IN THE CORONERS COURT
OF VICTORIA
AT MELBOURNE

Court Reference: COR 2011 1984

FINDING INTO DEATH WITH INQUEST

Form 37 Rule 60(1)
Section 67 of the ***Coroners Act 2008***

Inquest into the Death of: John TWYCROSS

Delivered On:	10 March 2017
Delivered At:	Coroners Court of Victoria 65 Kavanagh Street Southbank Victoria 3006
Hearing Dates:	6 October 2015
Findings of:	Coroner Paresa Antoniadis SPANOS
Representation:	Mr M. WAUGH, OF Counsel, instructed by Ms Debbie IRELAND from Harris Lieberman, appeared on behalf of Mrs Nina TWYCROSS and other relatives of the deceased. Ms T. RIDDELL, of Counsel, instructed by Ms Priyanthi MILTON of K & L Gates, appeared on behalf of Western Health.
Police Coronial Support Unit:	Leading Senior Constable Duncan McKENZIE, assisting the Coroner

I, PARESA ANTONIADIS SPANOS, Coroner,
having investigated the death of JOHN TWYCROSS

and having held an inquest in relation to this death at Melbourne on 6 October 2015:

find that the identity of the deceased was JOHN TWYCROSS

born on 9 March 1931

and that the death occurred on 31 May 2011

at Western Hospital, Gordon Street, Footscray, Victoria 3011

from:

I (a) COMPLICATIONS OF NECROTISING PANCREATITIS

I (b) PANCREATIC BIOPSY (E.U.S.)

in the following circumstances:

BACKGROUND & PERSONAL CIRCUMSTANCES[1]

1. Mr Twycross was an eighty-year-old married and retired man who resided with his wife in Wodonga. His past medical history included cholecystectomy and chronic renal insufficiency.

2. In early 2011, Mr Twycross had an episode of jaundice and imaging revealed a pancreatic lesion. He was admitted to Western Hospital [WH] on 20 May 2011 for an elective ultrasound guided biopsy of the pancreatic lesion and was discharged the same day. Mr Twycross was re-admitted with complaints of abdominal pain and diagnosed with pancreatitis which is a known complication of the procedure. His clinical course was complicated by renal impairment, worsening abdominal distension, vomiting and aspiration.

3. Mr Twycross was transferred to the Intensive Care Unit and from there to the operating theatre where necrotising pancreatitis was diagnosed, following which major surgery was undertaken with pancreatic dissection and subtotal cholectomy. Post-operatively, Mr Twycross continued to deteriorate and passed away on 31 May 2011.

4. No autopsy was conducted as the family raised no concerns for coronial investigation and Senior Forensic Pathologist Dr Michael Burke from the Victorian Institute of Forensic

[1] Under this heading is the substance of the "Finding Into Death Without Inquest" (Form 38) dated 24 August 2012 which was delivered prior to the family's application to re-open the investigation into Mr Twycross' death and the inquest, matters addressed in paragraphs 7 and following.

Medicine conducted a preliminary examination and advised that the medical cause of death was apparent without the need for autopsy. His preliminary examination included an external examination in the mortuary, perusal of the medical deposition and medical records provided by WH and post-mortem CT scanning of the whole body. Dr Burke attributed death to *complications of necrotising pancreatitis secondary to pancreatic biopsy (EUS).*

5. As Mr Twycross' death appeared causally related to a medical procedure, I asked the Health and Medical Investigation Team [HMIT][2] to review the clinical management and care provided to Mr Twycross at the WH. HMIT advised that the decision to exclude pancreatic carcinoma after CT imaging strongly suggested an ampullary tumour after an episode of pancreatitis, was reasonable, given the high mortality of this condition if diagnosed late.[3] HMIT could not fault the management plan which was determined by a Multidisciplinary Oncology Team, nor could they fault the manner in which the procedure was conducted. They also advised that Mr Twycross' management when he re-presented was timely and appropriate, with careful consideration and exclusion of differential diagnoses, regular review by the ICU Liaison Nurse while he was in the ward and appropriate transfer to the ICU when his respiration deteriorated.[4]

6. I find that Mr Twycross died from the complications of necrotising pancreatitis secondary to pancreatic biopsy (EUS). I further find that there is no evidence that any want of clinical management and care on the part of the staff of WH, caused or contributed to his death.

APPLICATION PURSUANT TO SECTION 77 OF THE CORONERS ACT 2008

7. Following delivery of a Finding Into Death Without Inquest [Form 38] dated 24 August 2012 in the above terms, lawyers representing Mrs Nina Twycross corresponded with the court culminating in an Application to Set Aside Finding [Form 43] dated 1 November 2012 on a number of grounds.

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[2] The HMIT is part of the Coroners Prevention Unit [CPU] established in 2008 to strengthen the prevention roel of the Coroner. CPU assists the Coroner to formulate prevention recommendations and comments, and monitors and evaluated their effectiveness once published. HMIT is staffed by practising Physicians and Nurses who are independent of the health professionals or institutions involved. They assist the Coroner's investigation of deaths occurring in a healthcare setting by evaluating the clinical management and care provided and identifying areas of improvement so that similar death may be avoided in the future.

[3] The literature suggests a 4% survival rate only at five years from diagnosis.

[4] A copy of the relevant HMIT report was provided to the family during the course of the inquest – see transcript pages 32-34.

8. By a Determination Following Application to Set Aside Finding [Form 44] dated 15 October 2013, I found that there were new facts and circumstances only as to one of the grounds advanced, namely whether Mr Twycross was adequately advised as to the indications for and risks of the pancreatic biopsy (EUS) procedure and whether the procedure was undertaken with his informed consent.[5]

9. The focus of the re-opened coronial investigation and inquest was therefore on the issue of informed consent.[6] The balance of this finding is based on the material the product of the coronial investigation of the issue of informed consent. That is, the brief of evidence compiled by my assistant, Leading Senior Constable Duncan McKenzie from the Police Coronial Support Unit; the statements, reports and testimony of those witnesses who testified at inquest and any documents tendered through them; and the final submissions of Counsel. All of this material, together with the inquest transcript, will remain on the coronial file.[7] In writing this finding, I do not purport to summarise all the material and evidence, but will refer to it only in such detail as is warranted by its forensic significance and in the interests of narrative clarity.

PURPOSE OF A CORONIAL INVESTIGATION

10. The purpose of a coronial investigation of a *reportable death*[8] is to ascertain, if possible, the identity of the deceased person, the cause of death and the circumstances in which death occurred.[9] The *cause* of death refers to the *medical* cause of death, incorporating where possible the *mode* or *mechanism* of death. For coronial purposes, the *circumstances* in which death occurred refers to the context or background and surrounding circumstances, but is

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[5] I noted in the determination that although a documented consent was sighted in the medical records, the adequacy of the process by which this consent was obtained was not scrutinized during the initial coronial investigation, given the absence of any concerns from the Senior Next of Kin [SNOK] or any other person with relevant knowledge of the circumstances in which the consent was obtained.

[6] Counsel for the family sought to pursue other issues during the course of the inquest, specifically the adequacy of clinical management and care provided to Mr Twycross on re-admission to WH after the procedure on 20 May 2011.

[7] From the commencement of the ***Coroners Act 2008*** (the Act), that is 1 November 2009, access to documents held by the Coroners Court of Victoria is governed by section 115 of the Act. Unless otherwise stipulated, all references to legislation that follow are to provisions of the Act.

[8] The term is exhaustively defined in section 4. Apart from a jurisdictional nexus with the State of Victoria (see section 4(1)), reportable death includes *"a death that appears to have been unexpected, unnatural of violent or to have resulted, directly or indirectly, from an accident or injury"* (see section 4(2)(a)). Note that a special status is afforded involuntary psychiatric patients, whose deaths are always reportable, irrespective of the cause of death (see section 4(2)(d)).

[9] Section 67(1).

confined to those circumstances sufficiently proximate and causally relevant to the death, and not all those circumstances which might form part of a narrative culminating in death.[10]

11. The broader purpose of any coronial investigations is to contribute to the reduction of the number of preventable deaths through the findings of the investigation and the making of recommendations by coroners, generally referred to as the *prevention* role.[11] Coroners are empowered to report to the Attorney-General in relation to a death; to comment on any matter connected with the death they have investigated, including matters of public health or safety and the administration of justice; and to make recommendations to any Minister or public statutory authority on any matter connected with the death, including public health or safety or the administration of justice.[12] These are effectively the vehicles by which the coroner's prevention role can be advanced.[13]

12. Coroners are not empowered to determine the civil or criminal liability arising from the investigation of a reportable death, and are specifically prohibited from including in a finding or comment any statement that a person is, or may be, guilty of an offence.[14]

MR TWYCROSS' CLINICAL COURSE FROM 13 APRIL 2011

13. The issue of informed consent requires some additional context, beyond the circumstances set out above. Mr Twycross had a modest past medical history for a man of his age. According to his wife, as at his 80th birthday on 9 March 2011, he was healthy fit and well, although he did suffer from back pain and gout.[15]

14. Mr Twycross' general practitioner for some 22 years was Dr Michael Giltrap provided a statement setting out his past medical history. That history included hypertension (stable at 144/71 on 6 December 2010) with normal renal function; longstanding asthma (stable with reasonable exercise tolerance and flare ups associated with infective exacerbations); glaucoma

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[10] This is the effect of the authorities – see for example *Harmsworth v The State Coroner* [1989] VR 989; *Clancy* v *West* (Unreported 17/08/1994, Supreme Court of Victoria, Harper J.)

[11] The 'prevention' role is now explicitly articulated in the Preamble and purposes of the Act, cf: the *Coroners Act 1985* where this role was generally accepted as 'implicit'.

[12] See sections 72(1), 67(3) and 72(2) regarding reports, comments and recommendations respectively.

[13] See also sections 73(1) and 72(5) which requires publication of coronial findings, comments and recommendations and responses respectively; section 72(3) and (4) which oblige the recipient of a coronial recommendation to respond within three months, specifying a statement of action which has or will be taken in relation to the recommendation.

[14] Section 69(1). However, a coroner may include a statement relating to a notification to the Director of Public Prosecutions if they believe an indictable offence may have been committed in connection with the death. See sections 69 (2) and 49(1).

[15] Exhibit A, statement of Mrs Nina Twycross dated 24 October 2013 at page 1 (page 12 of the coronial brief).

(stable with no requirement for medication); lower lip extropion (treated surgically) and skin cancers with a variety of basal and squamous cell carcinomas removed from his face and arms over the years. When last seen by Dr Giltrap on 1 March 2011, Mr Twycross presented with acute back pain with some sciatic radiation to the right side down to the level of the knee and this was managed conservatively with analgesics.[16]

15. It is apparent from other records and uncontentious that Mr Twycross also had a remote history of an appendix abscess and an open cholecystectomy (gall bladder removal) and that he was a reformed smoker and moderate drinker.[17]

16. On 13 April 2011, Mr and Mrs Twycross were in Melbourne visiting their daughter Heather over Easter, when Mr Twycross developed gastric pain and/or indigestion. Heather's daughter Bridie was a nurse at Western Hospital and suggested they take Mr Twycross there.[18] He presented to the Emergency Department the following morning complaining of upper abdominal pain of 24 hours duration, with some nausea and vomiting. Investigations were consistent with an inflammatory process with mild renal impairment and liver function tests consistent with obstructive jaundice. An ultrasound showed a suspicious lesion in the head of pancreas with associated biliary and pancreatic dilatation.[19]

17. Mr Twycross was diagnosed with acute pancreatitis thought to be related to either alcohol consumption or an obstruction and was admitted under the care of Dr Marty David Smith, a hepatobiliary, upper gastrointestinal, laparascopic and general surgeon. Dr Smith treated Mr Twycross' pancreatitis in the usual way with fluid resuscitation, analgesia, oxygen and regular medications and he made a rapid recovery.[20]

18. During the admission, Mr Twycross underwent a computed tomography [CT] scan to examine his pancreatic head, given the ultrasound findings suggestive of a lesion there. CT revealed a probable ampullary[21] carcinoma with possible liver metastases.[22] Also during the

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[16] Dr Michael Giltrap's statement dated 4 November 2013 is at pages 18-19 of the coronial brief

[17] Report from Dr Marty Smith to Dr Michael Giltrap dated 2 May 2011 at page 24 of the coronial brief.

[18] Exhibit A.

[19] Exhibit D, statement of Dr Marty David Smith dated 13 December 2013 at page 20 of the coronial brief.

[20] Exhibit D at page 21 of the coronial brief and transcript page 95 and following where Dr Smith is cross-examined about the management of Mr Twycross first episode of pancreatitis in April 2011.

[21] Pertaining to the hepatopancreatic ampulla, the dilatation formed by junction of the common bile duct and pancreatic duct just before they open together into the lumen of the duodenum. Dorland's Illustrated Medical Dictionary, 31st edition, page 68

[22] Exhibit D at page 21 of the coronial brief.

admission, Mr Twycross and the family were made aware of this finding and the possibility that he had pancreatic cancer and/or liver metastases.[23]

19. Mr Twycross' imaging and care was discussed at the Upper Gastrointestinal Multidisciplinary Meeting[24] and the recommendation from that meeting was that he should undergo a positron emission tomography [PET] scan to assess his pancreas and liver, and if that scan was negative, he was to be referred for endoscopic ultrasound plus or minus biopsy.[25] During the admission, Mr Twycross was also assessed by the hospital anaesthetist who determined that he would be fit for pancreatic surgery should this be appropriate.

20. On 21 April 2011, Mr Twycross was discharged from hospital having made a full recovery from his pancreatitis. In accordance with the treatment plan, he was referred to the Alfred Hospital for the PET scan the following week and then for follow-up with Dr Marty Smith in his private rooms with an appointment scheduled for 2 May 2011.[26]

PET SCAN @ 28 APRIL 2011

21. An appointment was made for Mr Twycross to attend the Alfred Hospital on 28 April 2011 for a PET scan and the relevant report emailed to Dr Marty Smith on or about that day. The conclusions of the radiologist were to the effect that there was no abnormal FDG uptake seen in the region of the head of pancreas/ampulla to suggest a primary malignancy or metastatic disease, particularly in segment seven of the liver. However, the radiologist's report ended on a cautionary note – *It should be noted however, predominantly mucinous primary pancreatic malignancies are often poorly FDG-avid and a false negative result is possible.*[27]

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[23] Exhibit C, Western Health hospital notes relating to patient #959877 John Twycross and Mrs Twycross' evidence at transcript pages 36 and following.

[24] Exhibit F, is the Western Health Oncology Multidisciplinary Meeting/treatment plan in relation to patient #959877 John Twycross, signed and dated 21 April 2011 that records this.

[25] I note that Dr Smith was Deputy Chair of the Oncology Multidisciplinary Meeting – see transcript pages 71-72 where he explains that some 25 people would attend and sets out their respective disciplines. The decision whether or not to take a biopsy or biopsies during the procedure is left to the proceduralist – see Dr Smith's evidence about the rationale for this at transcript page 99.

[26] Exhibit D at page 21 of the coronial brief and Exhibit E, Western Health Discharge Summary in relation to patient # 959877 John Twycross signed and dated 21 April 2011. Also referral letter dated 21 April 2011 from Dr Therese Nigro, Upper GI and Genral Surgery Intern, Western Hospital, to Dr Marty Smith.

[27] Exhibit G, the Alfred Hospital PET Body Report in relation to patient #604216 John Twycross dated 28 April 2011.

CONSULTATION WITH DR MARTY SMITH @ 2 MAY 2011

22. Mr Twycross attended Dr Smith's rooms at Cabrini Hospital in the afternoon of 2 May 2011 as arranged. He was accompanied by Mrs Twycross and other family members.[28] Including Dr Smith, there was a total of seven people in the room. Mrs Twycross' evidence was that Dr Smith was primarily addressing her husband and she did not hear every word spoken but as soon as they were told the PET scan results they were all elated.

23. Mrs Twycross was adamant that this was her husband's understanding as well as hers and that if cancer was still a possibility, he would have been more sombre.[29] Furthermore, if they had been warned that the biopsy could cause necrotising pancreatitis and/or death, Mr Twycross would have delayed the biopsy or may have elected not to have it at all as he felt extremely well at the time and was keen to go to Queensland to visit their son as planned.[30]

24. Although Dr Smith said that Mr Twycross was 'not out of the woods yet' their general understanding was that Mr Twycross did not have cancer and that the recommendation of an endoscopic ultrasound biopsy was not to exclude cancer but to determine the nature of the lesion. Mrs Twycross recalled Dr Smith saying that the procedure was a delicate one and may require an overnight stay in hospital. She did not recall any mention of the risks associated with the procedure.[31]

25. Dr Smith's evidence was significantly different. According to this statement, Mr Twycross was referred to Dr Peter Tagkalidis for an endoscopic ultrasound to exclude the possibility of an ampullary malignancy.[32]

26. Consistent with this was his report to Dr Giltrap dated 2 May 2011 in which he stated that he referred to the fact that the PET scan at the Alfred showed no evidence of FDG uptake in either his pancreas or his liver, and advised that he had a long discussion with Mr Twycross and his family regarding the likelihood of pancreatic cancer, *"which is perhaps reduced by the negative PET scan however not excluded...the way forward...to elucidate whether he truly*

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[28] According to Mrs Twycross, her son Phillip, daughter Heather and her husband Brian and Mr Twycross' brother James all attended the consultation. Exhibit A at page 13 of the coronial brief and transcript at pages 12, 43 and following.

[29] Strictly speaking Mrs Twycross was conveying her understanding of what Dr Smith said but it was implicit that this was also the understanding of other family members. Exhibit A at page 13 of the coronial brief and transcript page 13 and following and page 43 and following.

[30] Exhibit A at page 13 of the coronial brief.

[31] Ibid.

[32] Exhibit D at page 21 of the coronial brief.

has a pancreatic lesion or not, is to undergo an EUS...should this show a malignancy we are more than likely to offer him an exploratory operation, with intraoperative ultrasound of the liver, to characterise his lesion further and only proceed to resection of his pancreas should we be utterly convinced that his liver is normal. John understands the issues involved and is happy with this plan."[33]

27. Similarly, in his referral letter to Dr Peter Tagkalidis, also written on 2 May 2011, Dr Smith asked for an admission for Mr Twycross for an EUS and FNA [fine needle aspiration] of a potential ampullary lesion, stating that he and the Twycross family were keen to see the possibility of an ampullary lesion completely excluded and, if alternatively confirmed, such that he can be considered for resection surgery.[34]

28. At inquest, Dr Smith expanded on the evidence in his statement. He explained that the PET scan report clearly reflected the images that he had also seen and did not show any uptake of the tracer agent in either the head of the pancreas or ampulla or the liver. Therefore the risk of pancreatic cancer was reduced but not excluded. He noted that false negative results were possible, as sensitivity for a PET scan in detecting pancreatic cancer is only about 80-90%, and that false positive results are also possible but less common.[35]

29. Dr Smith testified that at the 2 May 2011 consultation he provided general information about the risks and complications of the procedure; that it was an invasive procedure and that all invasive procedures carry some element of risk, specifically a risk of perforation and pancreatitis. While he believed that the risks were less than 5% in each case, he probably didn't elaborate on that at the consultation.[36] Dr Smith's evidence was that he did not specifically mention the risk of death to Mr Twycross.[37] He explicitly denied saying anything to the effect that the PET scan was clear or that Mr Twycross was not suffering cancer.[38]

30. Apart from the general risk of pancreatitis associated with the EUS +/- FNA, Dr Smith did not think that Mr Twycross' age or comorbidities posed any additional specific risks. While he

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[33] Exhibit D (annexure) at page 24 of the coronial brief.

[34] Exhibit D at page 25 of the coronial brief. The referral letter was actually dated 2 April 2011 and it was clarified at inquest and uncontentious that it was likely typed on 2 May 2011 and that the date was a simple typographical error. Transcript page 82, 84.

[35] Transcript ages 73-74.

[36] Transcript page79.

[37] Transcript page 101.

[38] Transcript page 104.

thought the fact of a prior episode of pancreatitis probably increased his risk slightly, he did not know the applicable multiplier, did not think anyone could calculate the difference and, in any event, expected the risk have diminished almost back to a baseline by the time of the EUS some four weeks after the first episode of pancreatitis.[39]

31. At the 2 May 2011 consultation, Dr Smith did not recall either Mr Twycross or his family asking any questions about the risks or about Dr Tagkalidis who was to perform the procedure. Nor did he recall Mr Twycross being concerned about having another procedure.[40] When he reported to Dr Giltrap that Mr Twycross understood the issues and was happy with the plan, Dr Smith was referring to the need for biopsy of the lesion in the pancreas as there were ongoing concerns that it was cancer and that any consideration of surgery would be conditional on residual concerns about a liver lesion being negated.[41]

32. Dr Smith testified that his preference is to see complex cancer patients in his rooms rather than in a public hospital setting because it affords a quieter more controlled environment where he can spend longer with the patient. His regular practice is to speak to the patient initially, broadening the discussion to include significant others that may accompany the patient, trying to ensure that no one is left out. Beyond that, he could not recall the specifics of the communication with Mr Twycross and his family. Dr Smith's evidence was that he does not insist on patients undergoing surgery or even investigations, rather he speaks in terms of offering options, discussing risks and saying what he believes is in the patient's best interest.[42]

ENDOSCOPIC ULTRASOUND AND FINE NEEDLE ASPIRATION BIOPSY @ 20 MAY 2011

33. Mrs Twycross' evidence was she and her son Phillip and daughter Heather accompanied Mr Twycross to Western Hospital on 20 May 2011 for the EUS procedure. They knew to ask for Dr Tagkalidis and waited with Mr Twycross in the waiting room until he was called. They then left to do some shopping to pass the time, expecting to be contacted when he was ready

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[39] Transcript page 96-97.

[40] Transcript page 80.

[41] Transcript page 83.

[42] Transcript page 107, including the following *"The framing of words around that are that we say that we believe – or we have reasonable concerns that John had a pancreas cancer and we wanted to investigate, so as to potentially offer him a curative option because without an attempted cure his life span would've been in the vicinity of six months. So the benefit to this procedure is that we can make that diagnosis and potentially offer treatment."*

to be picked up. They knew to ask for Dr Tagkalidis at the reception desk but did not speak to him and were not present when he spoke to Mr Twycross shortly before the procedure for the purpose of obtaining his consent.[43]

34. Dr Tagkalidis is a Senior Gastroenterologist employed by Western Health with a specialisation and particular expertise in EUS, performing some 500 EUS procedures each year which he testified was more than any other practitioner in Melbourne.[44] He provided a statement and gave evidence at inquest.

35. In his statement, Dr Tagkalidis said that in 'accordance with his standard practice, prior to the EUS procedure, he undertook a careful informed consent process to inform Mr Twycross about the procedure, its benefits and risks, its side effects, complications and alternative treatments, including informing him of the 1% risk of major complications where a biopsy is undertaken. This included the risk of perforation, bleeding and pancreatitis. He had no reason to doubt that Mr Twycross had the capacity to understand the information he provided.[45]

36. Dr Tagkalidis also stated that he completed a consent form prior to undertaking the procedure in accordance with Western Health policy but acknowledged that he did not do so "completely" at all. According to his statement, Dr Tagkalidis indicated that he did not complete the section under "risks and complications" on the consent form and acknowledged that this was an oversight and not in accordance with his standard practice.[46]

37. On any view the pro forma consent form has scant detail of the information conveyed to Mr Twycross and was virtually illegible. With some knowledge of the case and a fertile imagination, it is possible to make out Mr Twycross' name and signature,[47] the date, and the fact that he was consenting to a procedure to be performed on himself. Dr Tagkalidis' name is impossible to make out but may have been legible to anyone familiar with his signature or

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[43] Exhibit A and transcript pages 18 and 20-21.

[44] Exhibit I, statement of Dr Peter Panagiotis Tagkalidis dated 20 December 2013 at page 28 of the coronial brief. Dr Tagkalidis evidence was that he has been performing EUS procedures since 2003 and does so at several hospitals across Melbourne, including Western Hospital, the Alfred Hospital and Epworth Hospital. He established the EUS services at Royal Melbourne Hospital and the Alfred where he is the sole EUS practitioner performing all the EUS studies at these two institutions. See also transcript at pages 111, 117.

[45] It is tolerably clear that the double negative in the statement is unintentional. Exhibit I at page 29 of the coronial brief. See also transcript page 116 in this regard.

[46] Exhibit I at page 29 of the coronial brief.

[47] It was not suggested that Mr Twycross did not sign the consent but that he was not properly informed. Indeed, Mrs Twycross identified his "shakey" signature on the consent form. Transcript pages 27-28.

handwriting. On its face the consent form documents that Dr Tagkalidis has explained the nature and effect of the procedure and that he is of the opinion that Mr Twycross understood the explanation. There is no documented detail of the risks and complications discussed. [48]

38. At inquest, Dr Tagkalidis properly acknowledged these inadequacies and testified that he had improved his practice as regards the documentation of a patient's consent prior to performing EUS procedures.[49] Indeed he explained that he tended to preference the discussion with the patient in which information about the procedure and risks and complications and so on is conveyed leading to the patient's consent, above documentation of the consent.[50]

39. While Dr Tagkalidis would make himself available to see a patient before EUS procedures if they wished, the great majority of patients did not avail themselves of this opportunity, so that they would see him for the first time on the day of the procedure and he would generally obtain consent shortly before the procedure proper. In terms of location, this would occur either in the admissions area, or more commonly, in the endoscopy room which is generally quieter and more private than the admissions area and would generally take three to six minutes.[51]

40. As to the content of his discussion with patients in this setting, Dr Tagkalidis did not recall the specifics of his discussion with Mr Twycross, but maintained that he would always start by taking a brief history from the patient and asking open questions to elicit what they know about the procedure and the need for it, starting from the premise that they know nothing, and then moving on to explain the procedure and the risks. He would then explain that the procedure carried a 1% risk of causing harm[52] and that a previous episode of pancreatitis meant that a slightly higher but unquantifiable risk of pancreatitis from the procedure.[53] Other

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[48] Exhibit B, Western Health Consent Form in relation to patient #959877 John Twycross dated 20 May 2011 at page 49 of the coronial brief.

[49] Transcript pages 119 – *"...essentially I didn't fill it in. My - my issue regarding – my views of consent are that I need to speak to the patient and tell them and the paperwork comes secondary. Now in retrospect that maybe was a mistake but the lack of filling in of that piece with the information does not – I've documented badly, I accept that, but there's no other - there's no other reason to explain why that wasn't done."* See also transcript page 140.

[50] Transcript pages XX 130

[51] Transcript pages 113-114, 120 and 131.

[52] Transcript page 124. The

[53] Transcript pages 115-116.

complications mentioned would be bleeding from the bowel and perforation.[54] Dr Tagkalidis would not discuss the risk of death as he asserted that at one fatality in 4000 over ten years (and none previously in his practice) it was not a risk worth mentioning.[55]

41. It was apparent that Dr Tagkalidis' evidence in this regard was informed to some extent by his usual practice. While he testified that he could not quote his discussion with Mr Twycross verbatim, he became aware about five days after the EUS procedure that Mr Twycross had been admitted and had a dire prognosis, and this crystallised matters in his memory.[56] As it was only one week earlier he could remember Mr Twycross quite well and recalled that he had indeed obtain the consent in the endoscopy room and how it was done. He mentioned a 1% complication rate and the three potential complications of pancreatitis, bleeding and perforation of the bowel. He did not recall Mr Twycross asking any specific questions, felt that he accepted what was said and appeared to understand.[57]

42. Prior to learning of Mr Twycross' readmission, the EUS procedure performed on 20 May 2011 was otherwise routine from Dr Tagkalidis' perspective. As it was, Mr Twycross' case stood out in his memory as he was the only fatality in some 4000 EUS procedures that he had performed over the last ten years, and not something he was likely to forget.[58]

43. Sometime before 2011, Dr Tagkalidis had developed an information sheet which was not then but is now routinely provided by his secretary to patients about to undergo EUS procedures.[59] It was apparent that he saw such fact sheets as useful but no substitute for having a discussion with the patient, particularly in terms of advice to re-present if something goes wrong.[60]

INDEPENDENT EXPERT EVIDENCE and the LAW OF CONSENT

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[54] Transcript page 117-118. It was not contentious but worth noting that Dr Tagkalidis did not discuss any alternative treatment options with Mr Twycross as the EUS +/- FNA was the definitive investigative modality in his circumstances. See transcript pages 118 and 120

[55] Transcript page 138.

[56] Transcript pages 116-117.

[57] Transcript pages 117-118.

[58] Transcript pages 115-116, 127-128. *"Marty called me about five or six days after the procedure ... he explained the dire situation; that he was in ICU and I think he'd just operated on him actually; ... explained that things were looking rather grim."* Also transcript page 124, 129.

[59] Transcript pages 131-132. That fact sheet does not mention the risk of death following an EUS procedure/biopsy – see transcript page 138

[60] Transcript pages 136

44. Dr Paul Niselle was asked to provide an independent expert assessment of the process by which Mr Twycross' "consented" to the EUS procedure, advise on the current state of the law regarding "informed consent" and to advise about best practice in this regard. His assessment was necessarily based on and therefore limited to the documents available at the time.[61] For all the reasons referred to above, he too was critical of the consent document.[62]

45. Dr Niselle contextualised his assessment by providing a summary of the law of consent as it applies to medical treatment and/or procedures. He noted the legal distinction between simple, legal or valid consent (legal consent) sufficient to defend against an accusation of battery and the informed consent required in respect of medical treatment and procedures since the High Court decision in *Rogers v Whitaker.*[63]

46. Legal consent is made out when a patient is advised about the nature and purpose of the treatment, ensuring they have the capacity to understand that information and that they give consent of their own free will.[64] As well as the nature and purpose of the treatment, informed consent requires a patient to be advised of material risks, being risks that are relevant to all patients, risks that are known by the medical practitioner to be relevant to the particular patient and any additional information that the patient requests. Again, the patient needs to have capacity to understand and to give consent freely.[65]

47. At inquest, Dr Niselle had the benefit of hearing the evidence of both Dr Smith and Dr Tagkalidis, before giving evidence himself. He testified that consent should be viewed as a process and noted that Mr Twycross had been given information about the possibility of pancreatic cancer and planned investigations during his admission in April 2011, during the

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[61] Exhibit M, expert opinion of Dr Paul Niselle at pages 31-40 of the coronial brief includes his formal qualifications, affiliations and experience –MBBS (University of Melbourne); Master of Health and Medical La (University of Melbourne); Fellow of the Royal Australian College of General Practitioners; general practice 1971-1989; worked for medical mutual defence funds in Australia 1989-2009; worked in London for the largest medical mutual indemnity fund in member medicolegal and clinical risk management education between 2009-2013 and has written, presented and facilitated many workshops on medicolegal and clinical risk management (including on the topic of "consent"). Since returning to Australia in 2013, Dr Niselle works part-time in general practice and as a medicolegal and clinical risk management consultant.

[62] Exhibit M at pages 32-34 of the coronial brief. See also paragraph 37 above.

[63] [1992] 175 C.L.R. 479, at 490 – *"The law should recognise that a doctor has a duty to war a patient of a material risk inherent in the proposed treatment; a risk is material if, in the circumstances of the particular case, a reasonable person in the patient's position, if warned of the risk, would be likely to attach significance to it"* The High Court thus imposed both an objective test (a reasonable person in the patient's position) and a subjective test (the particular patient).

[64] Transcript page 146.

[65] Transcript pages 148 and following.

consultation with Dr Smith on 2 May 2011 and by Dr Tagkalidis shortly before the EUS procedure. He recognised that there was a place for provision of "fact sheets" with information about procedures so that patients could digest the information in their own good time and have an opportunity to ask questions of their doctor/s or make their own enquiries. However, he saw such fact sheets very much as adjuncts, as part of the process, ideally an interactive process, but not a substitute for a face to face discussion wherein the patient's understanding can be gauged and the patient is afforded the opportunity to ask questions.[66]

48. Dr Niselle commented on the realities of the public health system and the increasing reliance on "open access" clinics such as the endoscopy unit in which the EUS procedure was performed. In such settings, Dr Niselle saw Dr Smith as the referring doctor sharing the burden of informing the patient with Dr Tagkalidis, a fact acknowledged by Dr Smith at inquest. In part, this was to ameliorate the disadvantage to the patient of receiving information at the eleventh hour and potentially feeling constrained to proceed. Dr Niselle testified that the information provided by Dr Smith, according to his own account, corroborated to some extent by his report to GP Dr Giltrap and the referral letter to Dr Tagkalidis, was adequate by reference to current standards of practice given his role as referring specialist.[67]

49. Simiarly, Dr Niselle testified that Dr Tagkalidis account of his conversation with Mr Twycross before signature of the consent form adequately addressed the need for and nature of the procedure and the material risks and complications of the procedure such that it could support a finding of informed consent.[68]

50. Mrs Twycross' surmise that her husband would not have undergone the EUS procedure or at least not before their planned holiday to Queensland, if he had been warned about the risk of death and/or necrotising pancreatitis was addressed at inquest to the extent possible, given that Mr Twycross' views were not otherwise ascertainable.

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[66] Transcript pages 159 and following.

[67] Transcript pages 155-156, 162-163. See also the annexures to Exhibit D.

[68] Transcript pages 163 and following.

CONCLUSIONS

51. The standard of proof for coronial findings is the civil standard of proof on the balance of probabilities with the *Briginshaw* gloss or explication.[69] The effect of the authorities is that coroners should not make adverse findings against or comments about individuals (or institutions) in their professional capacity the evidence affords a comfortable level of satisfaction that they departed materially from the standards of their profession and in so doing, caused or contributed to the death under investigation.

52. It is axiomatic that the assessment of clinical management and care must be undertaken strictly without the benefit of hindsight. This includes whether or not a patient was adequately advised about the nature and need for a procedure and the risks associated with it so as to be in a position to provide informed consent and indeed gave such consent.

53. Having applied the applicable standard to the available evidence, I find as follows:

    a. The Upper Gastrointestinal Multisiciplinary Meeting's recommendations, the negative PET scan, Dr Smith's decision to refer Mr Twycross for EUS procedure +/- FNA biopsy and Dr Tagkalidis decision to undertake the procedure and indeed to take biopsies, were all made in the context of a suspected diagnosis of pancreatic cancer and the possibility of curative surgery for an otherwise high mortality illness, if detected early.

    b. In combination, information provided to Mr Twycross by Western Health during the April admission, by Dr Smith in the consultation of 2 May 2011 and by Dr Tagkalidis shortly before the EUS procedure on 20 May 2011 supports a finding that Mr Twycross was in a position to provide informed consent to the procedure.

    c. Mr Twycross understood the information provided about the EUS procedure and gave informed consent on 20 May 2011.

    d. While Dr Tagkalidis did not specifically warn Mr Twycross about a risk of death from the procedure, this was a reasonable decision on his part given that the risk was so low and the need to exclude pancreatic cancer so exigent.

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[69] *Briginshaw v Briginshaw (1938) 60 C.L.R. 336 especially at 362-363.* "The seriousness of an allegation made, the inherent unlikelihood of an occurrence of a given description, or the gravity of the consequences flowing from a particular finding, are consideration which must affect the answer to the question whether the issues had been provided to the reasonable satisfaction of the tribunal. In such matters "reasonable satisfaction" should not be produced by inexact proofs, indefinite testimony, or indirect inferences..."

e. It is regrettable and unfortunate, but ultimately irrelevant, that the biopsies taken by Dr Tagkalidis support a finding that Mr Twycross was unlikely to be suffering from pancreatic cancer and that he died from the cascading complications of the EUS procedure and FNA biopsies taken.

f. Documentation of the consent process in the medical records is fundamental, and the manner in which Dr Tagkalidis documented the consent process in Mr Twycross' case was incomplete and not to an acceptable standard.

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

The Twycross family c/o Harris Lieberman

Western Health c/o K & L Gates

Dr Paul Nisselle

Signature:

PARESA ANTONIADIS SPANOS

Coroner

Date: 10 March 2017

Cc: Leading Senior Constable Duncan McKenzie, P.C.S.U.

Manager, Coroners Prevention Unit/Health and Medical Investigation Team