management of Acute Patient Guidelines to ensure that it includes the appropriate triage patient assessment tools and charts for identifying and immediately referring clinically unstable patients.
  - c) Review its Management of Acute Patient Guidelines to ensure that it refers to appropriate bedside patient assessment tools and charts for the accurate recording of patient symptoms, vital signs, medical assessment, and plan of care.
  - d) Review its blood screening processes and referral processes to ensure that timely urgent screening is available.
  - e) Review its prescribing processes and related charts to ensure that these are compatible with legislation and accepted practice.
  - f) Update its Management of Acute Patient Guidelines to reflect the prescribing processes.
  - g) Conduct an audit of the training provided by the clinical nurse educator over the last 12 months.
- <sup>268.</sup> Canopy Cancer Care Ltd is to report back to HDC on any issues regarding the above recommendations, and, if there are any shortfalls, advise how these are being addressed, within three months of the date of this report.
- <sup>269.</sup> With restorative principles in mind, I recommend that Canopy Cancer Care Ltd provide a written apology to Mrs A and her family for the failings identified in this report. The apology is to be sent to HDC, for forwarding to Mrs A, within three weeks of the date of this report.

#### RN B

- <sup>270.</sup> I recommend that with restorative principles in mind, RN B provide a written apology to Mrs A for the failings identified in this report. The apology is to be sent to HDC, for forwarding to Mrs A, within three weeks of the date of this report.
- In my provisional opinion, I proposed to recommend that RN B complete an appropriate clinical nursing documentation course. RN B has provided evidence that she completed this training on 13 September 2023. I am satisfied that this recommendation has been met. I also proposed to recommend that RN B complete an appropriate administration of prescription medicine course, and RN B has provided evidence that she completed this training on 26 September 2023. I am satisfied that this recommendation has been met.

# Dr C

- 272. I recommend that Dr C:
  - a) Complete an appropriate clinical documentation course within six months of the date of this report.
  - b) Complete an appropriate prescribing refresher course within six months of the date of this report.
  - c) With restorative principles in mind, provide a written apology to Mrs A for the adverse comments made in this report. The apology is to be sent to HDC, for forwarding to Mrs A, within three weeks of the date of this report.

# Dr D

273. I recommend that Dr D complete an appropriate clinical documentation course within six months of the date of this report.

# **Follow-up actions**

- 274. A copy of this report with details identifying the parties removed, except Canopy Cancer Care Ltd and the advisors on this case, will be sent to the Nursing Council of New Zealand, and it will be advised of RN B's name in covering correspondence.
- 275. A copy of this report with details identifying the parties removed, except Canopy Cancer Care Ltd and the advisors on this case, will be sent to the Medical Council of New Zealand, and it will be advised of Dr C's name in covering correspondence.
- 276. A copy of this report with details identifying the parties removed, except Canopy Cancer Care Ltd and the advisors on this case, will be sent to Te Whatu Ora|Health New Zealand, Te Tāhū Hauora|Health Quality & Safety Commission, and Te Aho o Te Kahu|Cancer Control Agency, and placed on the Health and Disability Commissioner's website, <u>www.hdc.org.nz</u>, for educational purposes.



<sup>13</sup> October 2023

# Appendix A: Independent oncology clinical advice to Commissioner

The following independent advice was obtained from Dr Richard Isaacs:

'October 12, 2020 Complaints Assessment Team Leader Health & Disability Commissioner

# Complaint: [Dr D] and [Dr C] at Canopy Cancer Care

## Ref: C19HDC01148

Thank you for seeking my opinion on the care provided to [Mr A] by [Dr D] and [Dr C] at Canopy Cancer Care from 26 [Month2] to 9 [Month3].

I do not have a personal or professional conflict in this case.

## **Clinical Summary**

[Mr A] presented with a 4 month history of altered bowel habit, associated with weight loss and lethargy. Colonoscopy confirmed a moderately differentiated carcinoma of the recto-sigmoid and he went forward to low anterior resection on 9 [Month2], which was performed without complication. The tumour was staged as T4N1b and he was referred to [Dr D] at Canopy Cancer Care to consider adjuvant chemotherapy.

His past medical history was confined to renal stones, treated by cystoscopies, and paroxysmal SVT, treated by cardiac ablation by [Dr E] in 2017. He had no history of ischemic heart disease and was on a diuretic, but no other cardiac medication.

[Dr D] discussed the options for adjuvant chemotherapy and provided written information on FOLFOX from the Eviq website.

On 1 [Month3] [Mr A] had an orientation meeting with one of the Canopy nurses to review treatment, including side effects and a baseline ECG was performed. He attended on his own.

He had a portacath inserted on 5 [Month3] and commenced chemotherapy on 7 [Month3].

On 9 [Month3] [Mrs A] phoned at 0930 to say [Mr A] had vomited several times overnight. He was brought in to Canopy Cancer Care for review and noted to be clinically dehydrated. He was given antiemetics and given 2 litres of IV fluids. Repeat ECG showed tachycardia, but no other clear changes from baseline study.

[Mr A] clinically improved and tolerated oral fluids, including 750ml water and a cup of coffee. He was encouraged to keep up oral fluids and was discharged to the care of his wife.

HX

[Mrs A] contacted Canopy again soon after arrival home, concerned he was still nauseated. He was subsequently found to have collapsed. CPR was attempted but he did not survive.

The coroner's pathologist report identifies an anomalous right coronary artery and gives the opinion that this caused a cardiac event and death.

#### Expert advice requested

I have been asked to comment on the following issues:

[Dr D]

Whether appropriate steps were taken to determine if FOLFOX was suitable for [Mr A] in light of his cardiac history.

[Mr A's] prior cardiac history was confined to that of a paroxysmal SVT that had been successfully treated with cardiac ablation in 2017. At that time, [Dr E] performed echocardiography which showed a structurally normal heart and there was no evidence of ischaemia. 5-Fluorouracil is a component of FOLFOX chemotherapy and carries a small risk of inducing coronary spasm and ischaemia, which is higher in those with known atherosclerotic ischaemic heart disease. The postmortem revealed normal caliber coronary arteries and no evidence of prior ischaemic damage to the myocardium.

The anomalous origin of the right coronary artery was undiagnosed until postmortem and [Mr A] had not described previous ischaemic symptoms to suggest increased risk.

It is my opinion that [Mr A] was at no known increased risk of cardiac toxicity from FOLFOX chemotherapy when he saw [Dr D].

Whether the information given to [Mr A] about the potential risks of chemotherapy, including the risks of cardiotoxicity and cardiac ischaemia, was in accordance with accepted practice; [Dr D] indicates in his reply that he provided [Mr A] with written patient information about the potential side effects of FOLFOX from the eviQ patient information website.

The relevant information in that document is:

 Heart problems
 • You may get:

 = chest pain or tightness
 = shortness of breath

 = an abnormal heartbeat
 - Tell your doctor if you have a history of heart problems or high blood pressure.

 • Tell your doctor or nurse immediately, or go to the nearest hospital Emergency Department if you get any of the symptoms listed above.

[Dr D] also states that it is his practice to emphasize the small, but significant risks "of angina or heart pain which can lead to a heart attack and that heart attacks are sometimes fatal".



It is my opinion that the information provided by [Dr D] on the risks of cardiac toxicity and cardiac ischaemia were in full accordance with accepted practice.

3. The standard of clinical documentation;

It is my opinion that the content of [Dr D's] initial letter and the provision of Eviq patient information is absolutely consistent with the current standard of care.

Any other matters that you consider amount to a departure from accepted standards. *I recognize no departures from accepted standards.* 

# [Dr C]

Whether the care provided to [Mr A] on 9 [Month3] was appropriate in the circumstances;

[Dr C] was asked to see [Mr A] on the morning of the second day after FOLFOX chemotherapy, with the history of a 12-hour history of vomiting, which had settled by the time he was seen. [Dr C] noted a history of heartburn with acid water brash, but "no shortness of breath" and "no concerning chest pain". His clinical assessment was that of dehydration and he prescribed intravenous fluids, with the expectation [Mr A's] condition would improve, but he did mention hospital admission was possible if he did not. He states that his expectation was to review [Mr A] after he had received his fluid.

# It is my opinion that this initial assessment was appropriate and consistent with an accepted standard of care, based on the expectation of subsequent clinical review of the patient.

[Mr A's] clinical presentation and the adequacy of the tests and assessments undertaken. Please comment on whether additional investigations were clinically indicated to rule out any cardiac causes for [Mr A's] symptoms;

[Mr A] was clinically assessed as being dehydrated. He had observations of blood pressure, heart rate and had a repeat ECG, but I received no evidence that bloods were performed before or after he received his IV fluids. These would have been informative, particularly the electrolytes and renal function after a prolonged period of vomiting.

I would not have pursued further cardiac investigations at that time, as the history was not suggestive of a primary cardiac cause, but rather acute chemotherapy-induced nausea and vomiting, with secondary and significant dehydration.

[Mr A] tolerated significant IV fluids and his tachycardia (which was not an arrhythmia) improved significantly after receiving the fluids. [Dr C] had also assessed his ECG at presentation and did not feel that there were changes suggesting an ischaemic event.

The risks of arrhythmia related to the coronary artery anomaly had not been identified at any time prior to the postmortem. This variant is a congenital abnormality, which has been linked to ischaemia and to sudden death from arrhythmia, typically occurring earlier in life. There was no clear evidence of cardiac ischaemia when [Mr A] attended Canopy and his improvement clinically after a significant fluid challenge indicates adequate cardiac function during fluid resuscitation.

It is my opinion that the initial assessment of [Mr A] was appropriate, with the exception of the patient not having a biochemistry screen<sup>96</sup>, which I would consider as a moderate departure from the standard of care in this setting, given the assessed degree of dehydration and the potential for electrolyte disturbance, renal impairment and the potential need for hospitalization.

[Dr C] acknowledges that blood testing would be important in this setting and indicated he would have expected bloods to be performed subsequently. I see the apparent failure to take blood tests as a process issue, rather than an individual failing.

The adequacy of [Dr C's] communication with nursing staff regarding his expectation to review [Mr A] again post rehydration.

[Dr C] clearly had an expectation to review [Mr A] prior to his discharge. From the clinical notes provided, it is clear that [Mr A] had improved significantly with 2 litres of fluid and was tolerating a significant volume of oral fluids. The notes also state that [Mr A] "declined to have a 3rd litre normal saline", and was "rushing to get home". There is no indication from the notes that [Dr C] was contacted prior to his departure and I note he states that, while he had not specifically instructed the nurses that [Mr A] should have been seen (again), he notes that review would "be standard practice given the level of intervention required up to that point".

It is my opinion that there should have been a clearer understanding of the need for clinical review prior to discharge. The decision by nursing staff to allow [Mr A] to leave was influenced by the improvement in [Mr A's] condition and apparently by his wish to go home as soon as possible, but I believe [Dr C] should have been informed of the patient's wish to leave prior to departure. With respect to departure from the standard of care for this communication, the failure to specifically request clinical review, I consider a mild departure from the standard of care. Failure of clinical review to occur would have been avoided by having clear practice guidelines in place, to ensure clinician review when this degree of intervention has occurred. Again these are process issues, influenced by factors involving the patient, nurse and clinician in this particular instance.

4. Any other matters that you consider amount to a departure from accepted standards. From the information I have been given there are no further issues to discuss.

Yours sincerely,

Dr Richard Isaacs MNZM MBChB FRACP D.Phil (Oxon) Consultant medical Oncologist'



Names have been removed (except Canopy Cancer Care Limited and the advisors) to protect privacy. Identifying letters are assigned in alphabetical order and bear no relationship to the person's actual name.

<sup>&</sup>lt;sup>96</sup> Clarified on 12 July 2023: I believe the biochemistry screen should have been done urgently (a result available within 2 hours).

<sup>13</sup> October 2023

# Appendix B: Independent oncology nursing clinical advice to Commissioner

The following independent advice was obtained from NP Sarah Ellery (10 June 2021):

'I, Sarah Ellery have been asked to provide an opinion to the Commissioner on case number **C19HDC01148**, and I have read and agree to follow the Commissioner's Guidelines for Independent Advisors, and I am not aware of any conflicts of interest.

I have over 20 years' oncology nursing experience and currently practise as a Nurse Practitioner in Oncology. Within my role as Nurse Practitioner, I subspecialise in colorectal cancer and provide independent management of patients with colorectal cancer including prescribing of chemotherapy. I hold a Master in Health Sciences (Nursing) degree.

## Background

[Mr A] was diagnosed with bowel cancer and underwent colorectal surgery on 9 [Month2]. He was then placed under the care of Canopy Cancer Care.

[Mr A] had his first consultation on 26 [Month2 and] commenced the FOLFOX regimen on 7 [Month3]. [Mr A] subsequently became unwell and presented to Canopy Cancer Care on 9 [Month3]. He was started on a saline drip with antiemetics. He was assessed and diagnosed with severe dehydration secondary to Chemotherapy Induced Nausea and Vomiting (CINV). He was charted two more litres of saline (making three litres in total). [Mr A] also began to tolerate liquids orally quite well. During [Mr A's] second bag of saline, he expressed the desire to return home. [Mr A] returned home; however, he died later that day from a sudden cardiac event.

#### Expert advice requested

Please review the enclosed documentation and advise whether you consider the care provided to [Mr A] by [RN B] was reasonable in the circumstances, and why.

In particular, please comment on:

- 1. The appropriateness of the nursing care provided to [Mr A] on 9 [Month3];
- 2. The appropriateness of the safety netting advice provided to [Mr A] prior to leaving Canopy;
- 3. 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?
- 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?
- c. How would it be viewed by your peers?

HX

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

#### Documents provided:

Copy of complainant letter Copy of nursing notes Expert request letter

# Appropriateness of nursing care provided to [Mr A] on 9<sup>th</sup> [Month3]

I note firstly the brevity of documentation across all entries.

- On presentation for review vital signs have been undertaken and note a low grade fever and tachycardia. Mouth noted to be dry. It appears other vital signs have been taken during this presentation but are not documented here as [RN B] comments "HR imp" which I interpret as heart rate improved.
- There is no nursing (or medical) documentation regarding [Mr A] experiencing heartburn, sweating, poor perfusion to legs, anxiety or confusion as his wife indicated.
- There does not appear to have been any assessment for "red flag" treatment related toxicity such as chest pain or diarrhoea by [RN B]. Diarrhoea may contribute to dehydration if significant and is considered a common side effect of both 5FU and oxaliplatin.
- There is no evidence of a general assessment for other side effects such as mouth ulcers (occurs more commonly with infusional 5FU, used in this regimen) or cold-induced dysesthesia from oxaliplatin administration which occurs in almost every patient within the first few days after administration.

Nursing care on the 9<sup>th</sup> [Month3], appears to have focused on nausea, vomiting and dehydration and the management of these with some subjective documentation indicating an improvement in condition with this management — [Mr A] was able to tolerate oral fluids and his heart rate had improved.

Based on the documentation provided, in my opinion, assessment of the patient appears minimal, whether this was on the phone or in person. Assessment for chemotherapy treatment related toxicity and known "red flags" with this particular regimen was not comprehensive. I consider this a major departure from accepted practice as would my peers.

# Appropriateness of safety netting advice prior to [Mr A] leaving Canopy.

Advice provided is brief: "enc PO fluids, reg antiemetics, small freq meals and monitor temp", and focuses on management of nausea and vomiting.



The comment to monitor temperature in my opinion has little context to the event but is not unreasonable given the presence of a low grade fever. It is not uncommon practice within oncology to inform patients receiving chemotherapy to monitor their temperature regularly, every day, or even several times a day even if asymptomatic. This practice varies with no standard approach at either treatment centre or clinician level.

The safety netting advice provided by [RN B] failed to provide any education on potential expected side effects of treatment and appropriate at home management of these given this was [Mr A's] first cycle of treatment.

There was also failure to outline a plan for [Mr A] if his condition worsened. The gaps in safety netting advice provided are a major departure from expected practice, in my opinion, and would be the same in my peers.

I have been asked to comment on the care provided by [RN B] in particular, and whether this was reasonable. There are clearly several failures as outlined above in the care provided by [RN B] and therefore the care was not to the expected standard. However, I feel obligated to comment on the contribution of the other health professionals involved, at least one other nurse and a doctor.

During my 20 years plus oncology career and since becoming a Nurse Practitioner I worked for several years in a triage service as part of the medical roster (not nursing) assessing patients on chemotherapy for treatment related toxicity or for wider oncology and medical issues, admitting patients as needed. Given my extensive and broad experience in oncology I wish to note the contribution of the other health professionals involved also appears to fail to meet the expected standard of care based on the documentation provided to me.

The brevity of documentation of all the health professionals is below the expected standard of documentation. It has failed to include comprehensive assessment, ruling in or out of differential diagnoses, or a comprehensive plan for the patient. Both the New Zealand Nurses Organisation (Guideline: Documentation, 2017, NZNO)<sup>1</sup> and Medical Council of New Zealand (Maintenance of patient records)<sup>2</sup> provide guidelines on documentation for health professionals.

The documentation does not support the other health professionals involved having undertaken comprehensive assessment in this situation. The initial telephone call taken by a nurse from [Mr A's] wife to alert Canopy that he was unwell does not demonstrate comprehensive assessment of his condition. The nurse did err on the side of caution and advised [Mr A] to attend for review. A further telephone call with another nurse later in the day also continues to focus on management of nausea and vomiting but does indicate he should attend hospital if vomiting, some safety netting provided.

The medical documentation notes no chest pain and the ECG changes as similar to baseline and attributes ST elevation to tachycardia. It appears a troponin level was not taken as his wife indicates no blood tests were performed. It is not clear if [Mr A]

informed either the nursing or medical staff of heartburn which should have alerted experienced oncology staff to consider a cardiac cause given, he was within the first 72 hours of 5FU based chemotherapy. Heartburn was never addressed at any point during this episode of care. In my experience cardiac presentations can be atypical and given the known risk of cardiac complications from 5FU a report of heartburn should be assessed, at the least with thorough history taking in the first instance.

## Recommendations

- Standard of documentation Canopy Cancer Care should provide written guidance for all staff on standard of documentation. If this is not in place currently, then it should be developed and if in place education should be provided to staff using this and the provided references on documentation as a base.
- 2. **Oncology Nurse training** Canopy Cancer Care should review their current policies, procedures, and training processes for nurses around chemotherapy administration and side effect management and triage training to ensure nurses are fully supported and safe to undertake these roles.

Background to the above recommendation — most cancer treatment centres provide a basic orientation programme for new staff and the depth of oncology knowledge and skills within these varies. Most of the development of knowledge and skills is learnt "on the job". A national Cancer Nurses Knowledge and Skills Framework<sup>3</sup> exists but has not been adopted into cancer centres nationally.

Nurses are generally required (but not mandated nationally) to become "chemotherapy certified" to administer chemotherapy and it is through this process they develop knowledge around chemotherapy drugs and associated side effects. There is not a single source for this training, many centres, but not all, use the eviQ module from Australia.

Most cancer treatment centres in New Zealand will provide some type of "triage service" which may vary from one centre to another. These services may include nurses taking, or making telephone calls proactively, and undertaking assessment and providing advice over the phone, or patients presenting for review to the service as in this report. Generally, at the very least, a 24 hour contact telephone number is provided to ensure early interaction due to the risk of serious toxicity from chemotherapy.

Undertaking this triage role requires training and support to be delivered at a high standard. Again there are no national formal training programmes/courses for this in the oncology setting, centres will develop their own but this may not occur at all centres.

# References

- 1. Guideline: Documentation, 2017, NZNO LinkClick.aspx (nzno.org.nz)
- 2. Medical Council of New Zealand. <u>Maintenance-patient-records.pdf (mcnz.org.nz)</u>
- 3. Knowledge and Skills Framework for Cancer Nursing, 2015, NZNO. <u>2015-01-28</u> <u>KSFCN 2014 FINAL5.pdf (nzno.org.nz)</u>

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Names have been removed (except Canopy Cancer Care Limited and the advisors) to protect privacy. Identifying letters are assigned in alphabetical order and bear no relationship to the person's actual name.

# Addenda (24 June 2021):

I have reviewed the statement provided by [RN B] and don't think this changes the statements I have made.

I note from [RN B's] statement she states she took a history which is not available to assess the extent of history taking. She also commenced IVFs at 200ml/hour but does not indicate if this was a standing order or verbal order from medical staff. She also undertook an ECG but does not outline why. Further into her statement she notes on reflection she did not undertake blood tests as these would require a medical staff order, however she may have prompted medical staff on this which would not be an unreasonable action if her history had indicated it and she was doing an ECG.'

# Follow up advice dated 12 July 2022:

'I, Sarah Ellery have been requested to review responses to my expert opinion previously provided for case number **19HDC01148**.

# Background

[Mr A] was diagnosed with bowel cancer and underwent colorectal surgery on 9 [Month2]. He was then placed under the care of Canopy Cancer Care. [Mr A] had his first consultation on 26 [Month2] and commenced the FOLFOX6 regimen on 7 [Month3].

[Mr A] subsequently became unwell and presented to Canopy Cancer Care on the morning of 9 [Month3]. [RN B] started a saline drip with antiemetics, and conducted an ECG, before [Mr A] was assessed by a Doctor. He was diagnosed with severe dehydration secondary to Chemotherapy Induced Nausea and Vomiting (CINV), and charted two more litres of saline (making three litres in total). The assessing Doctor and [Mrs A] refer to the symptom of heartburn but it is not recorded in notes. After [Mr A's] second bag of saline, he expressed that he wanted to go home. [Mr A] returned home, however, he died later that day from a sudden cardiac event. The complaint is brought to HDC by his wife.

There are conflicting accounts about [Mr A's] departure. [Mrs A's] account is that they were told they could leave by [RN B]. [RN B's] account is that she interrupted the Doctor's consult, and the Doctor said he could go home, she then informed [Mr A]. The Doctor's account is that after he had finished his consult, he was told by the nursing team that [Mr A] had gone home. Canopy Cancer Care's view is that [Mr A] left before being reviewed by the Doctor and "self-discharged".

# Expert advice requested

Please comment on whether any additional responses, statements or information causes you to change your original opinion and, if so please provide reasons for this. If the information does not cause you to change your original opinion, please also provide reasons for this.

# In particular:

- 1. Whether the Canopy nursing task allocation causes you to change your original opinion.
- 2. The appropriateness of the administration of antiemetics prior to the review by the doctor.
- 3. Whether the departures from accepted practice identified in your advice are attributable to the system or individual clinicians.
- 4. Whether or not there are "red flag" assessment tools for the management of acute oncology patients. If so, please advise what they are.
- 5. The adequacy of the subsequently implemented acute patient management policy.
- 6. Whether or not the nursing notes complied with the expected standard of the Nursing Council of New Zealand.
- 7. Any other matters that you consider warrant comment.

# Whether the Canopy nursing task allocation causes you to change your original opinion.

The additional information provided around the structure of nursing support provides a stronger context to care provided at Canopy Cancer Care. Understanding a nurse specialist has provided "chemotherapy education" to the patient prior to commencing treatment provides greater certainty that [Mr A] had received information on potential side effects and when and how to report these prior to commencing chemotherapy and therefore he had received safety netting information before treatment at least.

[RN B] has now provided a fuller response providing a stronger context to her assessment of [Mr A]. The depth of her assessment was not evident in the documentation made on the day and she acknowledges this "My notes do not reflect every aspect of my assessments (I have already said I accept my notes could be more detailed)". Therefore, the additional response from [RN B] provides information supporting a more comprehensive assessment by [RN B] than outlined in my original opinion.

The additional information provided supports a higher level of care being delivered to [Mr A] prior to the initiation of treatment and during this acute episode of care delivered by [RN B]. It does not cause me to change my original opinion on the brevity of documentation which did not provide a thorough view of the assessment, actions and advice provided by [RN B] in the care of [Mr A]. Given the volume of information provided to a patient commencing chemotherapy there is always opportunity to reinforce further on subsequent interactions with the patient. It is unclear if [RN B] did this for [Mr A] due to the brevity of documentation.

# The appropriateness of the administration of antiemetics prior to the review by the doctor.

While Canopy Cancer Care have a medication management policy outlining the process for verbal orders it does not appear that [RN B] obtained a verbal order prior to administration. I note the comment on standing orders for hypersensitivity reaction medications and therefore it would also appear [RN B] was not acting under a standing order for the administration of antiemetic medication.



I acknowledge the 20 years of experience in cancer care outlined by [RN B] and therefore she will have significant knowledge and experience in the use of antiemetics in chemotherapy induced nausea and vomiting and acted to provide the patient with appropriate medication to relieve symptoms with the best interest of the patient at the centre of her decision making.

It is acknowledged by Canopy Cancer Care that [RN B] departed from accepted standard of care by acting against policy, this departure from standard of care also applies to her scope of practice as a Registered Nurse by administering the medication without a verbal or standing order or written prescription.

[RN B] is bound by the Registered Nurse Scope of Practice and Competency 2.1 Provides planned nursing care to achieve identified outcomes. Indicator: Administers interventions, treatments and medications, (for example: intravenous therapy, calming and restraint), within legislation, codes and scope of practice; and according to authorised prescription, established policy and guidelines.

If [RN B] administered IV antiemetic medication prior to it being prescribed she has departed moderately from the expected standard of practice against policy, scope of practice and legislation. This departure is attributable to both the individual and the system, as this was [RN B's] decision which may have been influenced by her extensive oncology experience and also by time/resource constraints on the medical staff attending in a timely manner and the lack of standing orders in place.

There is no legislation to prevent an RN administering an OTC medication without prescription or order. However, IV antiemetics are not OTC and in most health settings two nurses are required to check IV medications prior to administration. It is not clear from the medication chart that two nurses checked this IV medication.

Consideration could be given to the development of standing orders by Canopy Cancer Care for the administration of antiemetics in the oncology triage setting. My own practice setting has these in place to support timely patient treatment.

# Whether or not the nursing notes complied with the expected standard of the Nursing Council of New Zealand.

I believe the minimal documentation in the assessment of, and advice provided to, [Mr A] has led to a lack of visibility of the actions of [RN B] and therefore subsequently a lack of visibility to the care [Mr A] likely received. I note the repeated acknowledgement from [RN B] on the standard of her documentation as not sufficiently detailed and commend Canopy Cancer Care for employing a nurse educator to support nursing practice and for providing education on clinical documentation.

Minimal documentation standards in this case are attributable to both the system and the individual, both have responsibility to ensure minimum standards are maintained.

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I note the use of MOSAIQ and the screenshots supplied which do outline date and time of entries. I note the common practice mentioned by [RN B] of having to write notes on paper to then be transcribed into the electronic system later by nursing staff. This identifies potential workflow issues in using an electronic system that is not immediately accessible at the bedside. [RN B] used abbreviations in her documentation. She should be aware of the accepted abbreviations within her employer policy on documentation.

In my opinion [RN B's] documentation did not fully meet the expected standard. However, considering the use of multiple systems (electronic and paper) and potential workflow issues that may have been encountered this is a mild departure from expected standard of practice.

Canopy Cancer Care should consider if a review of nursing workflow within this area may be beneficial and should also consider that enough hardware is provided to staff to undertake work in an efficient and timely manner to avoid transcribing from paper to electronic notes if possible.

Canopy Cancer Care are commended for having implemented education on acceptable documentation standards. An audit of documentation as a quality initiative may be used to monitor the impact of education provided.

# Whether or not there are "red flag" assessment tools for the management of acute oncology patients. If so, please advise what they are.

As noted in the initial report there are no "mandated standards" within the cancer care setting in New Zealand. Canopy Cancer Care do note high quality resources used which included UKONS and provided a copy of the nausea and vomiting guidance from UKONS.

UKONS has the triage toolkit — <u>Oncology/Haematology 24 Hour Triage Rapid Assessment</u> and Access Toolkit. This document provides an alert card, algorithm for assessment, triage assessment process and log sheet for documentation along with training and competency education to "credential" staff in triage in this setting.

The UKONS toolkit is one of the most comprehensive toolkits available and has been validated through a pilot study. Many centres have or are adopting this throughout Australasia. It is already in use in my own centre. Our nurse educators provide a half day triage workshop for our nursing staff to support this toolkit. Our nurses are "credentialled" in triaging by completing this package of training.

The algorithm is extremely valuable and undertaken on initial presentation (including phone triage) — covers the range of toxicities, scores them and provides level of urgency and actions needed. Completion of this tool would have led to greater visibility of assessment undertaken in the care of [Mr A] as one of the parameters is chest pain.

I would recommend its implementation at Canopy Cancer Care Centre to support the oncology nurses' practice in triaging unwell patients.



## The adequacy of the subsequently implemented acute patient management policy.

The acute patient management policy subsequently implemented appears adequate and I commend Canopy Cancer Care Centre for implementation. However, it should be recognised that a policy is not a comprehensive document to cover patient management for clinical staff. Guidelines or pathways aid in clinical management and as above I would recommend the implementation of the UKONS triage toolkit to support nursing practice with additional educational support from the nurse educator on relevant topics to maintain nursing knowledge and skills in this area.

# Discharge

It appears there are conflicting versions of whether [Mr A] was discharged by staff or self - discharged. I commend Canopy Cancer Care for development of the self-discharge form which may provide clarification in future cases on whether the patient self-discharged or not. Documentation has not supported clarity in the case of [Mr A].'



# Appendix C: Canopy Cancer Care policies

Canopy Medication Management Policy states:

## '3. Nursing staff

Are responsible for understanding the legislative, professional and ethical issues involved with the safe administration of medications. This ensures accountability.

#### 4. Medical staff

Are responsible for the prescribing and administration of drugs. Prescriptions should conform to the Code of Practice of the New Zealand Medical Council and in compliance with the laws pertaining to the prescribing of medicines.

## 7.1 Administration.

- Ensure that they are aware of the patient's current assessment and planned programme of care.
- Note any contra-indications or change in the patient's clinical condition which might require a drug to be withheld, and seek medical advice should the unplanned withholding of a medicine be indicated.

**8.1 Verbal orders**. Verbal orders must only be accepted in situations when it is impossible to obtain a written prescription but the administration of a drug is necessary to prevent deterioration in a patient's condition.

The instruction must be read back to the prescriber, checking the patient's name, the drug dose, and the method of administration. This should be confirmed by two nurses.

The nurse should note the verbal order/instruction in the patient's notes. Making note of the drug, dose method of administration and rationale.

**11. Standing Orders** A person who administers a medicine under a standing order must document the assessment and treatment of the patient (including any adverse reactions) in the clinical record, if necessary, any monitoring or follow up of the patient's treatment.'

Canopy Administration of Intravenous Medication Policy states:

#### **'4.2** Principles include:

• The electronic prescription for intravenous (IV) medication must be approved by the prescriber.

# 4.3 Verbal Orders

• Acceptance of verbal orders for the administration of medications is not specifically provided for under legislation. Verbal orders must only be accepted in situations



when it is impossible to obtain a written prescription but the administration of a drug is necessary to prevent deterioration in a patient's condition.

- The instruction must be read back to the prescriber, checking the patient's name, the drug, dose, and method of administration. This should be confirmed by two nurses.
- The nurse should note the verbal order/instruction in the patient's notes. Making note of the drug, dose, method of administration and rationale.

# 7. Pre-administration Checks

The medication needs to be checked by two people.

Check the "5 Rights"

- 1. Right drug
- 2. Right dose
- 3. Right time
- 4. Right patient
- 5. Right route

Any drug calculations should be undertaken by both nurses involved in administration/checking.'

Canopy Documentation/Clinical Records Policy:

# '4. Desired outcomes

The desired outcomes of this policy are:

- high standards of clinical record keeping
- clinical record keeping that supports communication and planning of care
- clinical record keeping that supports complaint investigation

•••

# 6. Clinical Records Management

- Clinical documentation should be recorded as near as possible to the time of an assessment, intervention or other action was undertaken. If there is a delay in documentation, the time of the event and the delay should be recorded.
- The record of care will include evidence of decisions made by clinicians, and discussions with any health care professional involved in the patient's care
- Any entries in the clinical notes will be clear, structured and detailed
- The record will identify any problems which have arisen and the action taken to rectify them, including any discussions with the family, friends or carers of the patient and other professionals or agencies

- The information will be factual, consistent and accurate.
- Use of abbreviations should be kept to a minimum

•••

#### 6.2 Late Entries

There may be circumstances when a late entry needs to be made to the clinical record. In such cases, a late entry must be made as follows:

- Clearly identify the entry as a "late entry"
- Include date and time the event being recorded occurred'

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Names have been removed (except Canopy Cancer Care Limited and the advisors) to protect privacy. Identifying letters are assigned in alphabetical order and bear no relationship to the person's actual name.

# Appendix D: Relevant standards

#### Medicines Act 1981:

#### '19 Administering prescription medicines:

- (1) A prescription medicine may be administered to any person only in accordance with --
  - (a) the directions of the authorised prescriber or delegated prescriber who prescribed the medicine; or
  - (b) a standing order.

#### Authorised prescriber means-

- (a) a nurse practitioner; or
- (b) an optometrist; or
- (c) a practitioner; or
- (d) a registered midwife; or
- (e) a designated prescriber'

The Nursing Council of New Zealand publication *Code of Conduct for Nurses* (June 2012) states:

## 'Principle 4

Standards

•••

4.8 Keep clear and accurate records (see Guidance: Documentation)

4.9 Administer medicines and health care interventions in accordance with legislation, your scope of practice and established standards or guidelines.

•••

Guidance: Documentation

• Keep clear and accurate records of the discussions you have, the assessments you make, the care and medicines you give, and how effective these have been.'

The NZNO<sup>97</sup> Knowledge and Skills Framework for Cancer Nursing states as an essential skill:

'Demonstrates knowledge of and accesses policies and guidelines that have implications for practice, when involved with providing care for the person affected by cancer.'

The NZNO Nurses Initiating and Administering Intravenous Therapy in Community Settings 2012 guidelines state:

'Intravenous Medications and Infusions.

1. Medications/fluids are charted by a registered medical practitioner/dentist, midwife

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<sup>&</sup>lt;sup>97</sup> New Zealand Nurses Organisation.

or nurse practitioner.

•••

6. Medication/fluids are checked against the prescription with another responsible person, preferably the prescriber or another health professional. If this is not possible, then the check should be with the recipient of the medication or their care provider.'

# Medical Council of New Zealand

# Statement — Safe practice in an environment of resource limitation (September 2016)

## Care of outpatients

'23. While a service or team making a decision about the management of a patient is responsible for the effects of that decision, as a doctor, you are still accountable for your actions within the team.'

## Statement — Good Prescribing Practice (November 2016)

'1. Make the care of patients your first concern. You should only prescribe medicines or treatment when you have adequately assessed the patient's condition, and/or have adequate knowledge of the patient's condition and are therefore satisfied that the medicines or treatment are in the patient's best interests.

•••

Never prescribe indiscriminately, excessively or recklessly.

•••

Prescribe in accordance with accepted practice and any relevant best practice guidelines. Prescribing outside of accepted norms should only occur in special circumstances with the patient's informed consent.

•••

3. Before prescribing any medicine for the first time to a patient, Council expects you to have an in-person consultation with the patient. If that is not possible because of exceptional circumstances,<sup>12</sup> consider a video consultation with the patient or discuss the patient's treatment with another New Zealand registered health practitioner who can verify the patient's physical data and identity. If you are providing locum cover for an absent colleague or are discharging a patient from hospital it is permissible to complete a prescription for a patient if you have access to that patient's notes and have reviewed that patient's notes.

27. If you are the doctor signing and issuing the prescription you bear responsibility for that treatment; it is therefore important that, as the prescriber, you understand the patient's condition as well as the treatment prescribed and can monitor any adverse effects of the medicine should they occur.

[12] Examples of exceptional circumstances include the urgency of the clinical situation or the unavailability of a doctor. It is good practice to document in the patient's clinical notes, the mode of the consultation and the reasons for not conducting an in-person consultation before prescribing any medication for the first time to a patient.'



## Statement — Managing Patient Records (October 2019)

#### **Introduction**

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...

Patient records are a crucial part of medical practice. They help ensure good care of patients and clear communication between doctors and other health practitioners.

#### Maintaining clear and accurate patient records

- 1. You must maintain clear and accurate patient records that note:
  - a clinical history including allergies
  - b relevant clinical findings
  - c results of tests and investigations ordered
  - d information given to, and options discussed with, patients (and their family or whānau where appropriate)
  - e decisions made and the reasons for them
  - f consent given
  - g requests or concerns discussed during the consultation
  - h the proposed management plan including any follow up
  - i medication or treatment prescribed including adverse reactions

...

3. Records must be completed at the time of the events you are recording, or as soon as possible afterwards.'