IN THE CORONERS COURT
OF VICTORIA
AT MELBOURNE

Court Reference: COR 2019 6921

FINDING INTO DEATH WITHOUT INQUEST

Form 38 Rule 63(2)

*Section 67 of the **Coroners Act 2008***

Amended pursuant to Section 76 of the Coroners Act 2008 on 28 April 2021[1]

Findings of:	Caitlin English, Deputy State Coroner
Deceased:	Ian Fraser
Date of birth:	25 January 1951
Date of death:	18 December 2019
Cause of death:	1(a) Complications of retroperitoneal haemorrhage 1(b) Inadvertent administration of the anticoagulants apixaban and enoxaparin
Place of death:	Footscray Hospital, 60 Gordon Street, Footscray, Victoria

[1] This document is an amended version of the Finding into Death Without Inquest of Ian Fraser, dated 26 February 2021. A correction to paragraph 56 has been made pursuant to section 76 of the *Coroners Act 2008* (Vic).

INTRODUCTION

1. On 18 December 2019, Ian Fraser was 68 years old when he died after suffering a haemorrhage following the inadvertent administration of two anticoagulants while in hospital. At the time of his death, Mr Fraser lived at Sunbury with his wife, Christine Fraser.

THE CORONIAL INVESTIGATION

2. Mr Fraser's death was reported to the Coroner as it fell within the definition of a reportable death in the *Coroners Act 2008* (**the Act**). Reportable deaths include deaths that are unexpected, unnatural or violent, or result from accident or injury.

3. The role of a coroner is to independently investigate reportable deaths to establish, if possible, identity, medical cause of death, and surrounding circumstances. Surrounding circumstances are limited to events which are sufficiently proximate and causally related to the death. The purpose of a coronial investigation is to establish the facts, not to cast blame or determine criminal or civil liability.

4. Under the Act, coroners also have the important functions of helping to prevent deaths and promoting public health and safety and the administration of justice through the making of comments or recommendations in appropriate cases about any matter connected to the death under investigation.

5. As part of my investigation I obtained a statement from Dr Paul Eleftheriou, the Chief Medical Officer at Western Health, Mr Fraser's medical records, and advice from the Coroners Prevention Unit as to the circumstances leading to Mr Fraser's death and whether his death was preventable.

6. This finding draws on the totality of the coronial investigation into Mr Fraser's death. Whilst I have reviewed all the material, I will only refer to that which is directly relevant to my findings or necessary for narrative clarity. In the coronial jurisdiction, facts must be established on the balance of probabilities.[2]

[2] Subject to the principles enunciated in *Briginshaw v Briginshaw* (1938) 60 CLR 336. The effect of this and similar authorities is that coroners should not make adverse findings against, or comments about, individuals unless the evidence provides a comfortable level of satisfaction as to those matters taking into account the consequences of such findings or comments.

MATTERS IN RELATION TO WHICH A FINDING MUST, IF POSSIBLE, BE MADE

Identity of the deceased

7. On 24 December 2019, Ian Fraser, born 25 January 1951, was visually identified by his son, Luke Fraser.

8. Identity is not in dispute and requires no further investigation.

Medical cause of death

9. Senior Forensic Pathologist, Dr Michael Burke, from the Victorian Institute of Forensic Medicine (**VIFM**), conducted an inspection on 23 December 2019 and provided a written report of his finding the same day.

10. The post-mortem examination revealed a large retroperitoneal bleed, coronary calcification, large left pleural effusion, and increased lung markings.

11. Toxicological analysis of ante-mortem samples taken on 13 December 2019 identified the presence of quetiapine (an antipsychotic) and paracetamol.

12. Dr Burke provided an opinion that the medical cause of death was *"1(a) Complications of retroperitoneal haemorrhage"* and *"1(b) Inadvertent administration of the anticoagulants apixaban and enoxaparin"*.

13. I accept Dr Burke's opinion.

Circumstances in which the death occurred

14. Mr Fraser's medical history included congestive cardiac failure, rheumatoid arthritis, atrial fibrillation,[3] smoking-induced chronic obstructive pulmonary disease (**COPD**), chronic left pleural effusion,[4] hypertension, osteoporotic spinal crush fractures, hyperthyroidism, and benign prostatic hyperplasia. His regular medications included carbimazole,[5] prednisolone,[6]

[3] Atrial fibrillation (**AF**) is the most common cardiac arrhythmia, whereby disorganised, erratic, and rapid electrical signals cause the atria heart chambers to contract irregularly. Symptoms can include palpitations, dizziness, shortness of breath, tiredness, and low blood pressure. Patients with AF are usually prescribed a blood-thinning agent (anticoagulant) to reduce the risk of such a stroke.
[4] Fluid between the lung and the chest wall. This can be due to many different causes including rheumatoid arthritis, infection, heart failure, cancer, or other health problems. Treatment varies depending on the size and cause of the pleural effusion. Mr Fraser's effusion had been drained in 2018 with symptomatic improvement of his shortness of breath.
[5] Agent used to treat hyperthyroidism.
[6] Anti-inflammatory steroid agent used to treat rheumatoid arthritis.

digoxin,[7] frusemide,[8] sertraline,[9] tamsulosin,[10] methotrexate,[11] nizatidine,[12] apixaban,[13] denosumab,[14] pregabalin,[15] Targin,[16] Spiriva,[17] and Symbicort.[18]

15. On 14 November 2019, Mr Fraser was admitted to Sunshine Hospital (Western Health[19]) following a one-week history of increasing shortness of breath on exertion and increased swollen ankles (peripheral oedema) that had not responded to four days of oral antibiotics. He was diagnosed with both an exacerbation of his congestive heart failure and community acquired pneumonia. These conditions were treated with a combination of intravenous diuretics and oral antibiotics that initially resulted in an improvement of his symptoms.

16. On 19 November 2019, Mr Fraser became increasingly short of breath. A chest x-ray showed a new pneumonia and his antibiotic coverage was broadened. Over the following days, Mr Fraser had multiple MET calls[20] for tachycardia,[21] tachypnoea,[22] hypoglycaemia,[23] and desaturation.

17. On one of these assessments, the Intensive Care Unit (**ICU**) team raised the possible therapeutic procedure of draining his moderately-sized pleural effusion in order to increase his respiratory reserve and hopefully avoid respiratory exhaustion.

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[7] Heart rate controlling drug used to treat atrial fibrillation in patients with heart failure.
[8] Diuretic agent used to offload fluid retention of congestive cardiac failure.
[9] Antidepressant agent.
[10] Agent used to improve urinary hesitancy of benign prostatic hypertrophy.
[11] Immunosuppressant agent used to treat rheumatoid arthritis.
[12] Histamine H_2 receptor antagonist that inhibits stomach acid production. Used to treat dyspepsia and to decrease the risk of peptic bleeding of patients on anticoagulation.
[13] Direct Oral AntiCoagulant (**DOAC**). A blood-thinning agent similar to warfarin used to decrease the risk of ischaemic stroke of patients who have atrial fibrillation.
[14] Used to treat osteoporosis.
[15] Antiepileptic agent that is also used in chronic pain.
[16] Oxycodone and naloxone slow release medication. Oral opiate medication combined with opioid antagonist to prevent misuse in the community (that is, it will cause withdrawal if one attempts to inject it).
[17] Tiotropium bromide, a bronchodilator inhaler similar to salbutamol (Ventolin). Used in asthma/ COPD.
[18] Budesonide and formoterol, a combination inhaler which contains bronchodilator and steroid medication. Used in asthma/ COPD.
[19] Western Health comprises of three acute public hospitals: Footscray, Sunshine, and Williamstown. Different specialty teams are located at specific hospitals which require patients to be transferred between sites/campuses.
[20] Medical Emergency Team. When a patient's observations (for example, heart rate, respiratory rate, oxygen saturations, blood pressure or conscious state) fall out of predetermined criteria, an overhead page requests an emergent review by both the responsible unit and the intensive care team.
[21] Increased heart rate.
[22] Rapid respiratory rate.
[23] Low blood sugar.

18. The medical unit discussed the possibility of a pleural tap[24] with the respiratory team but given that the effusion was both stable in size and loculated in radiologic appearance,[25] it was deemed that the risk outweighed the potential benefit at this point in time.

19. That assessment changed over the following days as the effusion enlarged slightly and his symptoms worsened.

20. On 27 November 2019, Mr Fraser's anticoagulation was withheld, and the procedure was performed draining more than one litre of fluid without complication and resulted in a significant improvement in Mr Fraser's symptoms.

21. A post procedure chest x-ray showed residual effusion suggesting a loculated effusion.[26] The respiratory unit suggested a computed tomography (**CT**) chest to further investigate. If confirmed, Mr Fraser would be referred to the thoracic surgery unit for consideration for a VATS[27] pleurodesis[28] and decortication[29] to improve lung capacity and symptoms. Mr Fraser's anticoagulation (enoxaparin) was restarted.

22. On 29 November 2019, Mr Fraser's symptoms had improved considerably, and he was keen for discharge home after his CT scan.

23. That morning, the respiratory registrar attempted to prescribe Mr Fraser's discharge medication (apixaban) but inadvertently prescribed it as an inpatient medication. Realising his mistake two minutes later, he attempted to correct it but inadvertently cancelled a discharge order for apixaban, leaving the inpatient order active.

24. Mr Fraser had his CT scan and it was reviewed by the thoracic surgical team. He was subsequently transferred to the Footscray Hospital (where the team were based) as it was thought they might be able do surgery the following day. Mr Fraser received both apixaban and enoxaparin before being transferred to Footscray Hospital.

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[24] Thoracentesis is a procedure to remove fluid from the space between the lining of the outside of the lungs (pleura) and the wall of the chest.
[25] Pleural effusions may either be simple fluid around the lung or loculated by fibrous bands – akin to bubble wrap which are more difficult and dangerous to drain.
[26] Rather than the effusion is composed of pockets of fluids meaning that while one large pocket was drained, other encased pockets remained.
[27] Video Assisted Thoracic Surgery (**VATS**) is essentially 'keyhole' chest surgery.
[28] The process of making the lining of the lung to stick to the lining of the chest wall this obliterating the space where a pleural effusion could accumulate
[29] Removing the acquired fibrous coating covering damaged lungs allowing them to expand better.

25. On 1 December 2019, the thoracic surgery morning ward round identified that Mr Fraser had received dual anticoagulants the previous day and so the decision was made not proceed to surgery and to withhold both anticoagulants for two days.

26. A few hours later, Mr Fraser complained of right-sided chest wall/upper abdominal pain. A review by the Acute Pain Management Service (**APMS**) increased his analgesia. A review by the general surgical team noted Mr Fraser's pain had resolved, his observations were within normal range, and his abdomen soft. No intervention was therefore required.

27. At 4.29 pm an urgent clinical review (**UCR**)[30] was called for an episode of hypotension,[31] which resolved spontaneously. As Mr Fraser voiced no issues, no intervention occurred.

28. At 6.08 pm, Mr Fraser suffered a syncopal episode,[32] which lasted two minutes post opening his bowels. A MET call was initiated, and the reviewing ICU and general surgical team noted that Mr Fraser was hypotensive. He was transferred to the ICU for stabilisation.[33]

29. In the ICU, Mr Fraser was initially treated for potential sepsis as a cause for his hypotensive shock until a dropping haemoglobin level[34] led the ICU team to consider bleeding. A CT scan of Mr Fraser's chest and abdomen was performed, which showed a large right-sided retroperitoneal haematoma[35] involving the psoas and iliacus muscle. Given both the location of this bleeding and Mr Fraser's anticoagulation state, surgery was not an option and so a CT abdominal angiogram was performed to locate the bleeding artery followed by embolisation[36] to successfully stop the bleeding. Mr Fraser was transfused four units of blood and attempts were made to reverse the effects of anticoagulation medications.[37]

30. On 11 December 2019, Mr Fraser had improved enough to be transferred to a general ward under the care of General Medical Unit to treat his ongoing issues of delirium, multifactorial dyspnoea, and deconditioning.

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[30] Similar to a MET (Medical Emergency Team) call in that is overhead medical page to the responsible medical team to review a patient who has not yet deteriorated to MET call criteria.
[31] Low blood pressure.
[32] Temporary loss of consciousness.
[33] Eventually requiring 90mcg/min of noradrenaline to support his blood pressure.
[34] Haemoglobin dropped form 100g/L to 80 g/L with normal being >130g/L.
[35] Retroperitoneal bleeding is behind the peritoneal lining of the abdominal cavity which includes the kidneys and the flank muscles such as iliacus and psoas muscle.
[36] CT-guided procedure where a specialised radiologist first locates the bleeding vessel then via a catheter inserted into the groin vessels navigates to that artery before releasing a medical clot to block that artery from bleeding.
[37] The haematology team stated that while there are no known effective DOAC agents, Prothrombinex both contains clotting factors and could be tried though unlikely to be effective. I was tried.

31. On 16 December 2019, Mr Fraser continued to deteriorate despite treatment and a family discussion determined that in accordance to his wishes,[38] his care was to transition from active management to comfort care.

32. Mr Fraser passed away on 18 December 2019.

CORONERS PREVENTION UNIT REVIEW

33. As noted above, I obtained advice from the CPU about the circumstances leading to Mr Fraser's death and whether it was preventable.

34. The CPU is staffed by healthcare professionals, including practising physicians and nurses. Importantly, these healthcare professionals are independent of the health professionals and institutions under consideration. They draw on their medical, nursing, and research experience to evaluate the clinical management and care provided in particular cases by reviewing the medical records, and any particular concerns which have been raised.

Useability of electronic medical records

35. The CPU identified that the useability of Electronic Medical Records (**EMR**) was a contributing factor in Mr Fraser's death. This issue was also identified by Western Health's internal review (discussed below), which found that the EMR displayed both inpatient and discharge medications on the same screen.

36. On the morning of 29 November 2019, and in preparation for Mr Fraser's discharge, the respiratory registrar attempted to prescribe Mr Fraser's discharge medication (apixaban) but inadvertently prescribed it as an inpatient medication. The doctor initially recognised this mistake and attempted to cancel the inpatient order but suspended the outpatient order instead of the intended inpatient order. This resulted in the accidental prescription of apixaban as an inpatient medication *rather than* the intended discharge medication. Unfortunately, the electronic medical record has no alert to warn that a patient is being prescribe two medications of the same class.

37. The EMR, also known as an Electronic Health Record (**EHR**), is the descriptive noun for the digitised version of a patient medical file.

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[38] On admission, Mr Fraser stated he did not want resuscitation or intubation if it was felt that he could not attain a good quality of life; being in a nursing home was not considered an acceptable outcome.

38. Usability, in the context of software engineering, refers to the degree to which the product enables users to achieve their objectives with effectiveness, efficiency and satisfaction. In short, good usability sets the user up for the right thing to happen. Poor usability sets the user up for the wrong thing to happen.

39. Poor usability in an EMR results in design-induced-errors and subsequent patient-harm.[39] [40] [41]

40. The increasing proliferation of EMRs combined with the documented usability issues means that the potential risk of patient harm is high. This is made worse by a lack of standardisation not only between different EMRs but even the same EMR across different health services. Individual health services or state health departments have little means of correcting usability issues and risk making things worse by increasing variation and complexity.[42] International vendors currently have no incentive to acknowledge or address these issues.

Internal review

41. Dr Eleftheriou stated that Western Health reported Mr Fraser's death as a sentinel event to Safer Care Victoria and a Root Cause Analysis was performed, which identified the following issues – all pertaining to EMR usability:

    (a) the EMR displays both inpatient and discharge medications on the same screen, which resulted in the accidental prescription of apixaban as an inpatient medication rather the intended discharge medication. In usability vernacular, this is known as 'mode-confusion'. This error was recognised by the doctor who attempted to cancel the inpatient order;

    (b) the EMR icon that differentiates inpatient from outpatient medication was too small to be appreciated on a standard computer monitor resulting the doctor suspended the outpatient order instead of the intended inpatient order;

[39] Schulte F, Fry E. Death by 1,000 clicks: Where Electronic Health records went wrong. Fortune Magazine. 18 March 2019. https://fortune.com/longform/medical-records/

[40] Howe JL, Adams KT, Hettinger AZ, Ratwani RM. Electronic Health Record Usability Issues and Potential Contribution to Patient Harm. JAMA. 2018;319(12):1276–1278. doi:10.1001/jama.2018.1171

[41] Joint Commission Sentinel Alert Issue 54, March 31, 2015 details 120 sentinel events between 2010 and 2013 involving issues involving information technology, 33% were related to usability issues. https://www.jointcommission.org/en/resources/patient-safety-topics/sentinel-event/sentinel-event-alert-newsletters/sentinel-event-alert-54-safe-use-of-health-information

[42] Approximately 60% of the Australian EMR market would belong to Cerner. But Cerner's entire Australian market would be approximately 10% of its US market.

(c) the EMR has no alert to warn that a patient is being prescribed two medications of the same class;

(d) the EMR terminology is unnecessarily confusing; medications are 'ordered' for inpatients and 'prescribed' for discharge. Medication orders/prescriptions can be either 'discontinued', 'suspended', or 'withheld';

(e) the EMR medication sheet can be customised at an individual level but not an organisational level;

(f) the EMR training did not cover how to change a medication's status; and

(g) the event occurred out of hours when EMR support is less.

42. The Root Cause Analysis identified the following recommendations:

(a) local modification of the EMR to create a standardised 'order' screen to clearly differentiate between 'inpatient' and 'discharge' medications;

(b) local modification of the EMR to remove the current option to 'suspend' discharge medications;

(c) local modification of the EMR to introduce an alert when a patient is being prescribed two drugs of the same class;

(d) revamping EMR training to include instructions on how to modify medication orders/prescriptions; and

(e) formal discussion and correspondence with Health Technologies Services[43] and the EMR vendor, Cerner Corporation, requesting that it rectify the lack of clarity of the different order types as it currently exists.

43. The CPU reviewed these recommendations and noted the following:

(a) local modifications to the program do not undergo usability testing to assess the modifications effectiveness or its unintended consequences. Furthermore, local modifications do not address the same issue occurring at other health services and

[43] A business unit of the Department of Health and Human Services of Victoria that is the key provider of outsourced Information and Communications Technology business systems to Victorian health services

increase the variation between versions of the same program at different health services;

(b) alerts, while effective in some domains (for example the airline industry where only highly consequential alerts are used to minimise distraction to situational awareness) are less effective in the EMR context where more than 93 per cent are overridden[44] by clinicians who are exposed to a high number of low-value alerts fail to respond to significant alerts (so called 'alert fatigue'). Adding alerts (something the vendor allows the health service to do) without addressing the underlying usability issues are unlikely to be effective and may worsen patient safety by increasing alert fatigue;

(c) training as a solution implies the it was a 'user error' rather than a 'user interface design induced error'. Training without addressing the underlying usability issues is relatively ineffective, particularly considering the high staff turnover rate of the public hospital system; and

(d) requesting the vendor (Cerner) to address underlying usability issue is dependent on the goodwill of a multinational corporation and any solution, if provided, may or may not be rolled out more widely.

44. The CPU noted that these points were not criticisms of the Root Cause Analysis recommendations, but highlighted the issues and limitations faced by an individual health service when trying to deal with usability issues involving software from a multinational company.

An emerging risk

45. Sadly, Mr Fraser's death is not the first associated with EMR usability issues. The Court is currently investigating two other deaths where a contributing factor appears to be associated with EMR usability.

46. In the matter of COR 2018 5744, a patient at a different health service did not receive venous thromboembolism prophylaxis during the introduction of the EMR and subsequently died from a pulmonary embolus. As part of this investigation, a statement a was sought from the Department of Health and Human Services (**DHHS**) Chief Digital Officer, Mr Neville Board,

[44] Bryant AD, Fletcher GS, Payne TH. Drug interaction alert override rates in the Meaningful Use era: no evidence of progress. *Appl Clin Inform*. 2014;5(3):802-813. Published 2014 Sep 3. doi:10.4338/ACI-2013-12-RA-0103

who stated the department would be amenable to working with clinical and safety leaders in Victoria and nationally to review how clinical information systems present and mange high-risk medicines, including anticoagulants.

47. In the matter of COR 2019 2574 a patient was inadvertently prescribed 10 times his intended opiate dose for three days before dying from pneumonia. In its review of the circumstances leading to death, the CPU suggested the coroner make a recommendation regarding the consideration of state or national standards with regards to EMRs due to issues of usability.

48. The CPU has identified a further three interstate deaths associated with EMR useability.[45]

An attempt for standardisation in Victoria

49. In 2004, Victoria launched an ambitious health information technology project. HealthSMART was a state-wide health information technology project centrally driven by the DHHS. HealthSMART aimed to centralise and integrate Victorian health services' medical record information in one EMR.

50. The centralised electronic record for Victoria proved to be problematic. The 2007 implementation due date passed and was followed by a 2008 Victorian Auditor General review and 2011 Victorian Ombudsman review. In 2012, the project was officially disbanded. It was concluded that a fully operational integrated Victorian health record was unachievable. However, before HealthSMART was disbanded, the DHHS initiated the implementation of a new clinical information technology system called Cerner[46] at Austin Health in 2011.

51. A 2016 review of safety and quality in Victorian hospitals led to the establishment of the Safer Care Victoria (**SCV**).[47] In particular, the Duckett report 'Targeting Zero' made specific recommendations on changes to digital technology in health as a way to support the flow of clinical and patient information to facilitate research and data analytics to inform clinical decision making and improve patient care and safety.

52. About this time, the DHHS released a report titled 'Digitising Health' that detailed a strategy and plans on how digital health projects were to be implemented in Victorian health services. The report listed some 12 reviews, including the Duckett review, and concluded digital

[45] See the findings of the New South Wales Coroners Court in the Inquest into the death of Paul Lau, dated 29 March 2018 and the Inquest into the death of Stephen Kline, dated 1 March 2019; and the finding of the South Australian Coroners Court in the Inquest into the death of Stephen Herczeg, dated 10 August 2017.
[46] Cerner Corporation is an American supplier of health information technology services, devices, and hardware.
[47] Duckett S. 'Targeting Zero. Supporting the Victorian hospital system to eliminate avoidable harm and strengthen quality of care.' Report of the Review of Hospital safety and quality Assurance in Victoria.

changes were required within the Victoria's health system to improve information sharing and patient safety.[48]

53. Victoria's policy remained focussed on a state-wide approach to health information technology. But now rather than the DHHS mandating an integrated information technology such as HealthSMART, there was flexibility – individual health services were allowed to seek their own solutions to improve patient care and safety by using electronic medical records.

54. The 2016-17 DHHS digital strategy broadly noted a need to expand current EMR systems to replace paper-based records such as discharge summaries and medication charts (National Inpatient Medications Chart) and to integrate bedside vital signs monitoring.

55. In particular, the DHHS digital implementation strategy resulted in capital funded projects during 2017-2018. These projects included an expansion in Cerner capability at Austin Health, Eastern Health, and the Alfred Health. The aim was to transition from a mix of electronic and paper based clinical information systems to a Cerner generated EMR.

56. Gradually over 2018 and 2019, Cerner was introduced at Western Health, Monash Health, Bendigo Health, and Barwon Health.[49]

57. Whist Cerner was introduced to these hospitals, the Royal Children's Hospital introduced a different EMR program called Epic.[50] The Parkville precinct hospitals (The Royal Women's, Peter MacCallum, and Royal Melbourne Hospital) joined the Royal Children's and implemented Epic.

58. The Sandringham Hospital is governed by Alfred Health; however, Sandringham Hospital maternity services are governed by the Royal Women's Hospital. The Royal Women's Hospital board recently decided Sandringham maternity will continue to use a paper based medical record and not implement Epic. The remaining Sandringham Hospital clinical services will implement Cerner.

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[48] The Department of Health and Human Services 'Digitising Health How information and communication technology will enable person-centred health and wellbeing in Victoria.' August 2016. Accessed on 16 August 2019 at www.2.health.vic.gov.au

[49] 'Northern Health' has been removed from paragraph 56 pursuant to section 76 of the *Coroners Act 2008* (Vic).

[50] Epic Systems corporation is a privately held American healthcare software company.

Opportunities for prevention intervention

59. In 2006, the Australian Commission of Safety and Quality in Health (**ACSQH**) introduced the National Inpatient Medication Chart,[51] which due to the design principles of standardisation and usability-testing, resulted in a significant reduction in errors.[52] These gains were lost when health services transitioned to various and varied EMR.[53]

60. In 2017, the ACSQH developed the 'National Guidelines for On-Screen Display of Medicine Information'[54] in an attempt to standardise the presentation of on-screen medications using human-factors principles and usability-testing to both minimise error and maximise patient safety. Unfortunately, these guidelines are not prerequisites for either Therapeutic Goods Association (**TGA**) registration nor are they used to guide local modifications which occur post-registration. The ACSQH also developed a taxonomy for EMR incidents but this is for local/ state use, not for feedback to the EMR vendor for improvement.

61. In the United States of America, the EMR is not regarded as a medical device and thus not registered or regulated by the Food and Drug Association (**FDA**)[55] though a movement has started to attempt to change this.[56]

62. In Australia, the TGA registers EMRs as 'software as a medical device' (**SaMD**) but does not have dedicated process of registering adverse events related to SaMD as it does for medications and non-software medical devices. The degree if regulation is thus unclear. A search of the TGA's Australian Register of Therapeutic Goods (**ARTG**) revealed six Cerner products with the "Pharmaceutical information system application software" being class 1, which defines it as 'low risk' and not requiring conformity assessment certification in order to be registered. The TGA as the regulatory body has the potential to both catalogue and address these issues via the same processes it already uses for both medications and medical devices.

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[51] https://www.safetyandquality.gov.au/our-work/medication-safety/medication-charts/national-standard-medication-charts

[52] Coombes ID, Reid C, McDougall D, Stowasser D, Duiguid M, Mitchell C. Pilot of a National Inpatient Medication Chart in Australia: improving prescribing safety and enabling prescribing training. *Br J Clin Pharmacol*. 2011;72(2):338-349.

[53] Gains were made with regards to legibility.

[54] https://www.safetyandquality.gov.au/our-work/e-health-safety/national-guidelines-screen-display-medicines-information

[55] Schulte F, Fry E. No Safety Switch: How Lax Oversight of Electronic Health Records Puts Patients at Risk. Fortune magazine. 21 November 2019. https://fortune.com/longform/medical-records-government-regulation-patient-risk/

[56] https://ehrseewhatwemean.org/calls-to-action-policymakers/

63. The CPU therefore suggested that I make a recommendation to the TGA so that adverse events related to the software for EMR can be registered and to require the software to be compliant with a useability standard. I consider this a reasonable course and will make recommendations with a view to prevent EMR contributing to deaths in similar circumstances.

FINDINGS AND CONCLUSION

64. Pursuant to section 67(1) of the Act I make the following findings:

(a) the identity of the deceased was Ian Fraser, born 25 January 1951;

(b) the death occurred on 18 December 2019 at Footscray Hospital, 60 Gordon Street, Footscray, Victoria, from complications of retroperitoneal haemorrhage and inadvertent administration of the anticoagulants apixaban and enoxaparin; and

(c) the death occurred in the circumstances described above.

RECOMMENDATIONS

Pursuant to section 72(2) of the Act, I make the following recommendations:

1. I recommend the **Therapeutic Goods Association** consider:

(a) reassigning the risk-level assigned to EMRs (specifically, the electronic prescribing component) to a risk level that requires assessment of and compliance with a usability standard. These standards should be developed in conjunction with key stakeholders (for example, the Australian Commission of Safety and Quality in Health, state government health departments, safety departments, and state government digital health officers, and relevant overseas agencies);

(b) developing pathways for users to report adverse events involving software as a medical device (including but not limited to electronic medical records) similar to the publicly accessible pathways that already exist for medical devices, medicines and vaccines;[57]

(c) assessing the EMR vendor improvements in response to incidents for usability and shared with other health services; and

[57] https://www.tga.gov.au/reporting-adverse-events

(d) developing promotional material for this pathway similar to those that already exist for medical devices, medicines and vaccines.[58]

2. I also recommend that **Safer Care Victoria** promote the Therapeutic Goods Association's reporting pathway to both health-service safety departments and clinicians.

I convey my sincere condolences to Mr Fraser's family for their loss.

Pursuant to section 73(1A) of the Act, I order that this finding be published on the Coroners Court of Victoria website in accordance with the rules.

I direct that a copy of this finding be provided to the following:

Christine Fraser, senior next of kin
Western Health
Therapeutic Goods Association
Safer Care Victoria
Chief Digital Health Officer (Victorian Department of Health and Human Services)
Australian Commission on Safety and Quality in Health Care
Cerner Corporation Pty Ltd
Constable Nicholas Seeley, Victoria Police, reporting member

Signature:

CAITLIN ENGLISH
DEPUTY STATE CORONER
Date: 26 February 2021

NOTE: Under section 83 of the ***Coroners Act 2008*** (the Act), a person with sufficient interest in an investigation may appeal to the Trial Division of the Supreme Court against the findings of a coroner in respect of a death after an investigation. An appeal must be made within six months after the day on which the determination is made, unless the Supreme Court grants leave to appeal out of time under section 86 of the Act.

[58] https://www.tga.gov.au/publication/help-us-promote-adverse-event-reporting-promotional-resources-kit