## **Coroners Act 1996**

[Section 26(1)]



#### Western

#### Australia

## RECORD OF INVESTIGATION INTO DEATH

Ref No: 1/15

I, Barry Paul King, Coroner, having investigated the death of Myosotis Julianna Moriarty with an inquest held at the Perth Coroner's Court, Court 51, CLC Building, 501 Hay Street, Perth, on 12 and 14 January 2015, find that the identity of the deceased person was Myosotis Julianna Moriarty and that death occurred on or about 18 December 2010 at Unit 22, 13 Cantonment Street, Fremantle, from acute gastrointestinal haemorrhage secondary to bilateral dental extraction in the following circumstances:

## **Counsel Appearing:**

Ms K Ellson assisting the Coroner Ms G McGrath (Panetta McGrath) appearing on behalf of Dr P J Colgan

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## **INTRODUCTION**

- 1. Myosotis Julianna Moriarty ("the deceased") had been on long term warfarin therapy for a heart condition.
- 2. On 16 December 2010 Fremantle dentist Dr Patrick Colgan extracted two of her teeth.
- 3. By 18 December 2010 the deceased had died from blood loss from the extraction sites in her mouth.
- 4. On 1 November 2011 the State Coroner Mr Alastair Hope directed that the deceased's death be investigated by an inquest.
- 5. On 12 and 14 January 2015 I held an inquest into the deceased's death.
- 6. The issues identified by Ms Ellson for investigation related to Dr Colgan's management of the deceased's treatment.
- 7. The documentary evidence adduced at the inquest comprised:
  - a) a report and a volume of documents compiled by the police officer who investigated the death, Constable S W Elers;<sup>1</sup>
  - b) a letter and attached copy of a 'search warrant'<sup>2</sup> I had issued to obtain records from the Australian Health Practitioner Regulation Agency relating to the deceased and Dr Colgan;<sup>3</sup>
  - c) a copy of an on-line page from Therapeutic Guidelines Limited, entitled 'Management of patients taking warfarin who require minor oral surgery';<sup>4</sup>

<sup>&</sup>lt;sup>1</sup> Exhibit 1

<sup>&</sup>lt;sup>2</sup> Authorisation of Coroner's Investigator under s 33(3) of the *Coroners Act 1996* 

<sup>&</sup>lt;sup>3</sup> Exhibit 2

<sup>&</sup>lt;sup>4</sup> Exhibit 3

- copy of extracts from a publication Therapeutic Guidelines Limited and the Australian Dental Association (the ADA) entitled 'Therapeutic Guidelines - Oral and Dental 2007 Version 1' (the Guidelines);<sup>5</sup>
- e) a copy of a handout provided to patients at the Oral Health Centre of Western Australia entitled 'Advice Following Dental Extractions and Oral Surgery';6
- a copy of an OPG radiograph of the deceased's teeth;7
- g) a photocopy of a photograph of a zip-lock bag containing a number of tranexamic acid tablets together with a zip-lock bag containing two tranexamic acid tablets;8
- h) a box of 'Spongostan' dental sponges;9 and
- i) copies of emails dated from 17 December 2014 to December 2014 between Dr Colgan and Ms Wendy Meggison of Panetta McGrath Lawyers. 10
- Following the holding of the inquest I obtained a 8. complete copy of the Guidelines. I also obtained a copy of an internet page produced by DPL Australia Pty Ltd trading as Dental Protection entitled 'Exercise in management: post-operative instructions Communication involves a great deal more than the process of one person talking and a second one listening, particularly if it is to be effective'. 11 A copy of the latter was provided to Ms McGrath.
- 9. Oral evidence was obtained from: the deceased's medical general practitioner Dr John Troy; clinical

<sup>6</sup> Exhibit 5

<sup>&</sup>lt;sup>5</sup> Exhibit 4

<sup>&</sup>lt;sup>7</sup> Exhibit 6

<sup>&</sup>lt;sup>8</sup> Exhibit 7

<sup>&</sup>lt;sup>9</sup> Exhibit 8

<sup>10</sup> Exhibit 9

 $<sup>^{11} \</sup> http://\underline{www.dentalprotection.org./australia/publications-resources/clinical-audit-tools/clinical-audit-aud$ tools-display/2014/08/27/, accessed on or about 15 January 2015

pharmacologist and toxicologist Professor David Joyce, oral medicine consultant and Director of Post Graduate Clinical Programmes at UWA School of Dentistry Associate Professor Gareth Davies; and Dr Colgan.

10. Ms Ellson provided oral submissions on 14 January 2015 following the oral evidence. Ms McGrath provided written submissions on 23 January 2015.

#### THE DECEASED

- 11. The following information relating to the deceased's background was provided by her daughter Fiona. 12
- 12. The deceased was born on 28 March 1942 in Budapest, Hungary. Her family name was Blaszanyik. Her family travelled to Australia after being smuggled through various countries and hiding in Austria for some time.
- 13. The deceased attended Star of the Sea and went on to Melbourne University where she became one of the first students to study social work. At university she met her husband to be, Michael Moriarty, who was studying law.
- 14. The deceased and her husband were married in 1966. They travelled in Europe and after two years returned to Melbourne to pursue their careers and raise a family of two girls and two boys. In her career the deceased specialised in international adoption for the Department of Human Services.
- 15. The deceased experienced a number of profound family tragedies. In 1990 the deceased's first son was killed in a car crash 10 days before his 21st birthday. In 2006 her husband became ill from liver failure and died at the age of 67. In March 2010 her second son died of a drug overdose.

<sup>&</sup>lt;sup>12</sup> Exhibit 1, Tab 9

16. From Dr Troy's records it appears that in May 2009 the deceased moved to Western Australia. Fiona recalled that the deceased moved to Fremantle to live close to her and to have easier access to flights to the Northern Territory where her youngest daughter Julia lived.

#### THE DECEASED'S MEDICAL HISTORY

- 17. In 1987 the deceased underwent surgery to receive an aortic valve prosthesis following infective endocarditis of a stenotic bicuspid aortic valve. It was thought that the endocarditis had developed as a result of a dental procedure which had been performed without antibiotic prophylaxis. The endocarditis also caused an embolus to the deceased's left eye which led to a loss of vision.<sup>13</sup>
- 18. For the following 13 years the deceased avoided doctors. In 2000 she sought medical attention for heart failure and was found to have atrial fibrillation. The evidence indicates that she was treated with the anti-coagulant warfarin from that time, but I suspect that it may have been prescribed in 1987 after receiving the prosthetic heart valve. It seems clear that in 2000 she was prescribed amiodarone for the arrhythmia. She developed hypothyroidism, a common side-effect of the use of amiodarone, and was treated accordingly with levothyroxine.<sup>14</sup>
- 19. After moving to Western Australia in 2009 the deceased saw Dr Troy and cardiologist Dr Mark Ireland. Dr Ireland assessed her with an echocardiogram in July 2010 and found that she was reasonably well. He intended to have her continue the current treatment and he would then assess her again in a year.<sup>15</sup>

<sup>14</sup> Tab 10

<sup>&</sup>lt;sup>13</sup> Tab 10

<sup>&</sup>lt;sup>15</sup> Tab 10

- 20. Dr Troy saw the deceased every six months or so to renew her prescriptions. She would regularly and often attend Perth Medical Laboratories for blood testing, especially in relation to the effect of the warfarin she was taking. A pathologist or a haematologist from the lab would contact her directly with test results and ongoing instructions of dosage and details of her next appointment.<sup>16</sup>
- 21. The measure of the effect of warfarin is known as the international normalised ratio or INR, which is a measure of how long it takes for blood to clot. An INR of 1 is normal for a person who is not taking warfarin, so the higher the number, the longer the clotting time.<sup>17</sup>
- 22. Patients are prescribed dosages of warfarin with a view to keeping them in particular INR target ranges, depending on the individual patient's condition. The INR for atrial fibrillation is usually 2 to 3; the INR for a patient such as the deceased who had mechanical prosthetic valves is usually higher. 18
- 23. Dr Troy's practice notes show that the deceased's INR levels varied from as low as 1.7 in February 2010 to as high as 4.3 in June 2010. In the months leading up to her death the deceased's INR levels were 2.4 on 28 September 2010, 3.0 on 13 October 2010, 2.9 on 10 November 2010 and 3.5 on 10 December 2010.

#### DR P J COLGAN

24. On 9 November 2009 the deceased went to her first consultation with Dr Colgan at his surgery in Fremantle. She was referred to him by one of his other patients.

<sup>17</sup> ts 24 per Joyce, D A

<sup>19</sup> Tab 10

<sup>&</sup>lt;sup>16</sup> ts 10 per Troy, J

<sup>&</sup>lt;sup>18</sup> ts 26 per Joyce, D A: Professor Joyce said 2.5 - 3.5; Tab 10 Coagulation Profile in Dr Troy's Patient Health Summary for the deceased at 7/09/10 indicates an INR of 3 - 4.5

- 25. Dr Colgan was a very experienced general practice dentist. He graduated dental school in 1966 and, apart from time spent with the WA dental service in 1967 to 1970 and a teaching role at North Western University in Chicago in 1977 and 1978 as a visiting assistant professor in prosthodontics, he was in family general practice since then.<sup>20</sup>
- 26. Dr Colgan had also been active in associations within the dental profession. He had been the president of the Australian Dental Association at both the State and Federal level and at the time of the inquest was the Australian Regent of the International College of Continuing Dental Education and a member of the Constitution and Ethics Committee of the ADA at State level. In 2001 he was made a member of the Order of Australia.<sup>21</sup>
- 27. Dr Colgan did not provide an estimate of how many of his patients over the years had been on warfarin therapy, but he implied that there had been many and that the number had increased in recent years.<sup>22</sup>
- 28. The deceased told Dr Colgan that she was long overdue for a dental assessment as she had not seen a dentist for some time and had some problems. She told him that she was anxious about consulting a dentist because she had developed subacute bacterial endocarditis in the past from a dental procedure. She said that she had required prosthetic aortic valve replacement and that she was on long term warfarin therapy with stable INR levels of between 3 and 3.4.<sup>23</sup>
- 29. Dr Colgan carried out a detailed examination of the deceased and took an OPG, a panoramic dental radiograph showing the upper and lower jaw. He discussed with her a proposed treatment which would initially include the extraction of two or possibly

<sup>&</sup>lt;sup>20</sup> ts 77 per Colgan, P J

<sup>&</sup>lt;sup>21</sup> Exhibit 1, Tab 8, Annexure PJC 1

<sup>&</sup>lt;sup>22</sup> ts 77 - 78 per Colgan, P J

<sup>&</sup>lt;sup>23</sup> Exhibit 1, Tab 8, paragraphs 23, 30

three teeth. He advised her to discuss the planned extractions with her doctor to ensure that her INR levels were within acceptable levels. He also noted that she would require antibiotic cover before commencing any invasive procedures.24

- After the appointment on 9 November 2009 the 30. deceased did not return to Dr Colgan's surgery for over a year. By chance she met Dr Colgan's receptionist in Fremantle and told her that she intended to make another appointment. An appointment was arranged for 8 December 2010.25
- second appointment the that deceased told 31. Dr Colgan that she was still on warfarin and that her INR levels were stable, which Dr Colgan took to mean that they remained between 3 and 3.4.26
- Dr Colgan advised the deceased to have two further 32. appointments. The first would take place in December 2010 and would involve the required extractions under antibiotic cover as well as sub-gingival curettage and fillings to three teeth. The second appointment would take place in 2011 and would involve the remaining The deceased agreed to the proposed fillings. treatment.27
- Dr Colgan said in oral evidence that an appointment 33. was made for 16 December 2010 as it would be shortly after the deceased's next INR test.<sup>28</sup> I note, however, that no mention is made of the deceased's pending INR test in Dr Colgan's practice notes or in the statement he prepared for the inquest. Instead, in his statement he merely states that he asked her to make an appointment with his receptionist.<sup>29</sup> When asked about his failure to include reference in his statement to an issue which he was sure had occurred 'because it

<sup>&</sup>lt;sup>24</sup> Exhibit 1, Tab 8, paragraphs 35 - 47

Exhibit 1, Tab 8, paragraphs 56 - 58

<sup>&</sup>lt;sup>26</sup> Exhibit 1, Tab 8, paragraph 64 <sup>27</sup> Exhibit 1, Tab 8, paragraphs 65 - 68

<sup>&</sup>lt;sup>28</sup> ts 89 - 90 per Colgan, P J

<sup>&</sup>lt;sup>29</sup> Exhibit 1, Tab 8, paragraph 69

was so pertinent to the patient', Dr Colgan apologised for the oversight.<sup>30</sup>

#### THURSDAY 16 DECEMBER 2010

- 34. On 16 December 2010 the deceased attended Dr Colgan's surgery at the midday break, an hour before the scheduled treatment appointment, in order to take a prophylactic antibiotic. Dr Colgan prepared the antibiotic and his receptionist provided it to the deceased in the waiting room.<sup>31</sup>
- 35. In oral testimony Dr Colgan said that about that time the deceased told him that she had undergone an INR test on 10 December 2010 and that her INR was 3.5.<sup>32</sup> This assertion was also absent from Dr Colgan's statement and was not recorded in his treatment record for the deceased.<sup>33</sup>
- 36. After waiting for the antibiotic to take effect, Dr Colgan had the deceased enter the consultation room where he administered local anaesthetic and carried out the planned fillings and cleaning. Once those procedures were complete, he extracted two of the deceased's teeth, identified as teeth 16 and 26. He took a radiograph of the third tooth identified previously as a possible extraction and determined that it did not require extraction.<sup>34</sup>
- 37. The extraction of the two teeth was atypical in that both teeth popped out with minimal effort, probably due to a lack of supportive bone around them. Dr Colgan checked the sockets and was satisfied that clots had formed and there was no bleeding.<sup>35</sup>

<sup>&</sup>lt;sup>30</sup> ts 120 - 121 per Colgan, P J

<sup>&</sup>lt;sup>31</sup> Exhibit 1, Tab 8, paragraphs 81 - 82

<sup>32</sup> ts 87 per Colgan, P J

<sup>&</sup>lt;sup>33</sup> Exhibit 1, Tab 8

<sup>&</sup>lt;sup>34</sup> Exhibit 1, Tab 8, paragraphs 83 - 88

<sup>&</sup>lt;sup>35</sup> Exhibit 1, Tab 8, paragraphs 89 - 91; ts 123 - 124 per Colgan, P J

- 38. Following the extractions Dr Colgan provided the deceased with dampened gauze folded to fit the sockets. Dr Colgan then gave her verbal post-operative instructions while she sat in the dental chair with the gauze in her mouth.<sup>36</sup> He arranged for her to be given extra gauze packs and follow up antibiotics.<sup>37</sup>
- 39. Dr Colgan said that the standard post-operative instructions that he gave were: to leave the gauze pack in place, to rest, to use the extra gauze packs if there were any oozing, not to rinse or brush, to use an extra pillow when sleeping to elevate her head a little, to use her usual painkillers and to call Dr Colgan's practice should she have any concerns, including concerns about bleeding.<sup>38</sup> He told her that he would not be present at the practice the following day, but his receptionist and clinical assistant would be available to speak with her.<sup>39</sup>
- 40. Dr Colgan provided the instructions verbally since he did not consider written instructions to be effective.<sup>40</sup>
- 41. The deceased then sat in the waiting area for half an hour or so while awaiting the arrival of her daughter's friend who would take her home. While the deceased was in the waiting room, Dr Colgan's receptionist observed her.<sup>41</sup>
- 42. After leaving Dr Colgan's surgery the deceased went home. Her daughter Fiona and her friend had insisted that she stay with them, but she had declined, saying that she just wanted to be in her own bed and to watch TV.<sup>42</sup>
- 43. On the morning of Friday 17 December 2010 Fiona dropped in to the deceased's home to see her.

<sup>&</sup>lt;sup>36</sup> ts 103,-104, 105 per Colgan, P J

<sup>&</sup>lt;sup>37</sup> Exhibit 1, Tab 8, paragraphs 95 - 97

<sup>&</sup>lt;sup>38</sup> ts 109 – 111 per Colgan, P J

<sup>&</sup>lt;sup>39</sup> Exhibit 1, Tab 8, paragraph 102

<sup>&</sup>lt;sup>40</sup> ts 105 per Colgan, P J

<sup>&</sup>lt;sup>41</sup> Exhibit 1, Tab 8, paragraph 96

<sup>&</sup>lt;sup>42</sup> Exhibit 1. Tab 9

The deceased was pale and weak, and there was dried blood around her mouth. She told Fiona that she had fainted the night before.

- The deceased told Fiona that she had called 44. Dr Colgan's surgery and had spoken to his clinical assistant to tell her that she had been bleeding and was told that she had been given extra gauze.43 However, the surgery had no record of her call.44 In the circumstances of this conflicting, effectively hearsay evidence, I am unable to conclude whether the deceased had made the call to the surgery, or whether she merely told Fiona that she had done so.
- After the deceased told Fiona about the bleeding, Fiona 45. told her that they were going to the hospital, but the deceased insisted that she felt much better and just wanted to rest. Fiona then went to a work function. After the function she called the deceased who said that she was feeling much better. To Fiona, she sounded much better, stronger and happier.<sup>45</sup>
- On the next morning Fiona waited until after 10.00 am 46. in order to let the deceased sleep in before calling her. When the deceased did not answer, Fiona ran to the deceased's home and was eventually able to gain entry. She found the deceased in bed with blood around her mouth, clearly dead. There was copious blood in the toilet bowl as well as on other surfaces in the bathroom.46

#### CAUSE OF DEATH AND HOW DEATH OCCURRED

Forensic pathologist Dr Gerard Cadden and 47. Anatomical Pathology Registrar Dr Angeline conducted a post mortem examination of the deceased on 21 December 2010 and found recent bilateral

<sup>&</sup>lt;sup>43</sup> Exhibit 1, Tab 9

Exhibit 1, Tab 8, paragraphs 119 - 120
Exhibit 1, Tab 9

<sup>46</sup> Exhibit 1, Tabs 6, 9

extractions of the upper first molars with blood clot in the mouth and fresh blood throughout the gastrointestinal tract. Toxicological analysis detected warfarin at what was flagged to be a low therapeutic level and alcohol and other common drugs were not detected.<sup>47</sup>

- 48. At. Dr Cadden's request, consultant forensic Knott odontologist Dr Stephen conducted odontological examination of the deceased and found pendulous blood clots attached to the sockets of teeth 16 and 26 indicating extensive haemorrhage having occurred after extraction of the teeth. The extractions had not caused any extensive tissue damage and the sockets were as expected after a recent extraction. There was no evidence of haemostatic or gauze packing and no sutures were present.<sup>48</sup>
- 49. Dr Cadden and Dr Teo formed the opinion, which I adopt, that the cause of death was acute gastrointestinal haemorrhage secondary to bilateral dental extraction. 49
- 50. On the basis of the evidence available to me, I am satisfied that while on long term warfarin therapy, the deceased underwent the extraction of two teeth, at some time after which she experienced ongoing bleeding from the sockets, which caused her death.
- 51. I find that death occurred by way of misadventure.

# THE THERAPEUTIC GUIDELINES AND COMMENTS ON DR COLGAN'S TREATMENT OF THE DECEASED

52. Due to the deceased's medical history, there were two important considerations for any invasive dental procedure such as extractions: her high risk of infective endocarditis due to her prosthetic heart valves

<sup>&</sup>lt;sup>47</sup> Exhibit 1, Tab 4

<sup>&</sup>lt;sup>48</sup> Exhibit 1, Tab 15

<sup>&</sup>lt;sup>49</sup> Exhibit 1, Tab 4

and her previous infective endocarditis<sup>50</sup> and the increased risk of bleeding from a wound as a result of her use of warfarin.<sup>51</sup>

- 53. It seems clear that a consideration of the appropriate treatment of a patient with those risks requires an appreciation of management recommendations such as those in the Guidelines. When asked whether there were lessons to be learned from the deceased's case, Associate Professor Davies said that he thought that it was important that dentists were up to date on guidelines for management of such patients and that they have direct access to these guidelines. It is clear that he was referring to the Guidelines.<sup>52</sup>
- 54. According to Associate Professor Davies, members of the ADA are provided with copies of the current Guidelines (last published in hard-copy in 2012), and on-line versions are available through the ADA's website.<sup>53</sup> The recommendations in the current Guidelines in relation to managing patients on warfarin who require minor oral surgery have not changed in substance from those in the 2007 Guidelines.
- 55. The 2007 Guidelines purported to be 'an acceptable basis for management of patients'. The aim of the organisation behind the publication was to provide clear, authoritative and succinct therapeutic information. The information in the text was independent and unbiased and was a distillation of current evidence and opinion. The Guidelines were not a set of rules or instructions, but were a consensus view of best practice based on the available evidence. 57

<sup>&</sup>lt;sup>50</sup> Therapeutic Guidelines - Oral and Dental 2007 Version 1, p.136; ts 44 per Davies, G R

<sup>&</sup>lt;sup>51</sup> Therapeutic Guidelines - Oral and Dental 2007 Version 1, p.62; ts 44 per Davies, G R

<sup>&</sup>lt;sup>52</sup> ts 65 per Davies, G R

<sup>&</sup>lt;sup>53</sup> Exhibit 1, Tab 17(a)

Therapeutic Guidelines - Oral and Dental 2007 Version 1, p.xvii

<sup>&</sup>lt;sup>55</sup> Therapeutic Guidelines - Oral and Dental 2007 Version 1, p.xviii

Therapeutic Guidelines - Oral and Dental 2007 Version 1, p.xviii

<sup>&</sup>lt;sup>57</sup> Therapeutic Guidelines - Oral and Dental 2007 Version 1, p.xxvi

- 56. Professor Joyce, Associate Professor Davies and Dr Colgan respectively testified that the Guidelines are: widely regarded as 'condensation of the best expert opinion in the area'58, up to date information used by general dental practitioners to manage particular problems and circumstances<sup>59</sup>, and a substantially valuable document that was very important for Dr Colgan to have regard to in treating the deceased.<sup>60</sup> Dr Colgan testified that he consulted the Guidelines more than once before treating the deceased in relation to both risks mentioned above.<sup>61</sup>
- 57. As to the risk of infective endocarditis, the Guidelines provided that a patient such as the deceased who had a high risk cardiac condition and was undergoing a high risk procedure by having extractions should be given an antibiotic before the procedure. A standard dose for an adult was 2g of amoxicillin taken orally one hour before the procedure. Dr Colgan administered the deceased a 3g sachet of amoxicillin. That appears to have been entirely appropriate. 63
- 58. I should note in passing that antibiotics, particularly broad spectrum penicillins, have been known to interact with warfarin but that reported cases are relatively rare. 64 Professor Joyce stated that increased risks of bleeding by and large correspond with long-term antibiotic use that interferes with the availability of Vitamin K. He said that a single dose of amoxycillin of 3 grams and later a couple of doses of amoxycillin with clavulanic acid should not interfere with coagulation. 65
- 59. As to managing the risk of bleeding from warfarin, the Guidelines provided a number of steps<sup>66</sup>, as follow in

<sup>&</sup>lt;sup>58</sup> ts 35 per Joyce, D A

<sup>&</sup>lt;sup>59</sup> ts 43 per Davies, G R

<sup>60</sup> ts 94 per Colgan, P J

<sup>61</sup> ts 78, 93 per Colgan, P J

<sup>&</sup>lt;sup>62</sup> Therapeutic Guidelines - Oral and Dental 2007 Version 1, p.137

<sup>&</sup>lt;sup>63</sup> Exhibit 1, Tab 11

<sup>&</sup>lt;sup>64</sup> Exhibit 1, Tab 11

<sup>65</sup> ts 31 per Joyce, D A

<sup>&</sup>lt;sup>66</sup> Therapeutic Guidelines - Oral and Dental 2007 Version 1, p.64

italics with my comments on Dr Colgan's compliance or otherwise.

a) Take a detailed medical history including: dose regimen, stability of INR, underlying medical conditions and need for antibiotic prophylaxis

Dr Colgan complied substantially with this step, though he should have obtained a record of the deceased's INR from Dr Troy rather than relying on a generalised history from the deceased.

- b) Organise a blood test for INR within 24 hours before surgery:
  - i) If INR is less than 2.2 and there are no contraindications, proceed; tranexamic acid mouthwash is not required.
  - *ii)* If INR is greater than 4.0, refer patient back to their general medical practitioner.
  - iii) If INR is 2.2-4.0, proceed, using the tranexamic mouthwash protocol.

Directly contrary to the Guidelines, Dr Colgan did not obtain a blood test for INR within 24 hours or at all. He proceeded with the extractions, but apart from administering an antibiotic he did not use the tranexamic mouthwash protocol, as I will explain more fully below.

60. As to the reason for not obtaining an INR test, on Dr Colgan's testimony, he was told by the deceased that on 10 December 2010, six days previously, she had an INR of 3.5. As mentioned previously, neither Dr Colgan's practice notes nor his statement prepared for the inquest makes mention of an INR of 3.5. Rather, they indicate that the deceased told Dr Colgan on 9 November 2009 that her INR levels were 3.0 to 3.4 and on 8 December 2010 that they had remained

stable. From that he concluded that her INR levels remained between 3 and 3.4.<sup>67</sup>

- 61. In answer to a question, Associate Professor Davies agreed that it was desirable or even necessary to ascertain a patient's INR in order to know that it was not above 4.0.68 He said that a patient's INR can change rapidly so it is sensible to check it within at least three days before a procedure, even in a patient who has been on a stable dose. He said that he always gets it done on the day before a morning surgery or on the morning of an afternoon surgery, but certainly no more than 48 hours beforehand.69
- 62. Associate Professor Davies said that if a patient had an INR of 3 to 3.4 over a long period of time and, if one that was taken five days before the extraction was within the same range, he would think that was quite reasonable. However, he said that if the INR was recorded in February at 1.7 and in June as 4.3 but had been relatively more stable in the preceding three months to the procedure, he would like to have an INR test done the day before. The said that if a patient had an INR test done the day before.
- 63. Assuming, as Dr Colgan did, that the deceased's INR level was within the range of 2.2 to 4, the Guidelines provide that the procedure can proceed with the use of 'the tranexamic acid protocol'. The guideline provides in block letters: DO NOT CEASE WARFARIN. The tranexamic acid protocol entails:
  - a. On the day of surgery the dentist is to obtain the INR, administer antibiotic prophylaxis and obtain a bottle of tranexamic acid.
  - b. During surgery (for extraction of teeth) after the extraction the dentist is to irrigate the sockets with a 4.8% tranexamic acid mouthwash, fill the sockets

<sup>&</sup>lt;sup>67</sup> Exhibit 1 Tab 8, paragraphs 30, 64

<sup>68</sup> ts 46 per Davies, G R

<sup>&</sup>lt;sup>69</sup> ts 47 per Davies, G R

<sup>&</sup>lt;sup>70</sup> ts 71 per Davies, G R

<sup>&</sup>lt;sup>71</sup> ts 74 per Davies, G R

- with a loosely packed haemostatic agent, place one suture per socket and get the patient to bite on a gauze pack soaked in tranexamic acid mouthwash.
- c. After the surgery the dentist is to give the patient tranexamic acid mouthwash with instructions to use it for 2 minutes, 4 times daily for 2 to 5 days and arrange for a review dental appointment for 2 days after the procedure.
- d. At the review appointment the dentist is to note any bleeding, delayed healing or infection and deal with it as necessary. A further review is to be arranged 1 to 2 weeks later.
- 64. Consistent with the Guidelines, Dr Colgan did not cease the warfarin and he administered the antibiotic as required. Dr Colgan did not use a haemostatic agent or place a suture in each socket. Though he makes no mention of these techniques in his statement, in oral evidence he said that the sockets were too shallow to put in a suture.<sup>72</sup> He did not use any of the other requirements of the tranexamic acid protocol. He did not obtain tranexamic acid in advance of the procedure, suggesting that he had no intention to follow the protocol.
- 65. Tranexamic acid is a drug which delays the natural breakdown of blood clots by inhibiting enzyme systems which cause clots to break down. The effect is a longer blood clot.<sup>73</sup> It is used in dental procedures as a mouthwash. The Guidelines pointed out that, if a 4.8% mouthwash is not available, a 5% solution can be made by crushing a 500mg tablet and dispersing it in 10ml of water before administration.<sup>74</sup> The tablets were and are readily available from pharmacies as prescription medication.<sup>75</sup>

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<sup>&</sup>lt;sup>72</sup> ts 98 per Colgan, P J

<sup>&</sup>lt;sup>73</sup> ts 32 per Joyce, D A

<sup>&</sup>lt;sup>74</sup> Exhibit 4, p.64

<sup>&</sup>lt;sup>75</sup>ts 55 per Davies, G R; ts 100 - 101 per Colgan, P J

- 66. Dr Colgan did not obtain tranexamic acid mouthwash. He did not administer any or provide the deceased with any. He told the inquest that he did not do so because he considered the local measures described in the Guidelines to be backup procedures that could be applied if needed.<sup>76</sup>
- 67. Ms McGrath submitted that the Guidelines are arranged in a manner that may lead to a lack of clear clinical direction to practitioners and that Dr Colgan took reassurance for his decision from comments in the Guidelines that any bleeding from the mouth could be easily managed by local means.
- 68. It is fair to say that, during closing submissions by Ms Ellson, I raised the issue of a possibility of greater clarity of the Guidelines.<sup>77</sup> However, on reflection it is difficult to see how they can be understood to mean anything other than to recommend that, if a patient's INR is 2.2-4.0, the tranexamic acid protocol is to be used for extractions.
- 69. As to Dr Colgan's reassurance from the Guidelines, it is clear that the reference in the Guidelines to the ease of managing bleeding is made in contrast to the risk of a stroke if anticoagulants are stopped. There is no indication that the 'Procedure for patients taking warfarin who require minor oral surgery'<sup>78</sup> would only be necessary in the event of local bleeding.
- 70. In addition, the Guidelines cite a 2003 Australian Dental Journal article for more information about dental treatment for patients taking an anticoagulant or antiplatelet drug. That article proposed a protocol involving the use of almost the same local measures later found in the Guidelines, including the use of tranexamic acid. The fundamental point of the article is that patients on warfarin can undergo extraction

<sup>78</sup> Therapeutic Guidelines - Oral and Dental 2007 Version 1, p.64

<sup>&</sup>lt;sup>76</sup> ts 122 per Colgan, P J

<sup>&</sup>lt;sup>77</sup> ts 133 - 134

<sup>&</sup>lt;sup>79</sup> Therapeutic Guidelines - Oral and Dental 2007 Version 1, p.62

without reducing warfarin <u>provided the protocol is</u> followed.<sup>80</sup> (underlining added).

- 71. In the deceased's case, Dr Colgan took a different approach. He considered that the extractions were straightforward, clots had formed and further observations did not trigger the need for additional measures so he chose not to use them.<sup>81</sup>
- 72. Given the risk associated with warfarin and the status of the Guidelines, it is surprising that Dr Colgan did not use the tranexamic acid protocol. While the Guidelines are not instructions or rules, they were not equivocal on the use of the protocol where the INR level was 2.2 to 4, nor was the protocol onerous. There were sound reasons to use the protocol and no good reasons not to do so.

#### 73. Associate Professor Davies said this:

It's a judgement call by the dentist in terms of how much experience they have had of dealing with these things before. But where there is a risk such as in a patient who is on warfarin, then obviously the use of all precautions is sensible. Even though there may be haemostasis that's already achieved, the use of tranexamic acid is going to stabilise that situation. It is certainly not going to make things worse.

74. Given the apparent unsuitability of sutures and haemostatic foam in the circumstances, potential benefits from the use of tranexamic acid may have been even more apparent than otherwise. In relation to that issue, Associate Professor Davies said that 'you use as much backup as possible to minimise risk'.82

<sup>&</sup>lt;sup>80</sup> Carter G, Goss AN, Lloyd J, Tocchetti R: Current concepts of the management of dental extractions for patients taking warfarin. *Aust Dent J* 2003; 48(2): 89 - 96

<sup>81</sup> ts 97 - 99 per Colgan, P J

<sup>82</sup> ts 74 per Davies, G R

75. Irrespective of how straightforward or atypical the extractions were, they were invasive procedures as was borne out by the subsequent ongoing bleeding from the sockets.

## DID DR COLGAN'S FAILURE TO FOLLOW THE GUIDELINES CONTRIBUTE TO THE DEATH?

- 76. Dr Colgan did not obtain an up to date INR for the deceased and he did not use tranexamic acid as directed in the Guidelines.
- 77. In relation to the INR on 16 December 2010, Professor Joyce said that the fact that it was 3.5 on 10 December 2010 would indicate that it would be within the range of 2.5 to 3.5 on 16 December 2010, but it should not be taken as a guarantee.<sup>83</sup>
- 78. In the absence of an INR test closer to 16 December 2010, it is not possible to be confident precisely as to what it was on that date. However, it is likely that the INR was within the 2.2-4.0 range identified in the Guidelines as appropriate for minor oral surgery with the use of the tranexamic acid protocol. On that basis, I cannot conclude that Dr Colgan's decision to proceed with extractions without having obtained an INR was likely to have contributed to the death.
- 79. When the deceased left Dr Colgan's surgery on the afternoon of 16 December 2010 and went home, it is likely that the sockets left from the extractions that day were not initially bleeding. Sometime that afternoon or evening they started to bleed and the bleeding did not effectively cease until the deceased was too weak to survive. What caused the sockets to commence bleeding? Would the use of tranexamic acid have changed the outcome?
- 80. Associate Professor Davies' colleague, Professor Raymond Williamson, provided a report to Dr Cadden

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<sup>83</sup> ts 28 per Joyce, D A

in which he stated that the deceased's lack of bleeding during surgery was certainly due to the adrenaline in the local anaesthetic. He said that reactionary haemorrhage is a recognised complication in patients on anticoagulants when the local anaesthetic wears off after two to four hours.<sup>84</sup>

- 81. Associate Professor Davies considered that a person on warfarin was more likely to take longer to have stable clots than a person not on warfarin, but that reactionary haemorrhage can occur in a patient not on warfarin. He said that a person with an INR of 3 would be expected to have a clot form in 45 minutes.<sup>85</sup>
- 82. Associate Professor Davies made the point that tranexamic acid prevents the physiological breakdown of blood clots but does not prevent their mechanical breakdown. Patients can knock out a clot with their tongue, with a toothbrush or by rinsing the mouth, and patients will automatically try to get rid of the taste of blood. The more they rinse, the more chance of disturbing a clot.<sup>86</sup>
- 83. Associate Professor Davies also noted that a dentist can take every possible precaution against a bleed and the patient still bleeds postoperatively.<sup>87</sup> He said that following recommendations, which I infer to mean the Guidelines, is sensible, but it is not a guarantee that adverse outcomes will be prevented.<sup>88</sup>
- 84. In the light of this evidence, it is not possible to conclude to the required level of satisfaction that Dr Colgan's failure to apply the tranexamic acid protocol caused or contributed to the ongoing bleeding which led to death.

<sup>85</sup> ts 58 - 59 per Davies, G R

<sup>&</sup>lt;sup>84</sup> Exhibit 1, Tab 12

<sup>86</sup> ts 60 per Davies, G R

<sup>87</sup> ts 52 per Davies, G R

<sup>88</sup> ts 56 per Davies, G R

## POST-OPERATIVE MANAGEMENT INSTRUCTIONS

- As noted above, Dr Colgan provided the deceased with 85. verbal instructions soon after the procedure had taken place and did not provide written instructions since he did not believe that they were effective. He assessed the deceased as being in a state of mind to be able to He considered that her demeanour was was appropriate, her intelligence high and her awareness of her health status was acute. He thought that those things combined meant that she was able to take on board what he said to her.89
- Dr testified Colgan that he did consider 86. not supplementing instructions with written oral instructions to be best practice, but believed it could be an additional practice.<sup>90</sup> He considered that his years of experience dealing with patients had enabled him to be secure in the thought that he was able to assess a person's ability to remember information after a dental procedure. He said that he thought that he had been able to do so with the deceased.91
- It seems to me self-evident that the use of written post-87. operative instructions as part of post-operative care is appropriate for patients who may experience worrying or life-threatening complications following a medical or dental procedure. In my view, written instructions oral instructions would accompanying ensuring as far as possible that the information is understood and retained.
- The Dental Protection web-page<sup>92</sup> makes the point in 88. the following terms:

dental Sadly the surgery environment not particularly conducive to effective Often the dentist and other communication.

<sup>89</sup> ts 107 per Colgan, P J

of to 107 per Colgan, P J

<sup>91</sup> ts 108 per Colgan, P J

<sup>92</sup> http://www.dentalprotection.org./australia/publications-resources/clinical-audit-tools/clinical-audittools-display/2014/08/27/, accessed on or about 15 January 2015

members of the dental team are dealing with a variety of patients, all with different needs, and they may be subject to severe time pressures. Meanwhile, patients can be distracted; they may be in pain and slightly nervous, or feeling vulnerable and unsettled by an unfamiliar treatment provided in an unfamiliar environment. They may even be overwhelmed by the relief of finding a sympathetic dental team.

To overcome these difficulties we need to choose words and phrases that the patient can understand and relate to. In addition it helps to find the right moment and an empathetic manner in which to deliver them. Even then, a nervous or distracted patient may not hear and/or understand the whole message we are trying to convey.

Post-operative instruction sheets are a useful adjunct to the communication process, and serve to reinforce the information that is given verbally. Once out of the surgery environment, a patient is usually much better placed to act upon the post-operative advice which can take many forms, depending upon the treatment provided.

- 89. The Dental Protection page identifies home management of an extraction site as an example for the use of a post-operative instruction sheet and provides a short example of the content of such a sheet.<sup>93</sup>
- 90. The need for written instructions was particularly clear in relation to the deceased. By 2009 the deceased had not seen a dentist for some years due to her anxiety about a heart condition which she justifiably understood to have been caused by dental treatment. In December 2010 she agreed to undergo treatment that she had put off for over a year. Following the

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<sup>&</sup>lt;sup>93</sup> http://www.dentalprotection.org./australia/publications-resources/clinical-audit-tools/clinical-audit-tools-display/2014/08/27/, accessed on or about 15 January 2015

- extractions she remained concerned about the possible need for follow up antibiotics.94
- The evidence supports the view that the deceased was 91. likely to have been experiencing considerable anxiety following the procedure. Common experience suggests that she may not have been able to process or remember all of the details Dr Colgan provided to her verbally in the way of post-operative instructions in relation to bleeding and appropriate pain control.
- In my view Dr Colgan should have provided the 92. deceased with clear written instructions regarding the possible effects of the extractions and the information necessary to deal with such effects, the latter including prohibitions on actions that might disturb the clots such as rinsing and brushing, as well as directions in relation to the tranexamic acid protocol.
- The written directions should have impressed upon the 93. deceased the need to seek treatment in the event of ongoing bleeding or any other problem, and the ways of seeking such treatment.95 The importance of not taking aspirin should also have been included, even if not expected to be necessary.
- Ideally, the person who arrived to take the deceased 94. home should also have been apprised of the existence of the contents of the instructions and have been The written instructions alerted the most crucial. should have included after hours emergency telephone numbers.96

## PREVENTION OF SIMILAR DEATHS

Associate Professor Davies noted that incidents such 95. as the deceased's, where the patient dies as a result of

<sup>94</sup> Exhibit 1, Tab 8, paragraph 9495 ts 63 per Davies, G R

<sup>&</sup>lt;sup>96</sup> ts 59 per Davies, G R

bleeding following dental extractions, are exceptionally rare.97

- 96. As mentioned previously, Associate Professor Davies said that a lesson to be learned from the deceased's case was the need for dentists to have access to up to date copies of the Guidelines. When asked about recommendations that might prevent similar deaths, he said that checklists, perhaps simply the Guidelines themselves, could be used during procedures to ensure that protocols are followed.
- 97. When asked whether anything could have been done to prevent the deceased's death, Associate Professor Davies said that it would have been so much better if the deceased had contacted either Dr Colgan directly. gone back to the practice, gone to her own GP, gone to another dentist, made a triple 0 call or just presented at a hospital emergency department.98
- 98. However, as Associate Professor Davies noted, many patients, particularly elderly patients think that they are bothering the doctor if they make a fuss, and patients need to be reassured that they are not.99

## CONCLUSION AND COMMENT

The deceased's death was a terrible irony. She delayed 99. seeking dental care for years because she had developed potentially fatal infective endocarditis in 1987 following dental treatment and was obliged to live with warfarin therapy. When she finally overcame her fear and anxiety in order to get much needed dental care, she died as a result of ongoing bleeding after what appeared to be minimally invasive extractions.

<sup>&</sup>lt;sup>97</sup> Exhibit 1, Tab 17; ts 69 per Davies, G R <sup>98</sup> ts 64 per Davies, G R

<sup>&</sup>lt;sup>99</sup> ts 63 per Davies, G R

- 100. I have no doubt that Dr Colgan acted in what he considered to be the deceased's best interests based on his long experience.
- 101. However, it appears that he saw the warfarin therapy as more of a strategic ally in relation to the threat of infective endocarditis than as a threat in itself. Perhaps as a result of that, he failed to apply the Guidelines and thereby increased the risk of post-operative bleeding. 100 The post-operative instructions Dr Colgan provided to the deceased should have been accompanied by written instructions to emphasise the need to seek attention in the event of ongoing bleeding.
- 102. While it is not possible to conclude that Dr Colgan's failure to apply the Guidelines or to provide the deceased with written post-operative instructions contributed to her death, it appears to me that the management by Dr Colgan of the deceased was deficient for the reasons discussed.
- 103. I note that since the death of the deceased Dr Colgan has made changes to the way in which he manages patients with anticoagulant therapy. He provided an example of a recent patient with past surgeries and on anticoagulant therapy who required extractions. Dr Colgan referred him to a specialist and Dr Colgan now has a relationship with the specialist which allows for expedited referrals of similar patients in future.
- 104. Dr Colgan also said that he now tends to view the tranexamic acid protocol as intrinsic to the process rather than as a backup in case of difficulties. He now keeps a supply of tranexamic acid in stock.
- 105. Notwithstanding the changes made by Dr Colgan, in my view it is appropriate that, under s 50 of the *Coroners Act 1996*, I refer the evidence of his conduct with respect to the treatment of the deceased to the

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<sup>100</sup> Exhibit 1, Tab 8, paragraphs 76, 126

- Dental Board of Australia as that evidence may lead the Board to inquire into his conduct.
- 106. It is clear that the deceased's death was preventable whether Dr Colgan's treatment contributed to the ongoing bleeding or not. Had the deceased sought treatment as suggested by Associate Professor Davies, it is likely that she would not have died.
- 107. It is not possible on the basis of the evidence before me to determine if the deceased had called the dental surgery following the extractions, or why the deceased did not actively seek treatment when she continued to bleed. It may be, as Associate Professor Davies intimated, that she simply did not want to make a fuss.
- 108. Whatever the reason, it is important that dentists emphasise to patients with potential ongoing complications that they must seek treatment without delay.
- 109. I shall therefore arrange for a copy of this finding to be provided to the ADA with a suggestion that it consider advising its members to provide patients who undergo extractions, especially patients on warfarin, with written post-operative instructions as discussed above.

B P King Coroner 9 February 2015