

PLACE INQUEST HELD: Townsville

Inquest opened: 1<sup>st</sup> June 2005.

Findings delivered: 12<sup>th</sup> December 2007

This is the inquest into the death of

*Frank Maurice Whittington*

1. I must deliver my findings pursuant to the provisions of the *Coroners Act 2003*. I do so, reserving the right to revise these reasons should the need or the necessity arise.
2. The purpose of this inquest is to find, if possible—
  - Who the deceased person is;
  - How the person died;
  - when the person died; and
  - where the person died; and
  - what caused the person to die.
3. It should be kept firmly in mind that an inquest is a fact finding exercise and not a method of apportioning guilt. The procedure and rules of evidence suitable for a criminal trial are not suitable for an inquest.
4. In an inquest there are no parties; there is no charge; there is no prosecution; there is no defence; there is no trial. An inquest is simply an attempt to establish facts. It is an inquisitorial process, a process of investigation: These observations were confirmed by Justice Toohey in *Annetts v McCann (1990) 65 ALJR 167 at 175*.
5. A Coroner's Inquest is an investigation. Nevertheless, the rules of natural justice and procedural fairness are applicable. Application of these rules will depend on the particular circumstances of the case in question.
6. I may not include in the findings any statement that a person is, or may be—
  - (a) guilty of an offence; or
  - (b) civilly liable for something.
7. I may if appropriate, comment on anything connected with a death investigated at an inquest that relates to—
  - (a) public health or safety; or
  - (b) the administration of justice; or
  - (c) ways to prevent deaths from happening in similar circumstances in the futurebut I may not include in the comments any statement that a person is, or may be—
  - (a) guilty of an offence; or
  - (b) civilly liable for something.

8. If, from information obtained while investigating a death, I reasonably suspect a person has committed an offence, I must give the information to
- (a) for an indictable offence- the director of public prosecutions; or
  - (b) for any other offence- the chief executive of the department in which the legislation creating the offence is administered.

I may give information about official misconduct under the Crime and Misconduct Act 2001 to the Crime and Misconduct Commission.

I may give information about a person's conduct in a profession or trade, obtained while investigating a death, to a disciplinary body for the person's profession or trade if I reasonably believe the information might cause the body to inquire into, or take steps in relation to, the conduct.

9. All proceedings before this Court are sad proceedings. At this stage I express my sympathy and condolences, and that of the Court, to the family of the deceased in their sad loss, in the tragic death of

Frank Maurice Whittington

His widow, Beryl Whittington has taken a very active role in informing herself of the circumstances surrounding his death. Her research prior to the inquest, I wish to acknowledge, has greatly assisted me as coroner in preparing for the inquest. She appeared by her counsel Harvey Walters in the later stages of the inquest. Queensland Health, three of the nurses involved in the care of the deceased post surgery, and Dr Rosato, the surgeon, were all given leave to be legally represented in the proceedings. As Coroner I was assisted by Mr Tony Collins of Counsel.

The issue for the coroner in this inquest is in short compass, namely whether an overdose of morphine administered to the deceased caused or contributed to his death.

10. Going to the incident giving rise to these proceedings:

Frank Maurice Whittington, the deceased, suffered from chronic pain, having sustained back and neck injuries in a motor vehicle accident in Cairns on 3<sup>rd</sup> September 1991. On 11<sup>th</sup> September 2002, at the Townsville Hospital, a Medtronic SynchronMed EL Implantable pump 8627L-18 Serial Number NGH020137R was implanted under the abdominal skin. This device delivers a measured dose of morphine sulphate through a catheter located under the skin directly into the Cerebro Spinal Fluid (CSF) to provide analgesia. This is called intrathecal delivery. Approximately one hundredth of the dose that is required to give the same relief via oral delivery is sufficient by this method. Such a device is only resorted to after all other methods of pain relief have been exhausted.

The pump has a metal casing, and is the shape of a disc, approximately 2.5cm thick, and 6 cm across. It has a port on one side of the disc, used to refill the pump reservoir on a regular basis, by inserting a needle through the skin into the port. It has another port (a male fitting) at the perimeter on one side, to which a fine silicon catheter is attached. The catheter is then inserted at its other end, at L3/4 during a lumbar puncture procedure, so that the fluid is delivered into the cerebro-spinal fluid (CSF).

The pump is a sealed unit and is programmed using telemetry via a laptop style computer, to deliver a measured dose on a continual basis. The patient must return regularly to the clinic to have the pump re-filled and re-programmed.

The deceased sustained a fall at home when a chair collapsed under him in early February 2004. Following this, he complained of increased pain. He returned to the Pain Management Clinic on 6th February 2004 for investigation, and the pump was checked telemetrically by Dr Vic Callanan, Director of Anaesthetics. He assessed the pump by carrying out a “pumpogram”, and was satisfied that the pump was working, but that the fault in non-delivery of the therapeutic dose to the patient appeared to lie in the catheter, which he thought might have a “kink” in it. The disconnection of the catheter from the pump was confirmed on 16<sup>th</sup> February by X-ray. Dr Callanan arranged for the deceased to undergo surgical replacement of the catheter on 24<sup>th</sup> February by Dr Rossato. This is a not uncommon procedure in the life of a pump.

The normal dose for an adult given for post-operative pain intramuscularly would be 10 mg. While the pump was not operative the deceased received daily intra-muscular injections of 20mg (i.e. twice the normal dose) from his local medical practitioner in Ingham. He was a retired ambulance officer and was given supplies to self-inject when the surgery was closed.

On 24 February 2004 Dr Reno Rossato, Clinical Director, Institute of Surgery, Townsville Hospital, Senior Staff Specialist Neurosurgeon carried out the surgical procedure. This involved opening of the abdominal wound, and removal of the pump. The lumbar wound was also opened, and the catheter displayed. The catheter was partially detached from the pump and no spinal fluid could be aspirated from the catheter. He also found that the other end of the catheter had fractured (broken in two pieces) (21<sup>st</sup> July p.9 l.2) in the fibrous tissue leading into the spinal canal. Accordingly he removed the faulty catheter, performed a new lumbar puncture and inserted a brand new intrathecal catheter. (21<sup>st</sup> July p.4 l.5) The system was reconnected and the pump replaced into position.

Following surgery, in the Recovery Unit, Dr Rossato and RN Marli Couper were responsible for refilling and re-programming the pump, Dr Rossato mainly for the calculation of the amount of the drug, and the issue of the order for the correct amount of morphine sulphate. The post operative priming bolus dose to be injected into the reservoir port was calculated by reference to a “cheat sheet” (Postoperative Priming Bolus Calculation Worksheet) (exhibit RGR3 to the statement of Dr Reno Rossato dated 29.6.2006) supplied by Medtronic, the manufacturer of the pump. RN Couper used the sheet and this was double-checked by Dr Rossato, who did the calculation separately on a piece of paper which was kept on the hospital file, Exhibit 18. He then issued the order for the amount required to fill the pump reservoir, internal tubing and catheter. The pump was re-filled, re-programmed to deliver the bolus dose and the usual daily dose.

An amount exceeding the dose necessary to prime the catheter and fill the reservoir by .26ml was ordered by Dr Rosato. He readily admitted, as did RN Couper, that this was an error. Clearly however, he and RN Couper were both led into error by the cheat sheet. Given that the pump is a sealed unit, and its interior is not able to be inspected, it is to be expected that those managing it will rely on the manufacturer’s

instructions, as was the case here. There is no warning on the sheet that it is applicable to programming and priming of new pumps only, or that allowance should be made for the presence of the fluid in pumps already in use.

The cheat sheet is the only sheet issued by Medtronic. Inside the pump is a length of tubing between the reservoir and the catheter port, which has a capacity of .26ml. If the pump has been previously used, as in the present case, the tube holds fluid, even when the reservoir is emptied. The cheat sheet provides a guide for calculation of what is known as the “bolus dose”, the dose necessary to fill the length of catheter from the catheter port to the site of delivery to the CSF, only in the case of a pump not previously used, i.e. assuming no fluid in the .26ml length of tubing. It makes no allowance for calculation where the tube is full.

By letter dated 31 August 2004, Gerry Bloe, Medtronic Representative in Australia promised to provide a “cheat sheet” adapted for use for change of catheter procedure as soon as possible to Dr Rossato, however Exhibit 24, a letter from Deacons Lawyers for Medtronic received by the Coroner after the conclusion of submissions states that Medtronic has not taken any steps apart from the issue of a Safety Alert, the relevant one of which forms part of Exhibit 24. That Safety Alert, “Patient Mortality after Implant and Initiation of Intrathecal Infusion Therapy for Pain” dated November 2006 notes that 9 patient deaths in the USA were reported to Medtronic between December 2005 and March 2006, within 3 days after the initiation or re-initiation following interrupted use of intrathecal opioid therapy for pain. Those deaths were accepted by Medtronic as being most likely caused by opioid and/or sedative overdose and that device malfunction was not the cause. In two cases the internal pump tubing and intrathecal catheter volumes were not accounted for correctly, which increased the intended dose of the intrathecal drug. Under the heading Device Programming the programmer is warned “be sure to account for the entire drug volume in the system-including the inner pump tubing and the intrathecal catheter. Overestimating the system drug volume to be primed can cause over infusion. For programming assistance, please contact Gerry Bloe on 0419 695 794.”

An extract from the Manual issued by Medtronic, Section 5 “Pump Implant: Critical Tasks and Procedures” was provided to the Coroner after the conclusion of submissions and has been marked by me as Exhibit 25. It includes the procedure to “Determine Postoperative Priming Bolus” at 5-14 and does not refer to the danger of overdose in circumstances where the pump has been previously primed, and the internal tubing with a volume of .26ml is already filled. The “cheat sheet” referred to in the evidence of Couper and Rossato is included in the References and Resources section of Section 5 of the Manual and offered as a “worksheet to guide you in determining the postoperative priming bolus”.

The deceased received an overdose of .26 mls in a short period of time.

Mrs Whittington gave evidence that having seemed normal when she collected him from the ward, her husband was staggering in the corridor after going down in the lift, and had to sit down. She described him as “a bit wonky” on his way out to the car, getting in the back seat instead of the front, then in car on way home trying to put CD’s in wrong hole and unwrapping all the lollies in the car. He kept playing a song that he hated. This was out of character. He was walking into things. He hopped into

the back of the car trying to look for a rag that wasn't there. She couldn't hold a sensible conversation with him. He wasn't sleepy, but instead, hyped up. He was unsteady on his feet, like he was drunk. At home he got undressed and got dressed again. He was walking around the house naked. He was usually a person where everything has its place and very pedantic. He was agitated and obviously something was not right. She didn't give him his tablets he usually has after 8.30 pm. She denied that he had had a large meal. He went to bed at 7pm and she checked on him at 8.30pm and again at 10.00pm when he was cold and she realised he was deceased.

His unusual behaviour has been unable to be explained, although it was postulated by Mr Walters for Mrs Whittington, that it might be the result of a "mini stroke". Dr Rossato agreed that it was not inconsistent with such an event, although he said that a mini-stroke is an event that cannot be proved, but the behaviour might equally have other causes. Mrs Whittington justifiably expressed her suspicion that the morphine overdose may have caused his behaviour and subsequent death, an event completely unexpected, given that apart from his increased pain, he was apparently well on admission for day surgery.

She was concerned that he had been discharged from hospital too quickly, and having got the hospital records under FOI, she observed a discrepancy between the times recorded in relation to the programming and re-start of the pump, and the conclusion of the operation and his removal to the recovery room, and eventual discharge. During the inquest she indicated that this was no longer a concern to her and indeed Dr Callanan gave evidence that the computer clock did not show the same time as the hospital clock. I am not satisfied there is anything suspicious in the time discrepancy. She accepted that the deceased was eager to go home.

She was concerned that the pump when sent to the USA by Dr Callanan for testing only contained 1ml of morphine, having been re-loaded only 2 days before the autopsy, from which I infer that she concluded that the missing morphine must have gone into the deceased's body. Dr Callanan gave evidence that he removed the morphine before sending it away, having satisfied himself that it was functioning. I am satisfied with that explanation in the light of the whole of the evidence. She was concerned that Professor Williams did not document all the tattoos on the deceased in his report, and some other aspects of his body. I am not satisfied that there is anything sinister in this, which was answered by Professor Williams. He has also explained why he did not take a sample of the CSF. I am satisfied that Dr Callanan's interrogations of the pump both on 6<sup>th</sup> February and post mortem were appropriate and I accept his evidence that it was functioning within acceptable parameters. Mrs Whittington seems to accept that rather than overdelivering, the evidence was that at any time of malfunction, the pump was underdelivering, however her point is that if it underdelivered, then it might just as easily malfunction and overdeliver. I accept the evidence of Dr Rossato and Dr Callanan that the malfunction identified on 6<sup>th</sup> February was caused by the damaged and dislodged catheter and not the pump malfunctioning.

Mrs Whittington alleged that the failure to mention in the death certificate that the deceased had had surgery in the preceding 4 weeks contravened statutory obligations. I am not satisfied there is any such obligation.

The autopsy report (Exhibit 6) prepared by Professor David Williams shows an enlarged heart and significant atheroma in the coronary arteries. The lungs demonstrate bilateral pulmonary oedema and congestion. There is no convincing evidence of bronchopneumonia. In his oral evidence, Professor Williams explained that the heart was very heavy at 592gm, the normal weight for a man of his height being about 350gm. The diseased and narrowed coronary arteries create a problem supplying oxygen to the heart. The liver was 2.7 kg in weight, the normal weight being about 1.5kgs, and the spleen was also twice as large as it should be. These are “part of the picture of cardiac failure” (7.11.2005 p.28 l.30). A small amount of haemorrhage is seen in the atheromatous plaque. This is an entirely natural cause of death. The Haemorrhage causes a sudden heart attack.

The deceased was moderately obese, weighing 119 kg. Professor Williams commented that having examined over 5,000 heart attack deaths, this was the largest amount of food he had ever seen in the stomach (.7kg) “a huge meal” (7.11.2005 p.28 l.43). Prof Williams attributes the heart attack to the huge meal as opposed to the morphine overdose. For morphine toxicity he would expect evidence of severe pulmonary oedema without evidence of heart failure.

The blood was taken for toxicological analysis from the femoral vein rather than taking CSF, as it is difficult to get reliable figures for fatal levels in CSF as it is not used as a toxicological medium. (7.11.2005 p.30 l.44). The cause of death in his view was clearly heart attack as a result of chronic heart failure. He was unable to throw useful light on the unusual behaviour post discharge.

The amended post mortem toxicology report (Exhibit 9) shows:

Alcohol: Nil

Morphine: 0.16mg/kg

Total Morphine (morphine plus Morphine Glucuronides): 0.19mg/kg

Promethazine: 0.04mg/kg

Sertraline: 0.2mg/kg

Norsertaline: 0.2mg/kg

No other drugs detected

Prior to the post-mortem examination, using radio telemetry Dr Callanan turned the pump off, and retrieved the pump, checked to see if the telemetry was working ,and then took the pump to test within the limits that he could, the accuracy of its delivery. (20<sup>th</sup> July 2006 p. 60 l. 28) He found that “it was within the accuracy one would expect” (p.56, l.37). He explained that the correct dose of morphine received by the deceased was 5 mg per day. The fluid in the pump contains 30 mg morphine in every millilitre. Thus the daily dose was one sixth of a millilitre. i.e. only few drops.

He then emptied the residual morphine from the reservoir, and sent the pump to the manufacturer in the USA for investigation. Exhibit 17 is the report, concluding: “the pump passed all functional flow test. Destructive analysis of the gear assembly revealed bridging residue between gears. Bridging residue may cause an intermittent motor stall and drug delivery”.

It is relevant to bear in mind that the problem complained of by the deceased had been under delivery of the therapeutic dose in the month before the replacement of the

catheter, rather than an excessive dose. Dr Callanan's opinion was that the greater likelihood was of under-delivery rather than over-delivery.

As to the effect of an overdose of morphine, he gave evidence that "a morphine overdose will kill someone by stopping their breathing" (20<sup>th</sup> July 2006 p.73, 1.52). He expressed the opinion that he did not believe that a bolus of 7.8mg in a person who was as tolerant as Mr Whittington was, would cause his death" (20<sup>th</sup> July 2006, p.75, 1.6) The stopping breathing would occur between 2 and 6 hours after the dose was given. The usual reaction is somnolence (patient becomes tired and sleepy), in contrast to the somewhat bizarre behaviour reported by his wife. Dr Callanan could not explain the abnormal behaviour. In response to the question of a fatal dose in this deceased, given his tolerance to morphine, his search of the literature revealed that such patients (albeit there was no information as to just how tolerant those patients were) could receive "20 milligrams (intrathecally) without any untoward effects" (20<sup>th</sup> July p.77, 1. 48). He conceded that the deceased got a higher than intended dose. The impact of the sudden infusion of .26 mls "would produce very quickly profound pain relief" (20<sup>th</sup> July p.86 1.44) all through the trunk (20<sup>th</sup> July p.89 1.40) "If he had no tolerance to opiates, it would be a potentially fatal dose" (20<sup>th</sup> July p.84 1.50) presupposing that after the dose the patient received no medical attention. The patient would be falling asleep. "Rare complications are euphoria, anxiety and hallucinations" (p89 1. 48) He accepted that some of the deceased's reportedly bizarre behaviour might be "conceivably a type of hallucinating" (20<sup>th</sup> July p.89 1.54)

The deceased received intramuscular morphine on the morning before the operation, accounting for the high level in the blood. According to Dr Callanan, this measurement would not be significantly affected by the amount delivered intrathecally. The non-functioning of the pump for about a month prior to 24<sup>th</sup> February would have affected his tolerance to intrathecally delivered morphine however it was not possible to say to what extent. (20<sup>th</sup> July p.97 1.25) This must be qualified in light of the double the usual adult dose required by him intramuscularly to give analgesia while the pump was not operative.

Dr Callanan understood the persons who programme the pumps to go through an instruction course provided by the manufacturer, Medtronic, "so that they fully understand the operation and programming of the pump" (20<sup>th</sup> July p.88 1.9) If so, it appears that the training received by Dr Rossato and RN Couper was not very thorough. No details of that were before the court.

Dr Callanan was unaware of any other cheat sheet produced by Medtronics to be used in the case of an already primed pump, such as in the present case, to ensure that the bolus dose did not include the .26ml already in the internal tubing of the pump.

In relation to the cause of death established at post mortem by Professor Williams, Dr Callanan confirmed that the enlarged liver (almost double the normal weight) was consistent with chronic heart failure, as was (albeit less commonly) the significantly enlarged spleen. Bleeding into the atheromatous plaque is not a symptom of morphine overdose.

Re the time inconsistency raised as a concern by Mrs Whittington, Dr Callanan said that he made an assumption that the pump was re-programmed in theatre rather than

in the post anaesthetic care unit, on the basis of the times on the printout and confirmed it would not be unusual for the time on the pump and the time on the clock and in ORMIS not to be coordinated. He conceded that the times in his statements may therefore not be accurate.

Mrs W through her counsel indicated on 21<sup>st</sup> July that she was no longer concerned about the time discrepancies, but that the issue is whether the overdose caused the heart attack. (21<sup>st</sup> July p.24 l. 8)

A statement was produced by Dr Kumar Gunawardane, Director of Cardiology, dated 19<sup>th</sup> July 2006. He was asked to comment on whether the behaviour described by the widow was consistent with a heart attack. He confirmed that an acute confusional state could be due to cardiac failure, however given that the death was, according to Professor Williams, a consequence of the cardiac event, and the confusional state predated that, I did not find his evidence on this point of great assistance in clarifying the behaviour. He agreed that a large meal can lead to a myocardial infarction. As to whether hospital staff should have detected the advanced cardiac condition, he said that an acute myocardial infarction can be the first manifestation of underlying coronary artery disease which may remain asymptomatic until the occurrence of a catastrophic event. Other medical evidence heard confirmed that in any case, given the analgesia to the trunk provided by the morphine pump, the deceased may have been at almost all times pain free, as far as cardiac symptoms are concerned, and any such symptoms would most likely have remained undetected.

The deceased had been assessed following the occurrence of chest pain in 1998 by the Cardiology Dept Queensland Health, as being unlikely to have any major coronary artery problems at that time. (Exhibit 20) This is however 6 years prior to his death.

Counsel assisting the coroner commissioned a report dated 11<sup>th</sup> September 2006 offering an opinion on the relationship if any between the apparent overdose of morphine and the death, from Dr Edward R Friedlander, M.D. Chair of the Pathology Department, Kansas City University (Exhibit 23, with email dated 20<sup>th</sup> August 2007, Exhibit 24). Mrs Whittington had corresponded with him and he indicated a preparedness to assist her. He was initially extremely critical of Professor Williams' post mortem report, however modified his criticism in response to Professor Williams' further report received by the court on 15<sup>th</sup> August 2007 and attachments, conceding that the cause of death proposed by Professor Williams was probably correct, but that the heart attack identified by Professor Williams was most likely precipitated on 24<sup>th</sup> February 2004 by the overdose of morphine.

Dr Friedlander gave evidence by telephone. He gave his views based on a copy of the transcript of the evidence of Professor Williams, his autopsy report and subsequent statutory declarations, copies of the slides, and Professor Lindsay Brown's report. He accepted that the deceased had coronary artery disease, "subject to sudden death" (p.14 l. 51) but queried what the stressor might have been that caused him to suffer a heart attack at the time that he did. He considered that the morphine glucuronides in his bloodstream made the deceased delirious. He conceded that he should defer to an expert in clinical pharmacology in relation to the issue of delirium arising from the glucuronides delivered intrathecally. He accepted that morphine is a respiratory

depressant. He considered the bizarre behaviour of the deceased to be indicative of delirium and that what caused “the delirium also probably contributed to his death” (20<sup>th</sup> August 2007 p.11 l.15) but that “it’s not an exact science” (l.18) He posited that the morphine overdose may have stimulated his appetite, to make him consume a large meal, (p.16 l.43) that may then have triggered his heart attack, however qualified this with the comment: “All this is stuff that probably I wouldn’t want to try to work out”. He subsequently in answer to the question from Mr Betts for Queensland Health as to whether Morphine would suppress appetite, answered “I would defer on that to a clinical pharmacologist”( p.17 l.23). He seemed to have little or no knowledge of the level of tolerance to morphine of the deceased, and conceded that he did not know the amount of the bolus dose. (20<sup>th</sup> August p.20 l.2)

In my assessment he was not qualified to give a credible opinion as to the impact of the overdose on the deceased. The impression I gained was that he was determined to attribute the death to the morphine overdose, regardless of his admitted absence of expertise to do so combined with his lack of knowledge of the amount given. He had to concede that given the specialised nature of toxicology, and his lack of expertise in this field he could not comment on the impact of the morphine metabolites. Dr Friedlander’s evidence was not of any real assistance in determining any relationship between the morphine dose and the cause of death.

Dr Lindsay Brown, Associate Professor in the Department of Physiology and Pharmacology, School of Biomedical Sciences of the University of Queensland provided a report at the request of Counsel assisting the Coroner, dated 14<sup>th</sup> November 2006. (Exhibit 22). He was eminently qualified to give pharmacological evidence, i.e. evidence as to the science of drug actions. He addressed in his evidence the likely interaction between the various drugs found in the system of the deceased.

Having regard to the available evidence of the bolus dose of .26 ml, containing 20.8mg of morphine, and that the deceased had been given morphine 30-40mg daily for the previous 8 days, he estimated the amount of morphine in the body at the time of death at 74.6mg. On the basis of the rate of metabolism of morphine, he calculated that most of the morphine in the body had been administered within about 6 hours of death. His view was that the plasma concentration found in the deceased could be characterised as a high but therapeutic concentration for pain relief. He also expressed the view that only 1/8 of the bolus dose should have been in the body at the approximate time of death, and that the amount in the body calculated from the toxicology report suggests the administration of additional morphine, assuming that no morphine had yet been released from the pump implanted that afternoon. Most morphine given in the hospital would have been eliminated before death, he said.

In relation to the strange behaviour of the deceased, Dr Brown’s evidence was that morphine toxicity is characterised by respiratory depression and somnolence. Given the absence of such symptoms in the deceased, his behaviour did not reflect the signs of morphine toxicity.

The strange behaviour may be explained by the combination of morphine and sertraline, inducing the serotonin syndrome. Such patients show pronounced behavioural changes such as agitation, confusion and disorientation. This syndrome can cause constriction in coronary arteries, thereby producing a myocardial infarction

in overdose in atherosclerotic patients. Dr Brown assumed a last dose of sertraline around 8pm on 23<sup>rd</sup> (sic) February, as usual. The amount in the body was within the therapeutic range, which is very wide.

The deceased was likely to have developed tolerance to morphine given he had taken morphine regularly and as a consequence this would decrease the response to a bolus dose of 20.8 mg morphine, as in this case.

He concluded that the behavioural effects reported by the widow do not resemble the signs of morphine overdosage.

In November 2006, Medtronic issued a "Safety Alert Important Patient Safety Management Information" in relation to Patient Mortality after Implant and Initiation of Intrathecal Infusion Therapy for Pain. This was following the reports between Dec 2005 and March 2006 of nine patient deaths in the USA within 3 days after the initiation or re-initiation following interrupted use, of intrathecal opioid therapy for pain. The conclusion by Medtronic was that the deaths were most likely caused by opioid an/or sedative drug overdose. The Safety Alert was received by me after the final submissions were received, following my request of the solicitors for Medtronics to provide any such alerts, given that none were tendered during the Inquest. I have marked the Safety Alert Exhibit with covering letter Exhibit 26.

11. I am satisfied that the death of Frank Maurice Whittington was due to a heart attack, and that he suffered from chronic coronary artery disease. I am further satisfied that he was administered an overdose of .26 mg morphine postoperatively on 24<sup>th</sup> February 2004, as a result of an error in the calculation of the post operative bolus priming dose required to refill the pump following replacement of the catheter attached to the Medtronics SynchroMed EL Implantable pump 8627L-18 Serial Number NGH020137R . This occurred due to reliance placed by Dr Reno Rossato, in my view, reasonably, on the calculation sheet provided by the manufacturer of the pump. The sheet fails to allow for correct calculation of the bolus dose in circumstances where the pump has been previously primed. Neither does the manual allow for such circumstances. A Safety Alert has been issued which mentions that allowance should be made for the inner pump tubing, however gives no information as to how that allowance should be calculated. In retrospect, it is obvious, however under the pressure of working conditions in the hospital, in my view, the manufacturer should make the position much clearer.

I am not satisfied that the overdose of morphine in the deceased who was highly morphine tolerant contributed to his death.

12. I am unable to make a conclusive finding as to the cause of the unusual behaviour of the deceased, except to say that it was not consistent with morphine overdose, and indeed is a factor that militates against any finding of morphine toxicity. Given the findings of Dr Brown, based on calculations from the toxicology report, it is possible that the deceased self-administered additional morphine following his discharge from hospital.

13. A life extinct Certificate was issued in respect of the deceased by a registered nurse at Ingham Hospital on 24.2.04 at 23.30 certifying that life was extinct.

14. Subsequently a post mortem was performed upon the body of the deceased and a record of this was issued (Exhibit 5 )

stating the following-

on 26<sup>th</sup> February 2004 at Townsville Hospital

Professor David Williams, Director of Anatomical Pathology

expressed the opinion that the medical cause of death was Coronary Atherosclerosis.

15. I make the following formal findings –

(a) who the deceased person is:

The deceased person is Frank Maurice Whittington who was born on 21.1.1938 and was aged 66 at the date of his death. His last place of residence was 10 O'Malley Street, Ingham. His occupation was retired Ambulance Officer.

(b) how the person died:

The deceased died in his bed at his home in Ingham, having returned home from Townsville Hospital after day surgery under general anaesthetic to repair the catheter on his Medtronic intrathecal morphine pump on the date of his death.

© when the person died:

He died on 24<sup>th</sup> February 2004 at around 10.00 pm.

(d) where the person died:

He died at 10 O'Malley Street, Ingham, Queensland 4850

(e) what caused the person to die:

1(a) Coronary atherosclerosis.

16. On the evidence before this Coroners Court, I do not reasonably suspect any person has committed an offence. Similarly there is no evidence of official misconduct, nor such that information about any person's conduct in a profession or trade, obtained while investigating the death, should be given to a disciplinary body for the person's profession or trade.

17. S 46 (1) A coroner may, whenever appropriate, comment on anything connected with a death investigated at an inquest that relates to-

(a) public health or safety; or

(b) the administration of justice; or

© ways to prevent deaths from happening in similar circumstances in the future.

I make the following recommendations:

1. Section 5 of the Medtronics Manual entitled "Pump Implant: Critical Tasks and Procedures" should have added to it a warning that the procedure described for Calculation of the Postoperative Bolus Dose should be modified in the case of a previously primed pump to take account of the fact that the internal tubing volume of .26ml should not be added.

A second Postoperative Priming bolus Calculation Worksheet should be developed that takes account of that, and it should be added to the References and Resources section of Section 5. of the Manual.

A person dissatisfied with a finding at an inquest may apply to the State Coroner or District Court to set aside the finding.

The Inquest is closed.

Stephanie Tonkin  
Coroner  
Townsville  
12<sup>th</sup> December 2007