STATE CORONER'S COURT OF NEW SOUTH WALES

Inquest:	Inquest into the death of Audrey MacGregor
Hearing dates:	24-25 November 2015, 22-23 February 2016, 15 April 2016, 16 September 2016.
Date of findings:	26 October 2016
Place of findings:	State Coroners Court, Glebe
Findings of:	Magistrate Harriet Grahame, Deputy State Coroner
Catchwords:	Coronial Law, cause of death, hydromorphone overdose
File number:	2013/322168
Representation:	Mr Stephen Kelly – Coronial Advocate assisting Mr Sergi, of counsel instructed by HWL Ebsworth for Ramsay Health Care, North Shore Private Hospital, RN Angela Thwaites, RN Kate Hartstone and RN Nicole McHugh Mr Gregg, of counsel instructed by Dr Julian Walter of MDA National for Dr Mau Mr Barnes, of counsel instructed by Avant Law for Dr Hansen

Findings:

On the balance of probabilities, I find that Audrey

Winifred MacGregor died at North Shore Private Hospital, St Leonards NSW, on 24 October 2013.

She died after a period of serious illness and following an overdose of hydromorphone.

The medical cause of her death was the combined effects of an overdose of hydromorphone and complications of pneumonia (following treatment for chronic *clostidium difficile colitis*) against a background of heart disease and lung disease.

Non Publication Orders

All previous non-publication orders are lifted.

Recommendations

I make the following recommendations to the Minister for Health.

That the NSW Department of Health give consideration to conducting an audit of its *High Risk Medicines Management Policy* with a view to ascertaining what practices and procedures have actually been implemented by Local Drug and Therapeutic Committees pursuant to the current section on Hydromorphone (part 3.2).

That NSW Department of Health strengthen its *High Risk Medicines Management Policy* in relation to hydromorphone and mandate that the drug must, rather than "should" be referred to as HYDROmorphine

Dilaudid or Dilaudid by hospital staff including prescribers, nurses and pharmacists.

That the NSW Department of Health consider issuing another "Safety Notice" (in addition to SA 004/11) for the purpose of reinforcing to all staff the potential confusions which still exist between morphine and hydromorphone and the confusions which may result in the use of differing concentrations of the drugs. This safety alert should include a mandated education component.

That the NSW Department of Health investigate options that may be available through Therapeutic Goods Administration (TGA) for the purpose of restricting the use of different sized/coloured ampoules and/or bottles with the intention of minimizing any confusion between lower and higher potency strengths of hydromorphone.

IN THE STATE CORONER'S COURT
GLEBE
NSW
SECTION 81 CORONERS ACT 2009

REASONS FOR DECISION

1. This inquest concerns the death of Audrey Winifred MacGregor

Introduction

2. Audrey MacGregor was an 88 year old lady who lived with her husband at Oxford Falls. She was an active person who enjoyed gardening, sewing and household chores. She and her husband were in control of their financial and other affairs. They had a large and close extended family and were involved in church and community activities.[1]

3. Mrs MacGregor was greatly loved and respected by her family. Family members attended each day of the inquest and were clearly extremely affected by her death.

The role of the coroner

4. The role of the coroner is to make findings as to the identity of the nominated person, and in relation to the date and place of death. The coroner is also to address issues concerning the manner and cause of the person's death.[2] In addition, the coroner may make recommendations in relation to matters that have the capacity to improve public health and safety in the future.[3]

5. In this case there is no dispute in relation to the identity of Mrs MacGregor, or to the time and place of her death. The inquest focussed on the manner and medical cause of Mrs MacGregor's death. It was also necessary to consider whether or not her death was

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[1] Statement of Jenny Compton, Exhibit 1, Tab 7.
[2] Section 81 *Coroners Act* 2009 (NSW)
[3] Section 82 *Coroners Act* 2009 (NSW)

in any way avoidable and if so what mechanisms, if any, could be put in place to help prevent such a situation recurring.

6. Section 81 (1) of the *Coroner's Act* (2009) NSW requires that when an inquest is held, the coroner must record in writing his or her findings in relation to the various aspects of the death. These are my findings in relation to the death of Audrey MacGregor.

Brief background

7. While independent, Audrey MacGregor had a number of underlying health problems. In In 1999 Mrs MacGregor had undergone aortic valve replacement at North Shore Private Hospital.

8. In May 2013 she presented with pneumonia and was treated with antibiotics at Mona Vale District Hospital. Unfortunately it appears that during this time she contracted *clostridium difficile* diarrhoea/colitis. She was subsequently admitted to Royal North Shore Hospital and then North Shore Private Hospital under the care of Dr Peter Hansen. He states that "her initial presentation was complicated by recurrent acute pulmonary oedema with heart failure secondary to severe bioprosthetic aortic valve stenosis and poor LV function. Mrs MacGregor also developed acute and chronic renal failure during this admission due to her diarrhoea and cardiac condition."[4]

9. At first Mrs MacGregor was very weak but she improved enough to walk around the ward unaided. Unfortunately her diarrhoea/colitis returned. At this time Mrs MacGregor was being assessed for a valve-in-valve transcatheter aortic transplant procedure (Viv TAVI), but this could not proceed if the severe diarrhoea persisted.

10. It was decided that a faecal transplant would offer Mrs MacGregor the best chance of a cure for the clostridium colitis and chronic diarrhoea. If successful an assessment for her suitability for the VivTAVI could proceed. She was admitted to North Shore Private Hospital on 8 October 2013 and "underwent bowel preparation workup, colonoscopy and subsequently faecal transplantation at the Centre for Digestive Diseases at Five

[4] Statement of Dr Peter Hansen, Exhibit 1, Tab17

Dock under the care and supervision of Professor Borody."[5] In Dr Hansen's view she appeared "stable and well prior to the faecal transplant...with no evidence of heart failure or chest infection."[6]

11. Unfortunately following the faecal transplant on 10 October 2013, Mrs Macgregor had several days of persistent gastrointestinal symptoms with nausea, dry retching, poor appetite and persistent diarrhoea.

12. On 13 October 2013 Mrs MacGregor was noted by nursing staff to be "chesty."[7] She appears to have deteriorated further over the next couple of days and on 16 October 2013 she was admitted to the Intensive Care Unit (ICU) with pneumonia and type 2 respiratory failure. Up until that point antibiotic treatment had been resisted as it would have threatened the effectiveness of the faecal transplant, but antibiotics were commenced at this time in attempt to manage her lung condition and raise her white cell count.[8]

13. She was discharged from the ICU on 17 October 2013.

14. From 19 October until 23 October her condition fluctuated to some extent. She appears to have had times when she was drowsy and tired and there were documented periods of tachypnoea, however she did not appear to be overly distressed.

15. At some point on 19 October it was documented that Mrs MacGregor was "not for resuscitation", but the family strongly supported the idea of continuing active medical treatment including fluids, IV antibiotics and chest physiotherapy. They strongly believed that Mrs MacGregor should be encouraged and given that they had seen her rally before, they expressed confidence in the possibility that she could do it again.

16. On 23 October Dr James Mau, the ward registrar, prescribed a small single dose of hydromorphone. The stated reason for this was "respiratory distress". Mrs MacGregor was then incorrectly given a 0.5mg dose of morphine. This was not what had been prescribed, although it appears staff did not become aware of the mistake until the

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[5] Statement of Dr Peter Hansen, Exhibit 1, Tab17
[6] Statement of Dr Peter Hansen, Exhibit 1, Tab17
[7] Nursing records for 13/10/13 at page 75, Exhibit 1, Volume 2
[8] Statement of Dr Peter Hansen, Exhibit 1, Tab17

following day. This initial mistake does not appear to have contributed to Mrs MacGregor's death.

What happened on 24 October 2013?

17. On 24 October 2013 Mrs MacGregor's care was again reviewed. At around 11.30am Mrs MacGregor was administered a dose of hydromorphone by nurses Angela Thwaites and Kate Hartstone. Dr Mau had prescribed a dose of 0.5 mg of hydromorphone to be given subcutaneously. This time it was recorded as a continuing dose. Unfortunately the nurses made an error. The hydromorphone accessed by the nurses was in a 1ml ampoule of the HP (High Potency) concentration (10mg/1ml).[9] Nurse Thwaites gave evidence that it looked "exactly the same as the morphine vial"[10] It appears that the nurses mistook 0.5mg as 0.5ml, which would be the size of the usual morphine dose they were accustomed to administering. The nurses were not familiar with hydromorphone and the mistake they made meant that Mrs MacGregor received 10 times the actual dose that she had been prescribed. This was in anyone's terms a "substantial overdose".

18. Mrs MacGregor was affected by the dose she was given and around 12.30pm Dr Mau was called back to the ward. He attended Mrs MacGregor and treated her with the opiate antagonist nalaxone. While Mrs MacGregor's respiratory rate increased and her oxygen saturation levels improved, her level of consciousness remained unchanged.

19. Mrs MacGregor died at approximately 4.30pm on 24 October 2013.

Scope of the inquest

20. A list of issues relevant to Mrs MacGregor's death was circulated prior to the inquest commencing. The following questions were posed

    - Was it appropriate for the deceased to receive palliative care whilst in hospital? Was there any undue pressure placed on the deceased and family to adopt palliative care by Staff at RNS Private?

[9] Statement of Nurse Thwaites, Exhibit 1, Tab 15[11]
[10] Statement of Nurse Thwaites, Exhibit 1, Tab 15[11]

- Was appropriate communication given to the deceased and her family regarding the deceased's prognosis and administration of analgesics on 23 & 24th October 2013?

- Was it appropriate to have administered hydromorphone to the deceased on the 24th October 2013 in lieu of morphine?

- What is the protocol for communicating between Doctors and Nursing Staff regarding the use / administration of analgesic medications at RNS Private?

- Was the deceased appropriately monitored by hospital staff after she had been administered hydromorphone on 24th October 2013?

- What changes have occurred to the prescribing and administering of hydromorphone since the death of the deceased?

21. The inquest proceeded over a number of sitting days. A large number of statements were tendered, as were expert reports, medical records and policy documents. Oral evidence was also received, including from family members, medical and nursing practitioners involved in Mrs MacGregor's care and independent experts.

22. Comprehensive submissions were received from all parties and oral submissions were taken. I have considered all the material very carefully but intend to distil my reasons fairly briefly under a small number of broad headings.

23. It should be stated that the atmosphere during the inquest was very tense. Both nurses, particularly Angela Thwaites, were distraught remembering the mistake which had been made. The family and doctors were in dispute at times in relation to factual matters and emotion was often close to the surface.

Palliative Care

24. It was agreed by all parties that at the time immediately preceding her death Mrs MacGregor was very unwell. While accurate prediction of imminent mortality is difficult, there was general consensus among her medical advisors that she had only a 5-10% chance of survival. Her family had seen her come back from difficult situations before and were confident there was a real possibility she could make it. They had faith in her and believed she wanted to continue the fight.

25. Palliative care is a specialty often misunderstood. The aim of palliative care is to support those living with a life-limiting or terminal illness. Some people will receive palliative care for years, others only in the period just before death. Palliative care specialists are often consulted to provide advice on symptom relief for patients who have intractable nausea, pain or other serious discomfort and who would not properly be described as "terminal".

26. Mrs MacGregor's condition, in the days before her death was such that sensitive discussion between doctors and Mrs MacGregor and her family in relation to issues touching on palliative care would not have been inappropriate. Nevertheless, there was no formal palliative care plan in place at the time Mrs MacGregor's death. On 19 October 2013 Dr Hansen had documented formal treatment limitation orders indicating that Mrs MacGregor was not for resuscitation.[11] However, this does not indicate a palliative care plan and it is clear that Mrs MacGregor continued to receive active treatment for her infection.

27. Unfortunately communication between the Hospital and Mrs MacGregor's family at this important time was sadly lacking. The family came to believe that some of the staff had lost faith in Mrs MacGregor's ability to recover, and it concerned them. Around this time Dr Mau spoke to a social worker, Felicity Reeman about organising a family conference. It was her understanding that there had already been discussions with the family about palliative care. A subsequent meeting between Ms Reeman and the family, on 23 October 2013, inflamed rather than calmed the situation. [12] Some members of the family were affronted by her approach and it confirmed their view that some staff had "given up" on Mrs MacGregor.

28. Crucially it was against this background that the medication error occurred. In my view, this earlier lack of positive communication between Hospital staff, including treating doctors and Mrs MacGregor's family, coloured the family's understanding of what subsequently happened.

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[11] Resuscitation/end of life orders, Exhibit 1, Volume 2
[12] Statement of Felicity Reeman, Exhibit 1, Tab 18 [8]

The prescribing of hydromorphone

29. In my view it is clear that the decision to use hydromorphone was Dr Mau's. While I accept that there was a telephone conversation between Dr Mau and Dr Hansen about the use of an opiate for respiratory distress, I find Dr Mau's suggestion in evidence that he mentioned the specific drug hydromorphone [13]most unlikely, in the face of Dr Hansen's account. I prefer Dr Hansen's recollection on this issue. In my view, Dr Mau chose which opioid to use and in what dosage, according to his own clinical judgement. It is slightly concerning that as a registrar he chose a drug that was unfamiliar to his senior colleague and apparently to the Nurse Unit Manager on the ward, without specific consultation. However, there had been general discussion about the prescription of an opioid.

30. The inquest heard considerable evidence in relation to the prescribing of hydromorphone. I have carefully considered all the available expert evidence and am of the view that it is established that hydromorphone can be an appropriate medication to prescribe for the management of serious shortness of breath.[14] There is some suggestion that where there is also renal impairment, it may even be the opioid of choice. Equally, in my view it is established that had the dose been given in the amount actually prescribed, "there should not have been a problem".[15]

31. I accept the reason Dr Mau prescribed the hydromorphone was for shortness of breath. There is however, some conflict in the evidence about whether Mrs MacGregor was in fact suffering such shortness of breath that she required hydromorophone. On the one hand Mrs Compton remembers her mother on the morning of 24 October as "chatty and her breathing appeared much better".[16] Mrs Compton remembered a discussion about business matters and noted that her mother's eating and drinking seemed to have improved. On the other hand, Dr Mau stated that when he reviewed Mrs MacGregor that morning she had deteriorated, "her work of breathing had increased,

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[13] Note that his original statement, made pursuant to legal advice did not mention this aspect of the conversation.
[14] See for Professor Ehrlich at Exhibit 1, Tab 26 and 27, Associate Professor Aggarwal at Exhibit 1, Tab 40 and Exhibit 6,
[15] See evidence of Dr Hansen on 24/11/15 at page 46, line 27.
[16] See Statement of Jenny Compton, Exhibit 1,Tab 7 at paragraph 43 onwards. See also her evidence at Inquest.

she was short of breath and her respiratory rate was very high (55), although her oxygenation was stable."[17] In his oral evidence he explained that having a respiratory rate at that level was like "someone running a marathon" or who is "peri arrest".

32. Charts indicate that Mrs MacGregor's respiratory rate was fluctuating over a number of days. There is really no doubt that Mrs MacGregor experienced shortness of breath from time-to-time during this period, however, the actual level of her physical discomfort on the morning of 24 October 2013 is now difficult to ascertain with any degree of accuracy. While Dr Mau believed her to be "uncomfortable" and this is supported by what one might expect from the objective contemporaneous rate recorded, her family did not hear her complain or see signs of severe respiratory distress. She was clearly a stoic woman who complained as little as she could. On Dr Irvine's evidence the level of respiratory distress recorded should have been evident to anyone, let alone to those who loved and cared so deeply for her. According to Dr Irvine, Mrs MacGregor would have been fighting for breath almost every second. It is hard to reconcile the two accounts.

33. Again, it appears to me to be a dispute at inquest that could have been largely avoided had there been better communication at the hospital. A frank and informative discussion about the need for opioid relief for shortness of breath does not appear to have taken place. If it had, these differences of opinion could have been explored at the time. In the circumstances, I accept Dr Mau made a clinical judgement that was open to him. There were objective indicators of respiratory distress. Had he communicated better with the loving family, who were present at that time, it is my view that this issue would not appear as polarised as it currently does. A wise doctor can learn a great deal by taking time to speak with carers and loved ones.

34. The original dose was charted as a single dose, as was appropriate for a person who was opiate naïve. Had it been given, as charted, ideally the doctor, family and Mrs MacGregor could have spoken openly about whether it was a useful addition to her treatment regime and whether it provided the relief required. Unfortunately, as we now know a less than optimal dose of morphine was incorrectly given so no useful

[17] See Statement of Dr Mau, Exhibit 1, Tab 14 at paragraph 57

assessment of what had actually been prescribed could possibly have taken place. Even more distressingly, the following day another, this time critical mistake, was made.

35. Many of the problems with the use of the drug hydromorphone on 24 October 2013 were because of the lack of knowledge of the drug on the part of medical staff involved. The nurses were unfamiliar with it and also appear to have received incorrect or misleading advice about its properties from the hospital pharmacy. Their lack of familiarity contributed to the error they made. It should be noted that it is not just nurses who lacked familiarity with the drug. Dr Hansen was not aware of it. It was Associate Professor Aggarwal's evidence that even most doctors regularly prescribing the drug would not necessarily be aware that the drug came in different strength ampoules.[18]

Preparation of the dose of hydromorphone

36. The facts regarding the process of preparing the drug for administration, while at the heart of the inquest, are not in serious contention. Nurse Hartstone recruited Nurse Thwaites to act as a checker for the selection and administration of the schedule 8 drug. The drug was locked in the cabinet, as it should have been. The verbal processes of checking the essential facts such as the identity of the drug and patient, the dosage, route and frequency of administration were carried out. It was just that a mistake had been made whereby a dosage that should have been given in milligrams was given according to millilitres. Had Nurse Hartstone drawn up 0.05 ml, she would have given the correct dose of 0.5mg. Instead she drew up 0.5ml. Thereby giving ten times the dose prescribed. It was pure human error and it was not noticed by either nurse present.

37. It is clear that there were a number of factors that contributed to the making of this error. The nurses appear to have assumed that hydromorphone was the same as morphine and they gave a dose of the size they would have been accustomed to giving with morphine. Perhaps they did not register that the dose was charted in milligrams and in any event they appear to have been unaware of the significance of the HP concentration version of the drug they had obtained. It was Nurse Thwaites's evidence

[18] Evidence at Inquest of Associate Professor Aggarwal on 22/2/16 at page 51, line 32 onwards

that they had actually contacted the Nurse Unit Manager and the pharmacist about hydromorphone and had been told "there was not a great difference between the two drugs other than their excretion properties"[19]. Of course they should have been told that the hydromorphone has about 5 times the potency of morphine. They could have been told that like morphine, the drug can come in varying potency forms and thus it is essential to check the concentration of the ampoule, when dispensing a drug that has been prescribed in milligrams. Nurses study the maths involved in this kind of routine calculation and should be aware of the potential dangers involved.

38. It must be noted that this is not the first time serious issues relating to the confusion of these drugs has arisen [20] and a significant number of policy changes touching on the prescription of hydromorphone had already been made by the NSW Department of Health prior to this inquest commencing.

Mrs MacGregor's response to the dose and her subsequent treatment

39. There is some real dispute about Mrs MacGregor's immediate response to the dose. Mrs MacGregor received the dose around 11.30 am. It was Mrs Compton's evidence that within 30 seconds of the injection her mother's eyes rolled back and her head went back. She told the inquest she asked Nurse Hartstone what was happening and was told her mother was "zonked" and that she would be like that for a couple of hours.[21] In cross-examination she agreed that her mother's reaction did not occur until Nurse Thwaites had left the room.[22] Mrs Compton was adamant that Nurse Hartstone saw how affected her mother was by the dose, and yet seemed unconcerned. It was her evidence that nobody conducted a proper check of her mother until she herself went to get assistance some time later.

40. In contrast, Nurse Hartstone said she checked on Mrs MacGregor 10 minutes after the injection and that she continued to check on Mrs MacGregor over the next 30 minutes

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[19] Statement of Angela Thwaites, Exhibit 1, Tab 15 at paragraph (10]
[20] See for example findings in *Inquest into the death of Rishi Deo Maharaj* (2011/388777) (Deputy State Coroner Freund) 9 May 2014. These findings, available only after Mrs MacGregor's death, explored many of the issues relating to the packaging and labeling of hydromorphone and morphine.
[21] Jenny Compton, Evidence at Inquest, 24/11/15, page 56, line 3 onwards.
[22] Jenny Compton, Evidence at Inquest, 24/11/15, page 58, line 40 onwards

as she wanted to ensure that she had no ill effects from the hydromorphone.[23] It was her evidence that she was the one who became concerned that Mrs MacGregor did not respond when spoken to or touched and so at 12.15 pm she went and told Dr Mau, who immediately came.[24] In cross-examination she seemed to concede that her "checks" may not have involved entering the cubicle, and may have been more like walking past and "looking at her and sticking my head in. I don't recall if I actually went in the room".[25] In cross-examination she also agreed it may have been Mrs Compton who raised the alarm first, rather than her.[26] I accept that Kate Hartstone made a personal note of what had happened after the event, which recorded how she had monitored Mrs MacGregor. However, after her cross examination I had considerable doubts about whether any proper monitoring had indeed occurred until Mrs Compton called for help. In my view this meant that Dr Mau was not alerted promptly. I am also inclined to believe that Nurse Hartstone used the word "zonked", given Mrs Compton's clear and very specific recollection and that this indicates she had some awareness of Mrs MacGregor's condition at an earlier point. If that is so, she failed to realize the seriousness of the situation.

41. The inquest was provided with medical evidence which shed some light on the likely amount of time it could take for a subcutaneous injection of this sort to have effect. Each of the doctors accepted that it involved some speculation as it was impossible to know how Mrs MacGregor's co-morbidities and other issues may have impacted on the effect of the drug. Dr Spence was questioned on the issue and he was of the view that an extreme reaction of the type described by Mrs Compton was very unlikely to have occurred within 30 seconds of a subcutaneous injection.[27] Dr Perl's initial opinion was that she would expect the onset of the reaction to be "within 15 minutes after the injection"[28]. However, in her oral opinion she suggested that the likely time range for the effect to be clear would be "somewhere between five and 25 minutes and most likely around the ten minute mark is when you would expect the peak level.[29] In my

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[23] Statement of Kate Hartstone, Exhibit 1, Tab 16, paragraph 14.
[24] Statement of Kate Hartstone, Exhibit 1, Tab 16, paragraph 15
[25] Kate Hartstone, Evidence at inquest 25/11/15, page 26, line 15 onwards
[26] Kate Hartstone, Evidence at Inquest 25/11/15, page 28, line 35 onwards
[27] Evidence at inquest, Dr Ian Spence, 22/2/16 page 23, line 48 onwards
[28] Report of Dr Perl, Exhibit 1, Tab 14
[29] Dr Perl, Evidence at inquest, 22/1/16

view, most significantly she added "you can actually lose consciousness before you've reached your peak."

42. I have considered all the evidence on this issue and I am of the view that it is safely established that Mrs MacGregor had a very noticeable reaction, quite soon after administration of the drug. I accept her daughter's evidence that she lost consciousness and did not regain it. This did not occur until after Angela Thwaites left the room and is likely to have taken some minutes. In the light of Mrs MacGregor's significant co-morbidities and lack of exposure to the drug, it would not be surprising if she lost consciousness before the drug "reached its peak". What Mrs Compton remembered as almost immediate, probably took some minutes, but I accept it was still a distinct and fairly quick reaction to the subcutaneous injection.

43. Certainly by the time Dr Mau arrived he accepted that there had likely been an opiate overdose that needed urgent treatment. His immediate impression was that she was "narcotized, that is, she was sedated secondary to the administration of narcotics".[30] Having seen her only hours before, he did not for one instant believe that her condition reflected merely that she was slowly dying of her known co-morbidities. He immediately ordered and administered naloxone. According to his evidence he took this course of action based on what he saw, rather than on information, which he received later, in relation to the incorrect dosing which had occurred.

44. The naloxone improved her respiratory rate and her oxygen saturation levels, but did nothing for her level of consciousness. In my view, the medical evidence suggests that it is quite likely Mrs MacGregor had already suffered a significant brain injury.

45. It was Dr Mau's evidence that later that afternoon when he was discussing the matter with Dr Hansen, he was informed that Mrs MacGregor had died. The family were later informed by Dr Hansen that "a likely drug error had occurred".

The cause of death

46. A limited autopsy was conducted by Dr Rebecca Irvine at the Department of Forensic Medicine, Glebe on 25 October 2013. Dr Irvine's examination was "external only". In

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[30] Statement of Dr Mau, Exhibit 1, Tab 14, paragraph 64

other words she was not asked to and did not perform a full autopsy. She did not examine Mrs MacGregor's brain for signs of hypoxic ischemic encephalopathy or examine the state of her lungs or heart. It is probable that she was directed to do a limited autopsy because the known medical history indicated that it was quite likely that the toxicologists would find a more conclusive result than they actually did. Dr Irvine looked at Mrs MacGregor's body externally and had access to her toxicological testing results and prior medical records.

47. The toxicological examination of the post mortem blood showed a blood hydromorphone concentration that was within the normal therapeutic range. Dr Irvine's "Limited Autopsy Report"[31] noted Mrs MacGregor's frailty and recorded the cause of death as "complications of pneumonia following treatment for chronic *clostidum difficile* colitis". The report noted that she had other significant conditions including valvular heart disease with congestive heart failure and chronic lung disease. It was Dr Irvine's opinion that the toxicology results did not provide "objective" evidence of death by hydromorphone toxicity.

48. Dr Irvine gave evidence at the inquest and was directly questioned about the role that the dose of hydromorphone may nevertheless have had in the death. She stated that she couldn't exclude it, "but I can't invoke it either".[32] This view was shared to some degree by Dr Spence. In his supplementary report he was prepared to say "I do not believe it is reasonable to attribute Mrs MacGregor's death directly to the administration of hydromorphone".[33] However his evidence at the inquest was slightly more equivocal.[34]

49. Associate Professor Aggarwal was an impressive witness and it was her evidence that the medication error "may" have contributed to Mrs MacGregor's death. Like other experts she needed to place it against the background that Mrs MacGregor may have been in the process of dying anyway. Dr Perl stated that "there was no way she could exclude hydromorphone being a factor".[35]

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[31] Limited Autopsy Report, Exhibit 1, Tab 3
[32] Evidence of Dr Rebecca Irvine, 22/2/16, page 11, line 8 onwards.
[33] Report of Dr Spence (dated 22 November 2015) Exhibit 1, Tab 39
[34] See for example his evidence at the inquest 22/2/16 page 25, line 2 onwards.
[35] See for example discussion of this issue in Dr Perl's evidence on 22/2/16, page 43

50. As one would expect, each expert gave evidence according to his or her own specialty. I have had the opportunity to consider all the expert evidence on this issue and draw together the reports of Mrs Macgregor's progress over the days preceding her death, her almost immediate reaction to the drug and subsequent total decline, and the opinion and actions of Dr Mau at the time.

51. Mrs MacGregor had a number of serious co-morbidities. Given the prognosis suggested by those involved in her care, it is certainly possible that she was dying or entering a disease phase from which she would not recover. However, I am satisfied that the overdose she received caused a severe and relatively sudden reaction. It quickly altered her level of consciousness and later caused Dr Mau to take immediate action to try to reverse the respiratory depression. Her condition did not gradually deteriorate. It changed quite quickly. An already frail lady was given ten times more hydromorphone than she should have been given and I am satisfied it contributed to her death at 4.30pm on 24 October 2013. The proximity of the overdose to her sudden decline is, in my view telling. I accept the blood tested *post mortem* did not reveal a necessarily toxic dose. However, she could have been well passed her peak by the time her blood was taken. Her age and her lack of previous tolerance to the drug, along with her very significant co-morbidities could also have meant that she was likely to have been affected more severely than another patient given the same dose. In my view it is no coincidence that her death occurred after the trauma of the overdose.

52. Given the medical evidence before me, it is impossible to say that the drug alone *caused* her death. Nevertheless, I am comfortably satisfied that the drug overdose was a contributing factor. It is more likely than not.

53. The cause of Mrs MacGregor's death should be recorded as "the combined effects of an overdose of hydromorphone *and* complications of pneumonia (following treatment for chronic *Clostridium Difficile Colitis*) against a background of heart disease and lung disease."

Problems identified at the hospital following Mrs MacGregor's death

54. Following Mrs MacGregor's death, North Shore Private Hospital instituted a number of measures designed to reduce the risk of an error such as occurred in the treatment of

Mrs MacGregor recurring. The Court was assisted in this regard by written and oral evidence of Ms Laura Davies, the former assistant Director of Clinical Services at the Hospital.[36]

55. The measures included two nursing education in-service seminars, which were mandatory.[37] There was also education for staff in relation to the early detection and treatment of deteriorating patients.[38] These programs aimed also to make staff aware of the relevant policies which were in place and available on the North Shore Private Hospital intranet.

56. As a result of a review after Mrs MacGregor's death, the Hospital developed a new policy entitled " Hydromorphone (Diluadid) Ampoules: Prescribing, Supply and Administration"[39] I am satisfied the adoption of that policy significantly reduces the likelihood of a medication error of the sort that occurred in this matter happening again. The Hospital is to be commended for making those changes. I do not intend to review the policy in detail here. However, among other things it limits the clinicians who can prescribe the drug to those in intensive care teams, palliative care teams or geriatricians, pain specialists or oncologists. It places restrictions on the drug's supply to the ward and mandates its immediate return to the pharmacy if unused. Requirements in relation to its administration have been tightened. A safety alert in relation to the drug must now be placed inside the door of the safe where it is kept. There is increased guidance in relation to prescribing, labelling and storage and in relation to appropriate patient monitoring and procedures where an overdose is suspected. I am satisfied that the policy addresses the material requirements of NSW Health's "High-risk Medicines Management Policy"[40] and in some important respects goes further.

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[36] See Exhibit 1, Tabs 30 and 36 and also the oral evidence of Ms Davies, 22/2/16 page 57 -64
[37] See for example evidence of Angela Thwaites 25/11/15, page 40 onwards
[38] See discussion of the "Are you aware" program by Angela Thwaites 25/11/15, page 41 onwards
[39] Hydomorphone (Diluadid) Ampoules; Prescribing, Supply and Administration (Hospital Policy PH 1.24) Exhibit 1, Vol 1, Tab 31
[40] High-risk Medicines Management Policy (PD 2015_029) NSW Health

What else can be done?

57. The inquest canvassed the important issue of whether there is anything else that can be done to reduce the possibility of this kind of tragic medication error happening again. There have already been a number of attempts by both the NSW Department of Health and various private hospitals to address the issue. Some of those efforts were documented in Her Honour, Magistrate Freund's findings in *The inquest into the death of Rishi Deo Maharaj.* [41] In response to that death, the Clinical Safety, Quality and Governance Branch of the NSW Department of Health had published a new Safety Alert (number 004/11) in April 2011. The alert drew attention to the ongoing confusion between morphine and hydromorphone and noted the potential for adverse patient results. While there was not a firm requirement to use the brand name, it was encouraged. Issues in relation to storing the drugs together were also canvassed. At the conclusion of the *Maharaj* inquest Magistrate Freund recommended further changes aimed at reducing the dangers in confusing hydromorphone with morphine and in relation to the storage and prescription of the drugs.[42] Some of those recommendations have now been forwarded into policy, however not all the recommendations arising from that inquest, which involved a related but different factual scenario to the present case, appear to have been acted upon at this stage.

58. It is important to grapple with the precise nature of confusion that arose in Mrs MacGregor's case if useful further recommendations can be made from the facts before me. Any recommendation must arise specifically from the issues at hand. The drug here was appropriate and prescribed in a correct dose. On the day in question the correct drug was sent from the pharmacy, although one wonders why the HP version was sent, given the size of the dose required.[43] Quite simply, the nurses gave the wrong dose. However, it appears that they gave a dose that would likely have been correct, had the

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[41] *Inquest into the Death of Rishi Deo Maharaj*, (2011/388777)

[42] See a summary of the recommendations made as a result of this Inquest and the responses received by the Department of Health at page 121 of Mr Kelly's submissions in this matter (attached to the Court file)

[43] The confusion between hydromorphone and morphine is still evident. While it did not cause Mrs MacGregor's death, it is important to remember she was actually given morphine the previous day *instead* of hydromorphone.

drug prescribed been morphine of a strength they were accustomed to giving. They appeared to believe, erroneously but on advice from the pharmacy, that hydromorphone was "pretty much the same" as morphine. Even so, it appears that they did not think through the dose prescribed, given the higher potency concentration form they were supplied with. It may be that they did not give sufficient consideration to the concentration issue at all and merely transposed a dose prescribed in milligrams to one given in millilitres.

59. There are in effect at least two confusions. One in relation to drugs with different properties that have similar names, and one in relation to the different concentrations drugs can be presented in.

60. A simple way to avoid confusion in relation to the different drugs is to always use the brand name (Dilaudid) for hydromorphone when prescribing or at least to always add it in the following way – HYDROmorphone (Dilaudid). This is not a new suggestion and was canvassed fully in the *Maharaj* Inquest [44]. However it has yet to be accepted across the board in NSW. In my view, it would be best practice and more must be done to bring the recommendation to reality. NSW Health Department's current policy, High-Risk Medicines Management Policy (PD2015-029)[45] states that prescribers "should also include in the order the trade name" but it is difficult to know how closely this policy recommendation is followed.

61. The concentration issue was not directly raised in the *Maharaj* Inquest, but presented a significant and related problem on the facts before me. A simple way of distinguishing and highlighting different concentrations would be to make them available in very different packaging and by always insisting on having a very prominent warning on the high potency version. Warnings and separate packaging (including the bagging of hydromorphone) has been recommended before, but restricting and differentiating packaging of different concentrations of the same drug, at source, may take the issue further.

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[44] *Inquest into the Death of Rishi Deo Maharaj*, (2011/388777)

[45] High-Risk Medicines Management Policy (PD2015-029)

62. One suggestion made during the inquest[46] was that the Therapeutic Goods Administration (TGA) should consider restricting the way in which different concentrations of hydromorphone are made available in Australia. For example, the lower concentration could be made available in a glass ampoule only (using a different colour to morphine). The higher potency (HP) concentration could be made available in flip top lid bottle only and contain a prominent and specific warning in relation to its concentration. At present it appears both concentrations of the drug are available in both formats. This is the kind of very specific packaging feature which should be carefully considered.

63. It is my view that these changes, if implemented could have had the potential to make nurses pause and reflect, before dosing a patient and thereby improve the "checking" process before administration takes place.

64. I have also carefully considered whether mandating earlier observation checking times could have prevented tragedy in this case. As stated earlier, I am of the view that Mrs MacGregor was left without proper monitoring for too long. However, in my view the critical issue was Nurse Hartstone's inability to recognise an overdose had occurred at an early stage. I am of the view that she should have recognised the signs that Mrs MacGregor was over-medicated during her initial contact. She saw enough to state that Mrs MacGregor was "zonked", but she failed to recognise the potential seriousness of her condition. I note that North Shore Private Hospital has already provided education to nurses and other staff in relation to the early detection and treatment of deteriorating patients.[47] This appears to me to go some way to reducing the potential problem. On the evidence before me, I am not persuaded to make a further recommendation in this regard.

Findings made pursuant to section 81 of the *Coroner's Act* 2009 (NSW)

65. On the balance of probabilities, I find that Audrey Winifred MacGregor died at North Shore Private Hospital, St Leonards, NSW on 24 October 2013.

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[46] See Submissions for Dr Mau (No 2) (attached to Court file)
[47] See evidence at Inquest of Kate Hartstone, 25/11/15, page 41, line 25 onwards and Exhibit 1, tab 32.

66. She died after a period of serious illness and following an overdose of hydromorphone.

67. The medical cause of her death was the combined effects of an overdose of hydromorphone and complications of pneumonia (following treatment for chronic *clostidium difficile colitis*) against a background of heart disease and lung disease.

Recommendations pursuant to section 82 of the *Coroner's Act* (NSW) 2009

68. For reasons set out above I make the following recommendations to the Minister for Health.

69. That the NSW Department of Health give consideration to conducting an audit of its *High Risk Medicines Management Policy* with a view to ascertaining what practices and procedures have actually been implemented by Local Drug and Therapeutic Committees pursuant to the current section on Hydromorphone (part 3.2).

70. That NSW Department of Health strengthen its *High Risk Medicines Management Policy* in relation to hydromorphone and mandate that the drug must, rather than "should" be referred to as HYDROmorphine Dilaudid or Dilaudid by hospital staff including prescribers, nurses and pharmacists.

71. That the NSW Department of Health consider issuing another "Safety Notice" (in addition to SA 004/11) for the purpose of reinforcing to all staff the potential confusions which still exist between morphine and hydromorphone and the confusions which may result in the use of differing concentrations of the drugs. This safety alert should include a mandated education component.

72. That the NSW Department of Health investigate options that may be available through Therapeutic Goods Administration (TGA) for the purpose of restricting the use of different sized/coloured ampoules and/or bottles with the intention of minimizing any confusion between lower and higher potency strengths of hydromorphone.

Conclusion

73. Finally, I offer my sincere condolences to Mrs MacGregor's family. Their love for Audrey Winifred MacGregor was palpable as they sat listening to the evidence each day. I have no doubt the pressures of an inquest interrupted their grieving process and yet they stuck with it in the small hope that their active participation could possibly reduce the chance of similar tragedies occurring to other families. I thank them for their active participation in this process.

74. I close this inquest.

Magistrate Harriet Grahame

Deputy State Coroner

26 October 2016