



CORONERS COURT OF QUEENSLAND

FINDINGS OF INQUEST

CITATION: **Inquest into the death of Gwendoline Mead**

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JURISDICTION: Brisbane

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FINDINGS OF: Ainslie Kirkegaard, Acting Coroner

CATCHWORDS: Coroners: colorectal surgery, post-operative fluid balance management, persisting low urine output and intermittent hypotension, hypoalbumaemia, multidisciplinary team, inter-team patient referrals

REPRESENTATION:

Counsel Assisting: Ms Melinda Zerner

Darling Downs Hospital and Health Service: Mr D Schneidewin instructed by Barry Nilsson Lawyers

RN Comber: Ms Sally Robb instructed by Roberts & Kane Solicitors.

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Introduction

Gwendoline Mead was a 73 year old woman who died at the Toowoomba Base Hospital on 1 March 2015 from complications of elective surgery to treat recently diagnosed high grade synchronous caecal and rectal tumours.

Mrs Mead lived with her husband in Oakey. The couple's two adult children lived locally and were very supportive of them in their retirement.

Mrs Mead had been diagnosed with high grade rectal cancer in September 2014 and underwent neoadjuvant chemoradiotherapy in preparation for surgical resection of synchronous tumours. Her treatment plan was developed by the hospital's Surgical Oncology Multidisciplinary Team. She was admitted to the Toowoomba Base Hospital on 17 February 2015 for an elective right hemicolectomy and low anterior resection +/- defunctioning ileostomy performed by consultant surgeon, Dr Richard Benny.

The surgery was more complicated than anticipated due to the extent of the rectal tumour. Despite this, Mrs Mead tolerated the surgery quite well and was admitted to the surgical ward that evening. Over the following six days she experienced episodes of hypotension and persistent low urine output, at times triggering reactive Ward Call and Medical Team review. The surgical team attributed her low urine output to intravascular depletion which they managed with repeated fluid challenges, hourly urine measures and low doses of intravenous Frusemide. Over time, Mrs Mead became more and more oedematous with serous fluid leaking from her arms and into the surgical drain.

On the morning of 23 February, day 6 post-operatively, the surgical team removed the indwelling catheter despite earlier Medical Registrar recommendation for strict fluid balance monitoring and continued hourly urine measures. Mrs Mead became unwell that day prompting the Surgical Intern to seek assistance from another Medical Registrar who identified Mrs Mead as needing Medical Consultant review. When seen by the Medical Consultant soon afterwards, Mrs Mead was identified as critically unwell and swiftly transferred to the intensive care unit (ICU) where she was diagnosed and treated for urosepsis and acute kidney injury, and commenced on intravenous antibiotics and continuous haemodialysis.

Mrs Mead's condition improved over the following 24 hours such that she was considered well enough to receive intermittent haemodialysis under the renal team. She was discharged back to the surgical ward on the afternoon of 25 February. However, her condition deteriorated again and following intensive care and renal review the next morning, 26 February, she was readmitted to ICU.

Once back in ICU, efforts to insert a femoral arterial line were unsuccessful. Overnight, Mrs Mead's haemoglobin level dropped significantly and she developed a tender tense left upper thigh/groin haematoma. With surgical team input, this was initially managed conservatively with transfusion and fluids to try to correct the coagulopathy.

By the next morning, 28 February, the haematoma had increased in volume and her haemoglobin remained low. Following discussion with Dr Benny, Mrs Mead was taken for a CT angiogram to investigate the cause of the bleeding. The CT angiogram showed extensive haematoma and active bleeding. Mrs Mead arrested while in radiology. She was resuscitated, intubated and ventilated, and taken to theatre for emergency surgery which managed to bring the bleeding under control.

However Mrs Mead remained coagulopathic with a very poor prognosis. Following discussion with her family, it was decided that if she did not respond to massive blood transfusion protocol she would be transitioned to comfort cares. She continued to deteriorate overnight. She was commenced on comfort cares early the next morning and died peacefully at 6:00am on 1 March 2015.

The investigation

Mrs Mead's death was appropriately reported as a health care related death under the *Coroners Act 2003* due to the treating team's opinion that she died from haemorrhagic shock arising from femoral artery damage sustained during attempts to insert a femoral artery line.

Preliminary clinical review of the hospital record undertaken by an independent doctor from the Department of Health Clinical Forensic Medicine Unit (Dr Gary Hall) identified a range of concerns about Mrs Mead's pre-operative and post-operative management, namely:

1. the appropriateness of the surgical decision making
2. whether her pre-operative malnutrition and low albumin (hypoalbuminemia) could have been better optimised prior to surgery
3. the adequacy of the surgical team's post-operative management of her episodic hypotension and persistent low urine output and whether the urosepsis could have been diagnosed sooner
4. whether earlier formal medical review may have changed the outcome for Mrs Mead.

Having regard to this preliminary advice, I determined the death required further coronial investigation, including autopsy.

The Darling Downs Hospital & Health Service (DDHHS) was given an opportunity to consider and respond to the clinical management issues raised by Dr Hall. The DDHHS considered these issues via a comprehensive SAC 1 Clinical Review process. In essence, while acknowledging there was a delay in seeking medical review, the clinical review team did not believe it would have changed the course of events. The clinical review team was satisfied Mrs Mead was managed by a multidisciplinary team and believed the decisions made were reasonable. It recommended review of the capacity of the hospital's patient flow management system to better record and action inter-team referrals.

The investigation was further informed by independent surgical review and opinion provided by Associate Professor Daryl Wall, Director of Trauma Services at the Royal Brisbane and Women's Hospital. Dr Wall has experience in colorectal surgery. In summary, Dr Wall:

- also expressed concerns about the management of Mrs Mead's pre-operative risk factors, the surgical decision making and the surgical team's management of her post-operative hypotension and low urine output.
- considered a lack of initiative in the early stages of Mrs Mead's deterioration was substantially causative of her death.
- was highly critical of communication within the surgical team and with other treating teams describing it as 'dangerously limited'.
- was highly critical of the lack of consultant documentation.
- stated, perhaps somewhat controversially, *Modern specialist surgeons are increasingly ill-equipped to contribute to the care of the dangerously ill. This is a system error which demands that the consultant frequently seeks advice from other consultants.*
- was critical of both the medical and intensive care team response to Mrs Mead's gross metabolic derangement, delay in diagnosing urosepsis and inappropriate discharge from ICU, coining the phrase 'Failure to Rescue' in describing this case.
- considered the damaged femoral artery and subsequent interventions made a minor contribution to Mrs Mead's death given her prognosis was extremely poor by that stage.

The DDHHS was given an opportunity to consider and respond to Dr Wall's report. Dr Martin Byrne, Director of Clinical Governance, communicated a firm rejection of Dr Wall's views, reiterating the DDHHS opinion that while Mrs Mead had many complications leading to her death, her care was appropriate in that facility. Dr Byrne repeated the DDHHS' acknowledgement that there were some opportunities for improvement and more timely review, but noted Mrs Mead was very unwell and had many comorbidities.

Dr Wall acknowledged the efforts of DDHHS to evaluate most of the issues of concern openly and fairly. However, he remained concerned that its response did not identify Failure to Rescue which he considered to be hard evidence of system failure at Toowoomba Base Hospital, and consequently no plan had been developed to overcome Failure to Rescue.

Doctors involved in Mrs Mead's pre-operative and post-operative care were asked to provide formal statements responding to the issues identified by preliminary and independent expert review. Of particular interest to me in these responses were Medical Consultant observations about the potential benefit of earlier dedicated perioperative medical input as a means of having given Mrs Mead the best chance of a changed outcome, together with thoughts about how this might be better achieved at Toowoomba Base Hospital.

The investigation was further informed by expert review and opinion of Dr Steven O'Donoghue, consultant intensivist and anaesthetist at the Royal

Brisbane & Women's Hospital. While Dr O'Donoghue did not share many of Dr Wall's concerns about Mrs Mead's pre-operative and post-operative management, he provided a carefully considered opinion about what may have been causing Mrs Mead's hypotension and persistent low urine output, including but not limited to evolving kidney injury. His major concern was the apparent failure to manage these ongoing issues after the same treatment was repeated on a number of occasions with the same transient response, with increasing oedema and body weight.

Dr O'Donoghue considered Mrs Mead's care might have been improved if a senior physician was involved after a pattern of multiple MET calls for her recurring problems. He suggested this approach could have resulted in a clearer plan for her management and transfer to a High Dependency Unit environment for closer haemodynamic monitoring and more aggressive interventions to manage her hypotension and low urine output. In turn this may have resulted in earlier investigation of why she was not sustaining a response to fluid therapy. However, his report stopped short of expressing an opinion as to whether this approach would have changed the outcome for Mrs Mead.

Dr O'Donoghue also questioned, with the benefit of hindsight, whether a more aggressive transfusion approach and earlier decision to undertake a CT angiogram and surgical repair might have been more successful in achieving earlier control of the bleeding in Mrs Mead's thigh during her readmission to ICU.

Autopsy results

An external examination and full internal autopsy was performed at the John Tonge Centre on 11 March 2015. Autopsy scheduling was complicated by the hospital's inadvertent release of Mrs Mead's body to the family's funeral director without coronial authorisation. The body was subsequently embalmed in preparation for a funeral service. Most regrettably, this sequence of events caused great distress to Mrs Mead's family.

Notwithstanding extensive artefact due to removal of the surgical drains and the embalming process, the autopsy revealed multiple intimal tears in the left common femoral artery (sutured), superficial femoral artery and deep femoral artery and extensive haemorrhage into the left anterior thigh. The bowel anastomosis was intact with no evidence of infection, inflammation or leakage. There was no evidence of infection or inflammation at the stoma site. There was no evidence of mucosal lesions, inflammation or necrosis in the small and large bowel. The rectum was absent. Microscopic examination showed extensive inflammatory changes in the rectal stump with associated tissue necrosis. There was microscopic evidence of hypertensive changes in the kidneys. There was no evidence (macroscopically or microscopically) of mass lesion or cancer. There was moderate coronary atherosclerosis and microscopic evidence of patchy bronchopneumonia and emphysematous changes in the lungs.

Having regard to the autopsy findings and the clinical history, the pathologist determined the cause of death to be multiple organ failure due to, or as a

consequence of sepsis due to, or as a consequence of rectal and caecal adenocarcinoma (surgically treated).

The inquest

The inquest was held over four days, 30 and 31 January and 1 and 6 February 2017. Members of the medical oncology, surgical, anaesthetic, medical and nursing teams involved in Mrs Mead's care gave evidence, as did both experts, Professor Wall and Dr O'Donoghue.

In addition to the findings required by the *Coroners Act 2003*, s. 45(2), the inquest examined issues arising from Mrs Mead's clinical management at the Toowoomba Base Hospital including:

- a) the adequacy of the multidisciplinary team approach to her care
- b) the appropriateness of the surgical decision making
- c) the adequacy of communication between multiple treating teams about her post-operative condition and its management
- d) the adequacy of the pre-operative assessment and planning of her care
- e) the appropriateness of her discharge from the ICU on 25 February 2015
- f) whether aspects of Mrs Mead's clinical management reflect broader system failures and if so, what system changes could be made to minimise the risk of adverse health outcomes in the future.

In doing so the inquest traversed quite complex evidence regarding post-operative fluid management, the clinical significance of hypoalbuminemia and the use of Albumin in fluid resuscitation, an issue which highlighted to me a somewhat curious divide between the surgical and non-surgical approach to this aspect of Mrs Mead's post-operative management.

I have been greatly assisted by Counsel Assisting's comprehensive submissions and those provided by Counsel representing DDHHS and RN Comber. A few weeks after the close of submissions, Dr Sharma provided a personal submission addressing aspects of those made by Counsel Assisting. This was circulated to Counsel Assisting and the interested parties, none of whom wished to provide further submissions.

Clinical narrative and discussion of inquest issues

Diagnosis and pre-operative management: September – December 2014

Mrs Mead was formally diagnosed with high grade rectal cancer in September 2014.

She had been referred to the Toowoomba Hospital by her general practitioner on 21 August 2014 for further investigation of a caecal mass identified on CT scan of her abdomen and pelvis. She had been experiencing intermittent abdominal symptoms since January 2014 with lower abdominal pain, vomiting, constipation and weight loss of more than 10kg over the course of the year.

She was reviewed by the general surgical team under consultant surgeon, Dr Richard Benny, on 29 August 2014 and underwent a colonoscopy on 3 September which revealed multiple masses in the caecum, colon and rectum. A MRI performed on 5 September revealed a primary rectal adenocarcinoma staged T4N1 with metastases in lymph nodes and possibly the liver.

Dr Benny's team presented her case to the Surgical Oncology Multidisciplinary Team (SOMDT) on 9 September 2014. The SOMDT involves participation by the medical oncology, radiation oncology, surgery and pathology teams. This process does not involve general medical teams.

The SOMDT recommended referral for neoadjuvant chemoradiation therapy with the aim of shrinking the tumour prior to surgical intervention with right hemicolectomy and anterior resection. The intent of Mrs Mead's treatment was curative.

Mrs Mead was reviewed by the radiation oncology team based at St. Andrew's Private Hospital Toowoomba in late September 2014 who recommended a course of radiotherapy over five weeks in combination with chemotherapy at the Toowoomba Base Hospital.

She was then reviewed by the medical oncology team under Dr Amit Sharma, consultant medical oncologist at the Toowoomba Base Hospital on 7 October and commenced chemoradiation on 14 October 2014 (infusional 5-Fluorouracil chemotherapy with radiation). She was expected to complete the neoadjuvant therapy by 21 November 2014.

I accept the clinical consensus that the only way to achieve a curative outcome for Mrs Mead was surgery, optimised by neoadjuvant therapy.

Mrs Mead had already experienced weight loss prior to her formal diagnosis. The side effects of her neoadjuvant therapy were known to include bowel and bladder irritation, anorexia, nausea and vomiting, fatigue and skin irritation. Consequently she was referred for dietician review as part of her pre-operative management.

She was reviewed by a dietician in the oncology outpatients department on 14 and 28 October 2014. When seen on 28 October, Mrs Mead was noted to be malnourished with a 4.5% weight loss since commencing treatment. She was described as having moderate malnutrition secondary to her reduced oral intake and increasing requirements associated with her malignancy and chemoradiation therapy. She was advised to have oral intake two-hourly. She was noted as not wanting to try Sustagen yet. She was for further dietician review at her next outpatient appointment.

Hospital admission – 4-10 November 2014

On 4 November 2014, Mrs Mead was admitted to the Toowoomba Base Hospital from the oncology outpatient clinic with non-neutropenic fever and a one week history of crampy abdominal pain, occasional nausea and vomiting and loss of appetite. She was admitted under Dr Sharma. She was treated

with intravenous antibiotics and managed for nausea, vomiting and renal impairment thought possibly due to gastroenteritis. She was noted to have been hypotensive on occasion during this admission but was asymptomatic. Her renal impairment improved with intravenous fluids.

When reviewed by a dietician on 5 November, Mrs Mead was noted to weigh 51.7kg, up from 49.9kg when weighed on 28 October. She was considered to be moderately malnourished as a result of poor appetite and increased requirements arising from her cancer. She was to be changed from full diet to a high protein-high energy diet, given Fortsip oral supplement and for review in a week's time.

She was discharged home on 10 November and seen in the oncology outpatients department the next day. Her renal function was still not back to baseline. Her liver function tests were deranged, so she was referred for an ultrasound of the liver, kidneys, ureter and bladder and repeat blood tests for further review in the outpatient clinic on 13 November 2014. Her chemotherapy was withheld at this time.

Readmission to hospital – 13-28 November 2014

When seen in the outpatient clinic on Thursday 13 November, Mrs Mead was noted to have signs of fluid overload (small amounts of ascites, bilateral pleural effusion and bilateral pedal oedema). Her liver function tests were returning to normal but she had asymptomatic low potassium (hypokalaemia). She was readmitted to hospital under Dr Sharma. Her chemotherapy was withheld pending stabilisation of her fluid status and electrolytes.

Mrs Mead was reviewed by a surgical team (not Dr Benny's surgical team) after developing nausea and vomiting, diarrhoea and abdominal distension over the weekend. Abdominal x-ray performed on Sunday 16 November showed features consistent with a bowel obstruction possibly related to the hepatic flexure. A CT scan of the abdomen and pelvis performed on Monday 17 November showed significant ascites around the liver and spleen with thickening of the wall of the gallbladder, no faecal loading, a pelvic mass thought most likely to be a fibroid or (query) ovarian mass and thickening of small bowel loops thought possibly consistent with post chemotherapy changes involving the bowel. The reporting radiologist noted the possibility of obstruction less likely. The surgical team considered there was no evidence of bowel obstruction or cholecystitis and that Mrs Mead had a likely pseudo-obstruction secondary to her neoadjuvant therapy. She was made nil by mouth and managed with intravenous fluids and replacement electrolytes. Her chemotherapy was withheld but she continued with the radiation therapy. The surgical team remained involved in her care until 21 November after which she continued to be managed by Dr Sharma's medical oncology team.

Mrs Mead continued to experience episodes of vomiting and diarrhoea, and ongoing electrolyte abnormalities. Her ascites were investigated with an ultrasound guided ascitic tap. She was also booked for an outpatient gastroscopy.

Mrs Mead was reviewed by the dietician on 17, 19, 20, 21, 24 and 27 November. She was initially nil by mouth until 19 November after which time the surgical team ordered that she be placed on a soft high protein diet.

Following review by Dr Sharma and his team on 26 November, the management plan included dietician review of possible supplements given Mrs Mead's hypoalbuminemia (low albumin). Dr Sharma thought her low albumin was most likely due to chemotherapy toxicity which was causing her diarrhoea, nausea, vomiting and poor oral intake. He considered she needed some time to recover from the chemotherapy toxicity and in that time she might start eating better with the likelihood her albumin level would improve.

When last seen by the dietician on 27 November, prior to discharge home, she was noted to have declined nutritional support products such as Sustagen as she disliked them but was having one protein enriched drink per day. She was tolerating oral intake and advised of the importance of increasing her protein intake. She was given advice about how to achieve this by small frequent meals and snacks including milky drinks and adding milk powder. Her progress was to be reviewed when she next attended the outpatient clinic.

Mrs Mead did not resume chemotherapy as she was unable to tolerate it. She completed her radiation therapy on 26 November and was discharged home on 28 November. A discharge summary for this admission was prepared by a member of Dr Sharma's medical oncology team. She was not seen again by the medical oncology team or by the dieticians after this admission.

The radiation oncologist wrote to Dr Benny on 26 November advising him Mrs Mead had completed her course of radiotherapy. This letter referred to her having had a 'rocky course' with admission to hospital for a small bowel ileus and hypokalaemia and requiring a three day break between 17-19 November for bowel rest. She had successfully upgraded to a soft diet which she was tolerating well. She was scheduled for post-treatment review by the radiation oncology team in four weeks' time.

Surgical outpatient review - 12 December 2014

Mrs Mead was reviewed by Dr Benny in the surgical outpatients clinic on 12 December 2014.

Dr Benny explained they usually have 30 to 40 patients in the surgical outpatients clinic and he relies on his Registrar (at that time) to review the patient's medical record and advise him of any concerns before he consults the patient.

Dr Benny's Registrar noted it had been eight weeks since Mrs Mead's last surgical review and she had completed chemotherapy early, and her radiation therapy two weeks earlier.

The Registrar consented Mrs Mead for an open right hemicolectomy and low anterior resection +/- defunctioning ileostomy. This involved surgery to both ends of the large intestine and rectum at the same time. She was to be

scheduled as a priority category 2 patient. Mrs Mead signed a generic adult consent form which did not cite mortality risk rates for this particular procedure and there is no documentation in the chart of any specific discussion with her by Dr Benny or his Registrar about the rationale for this surgical approach and its specific risks. The elective admission booking form emailed on that day contains a notation that Mrs Mead's surgery was to be done in mid to late February 2015.

Dr Benny says he discussed the surgery with Mrs Mead that day, advising he routinely quotes a perioperative mortality of greater than 7% for any patient in Mrs Mead's age group at her disease stage.

He acknowledges she had multiple risk factors which increased her risk of perioperative morbidity and mortality including her age, synchronous obstructing caecal cancer and perforated rectal cancer and malnutrition. His statement refers to clinical studies which have shown that patients with colorectal malignancy with features of bowel obstruction, perforation, hypoalbumaemia and ascites carry a high perioperative mortality, citing mortality rates of 30-40% for perforated colorectal cancer and 30-40% for malignant bowel obstruction.

Dr Benny maintains that Mrs Mead fully understood the risks and chose to proceed.

Appropriateness of Dr Benny's surgical decision making

The inquest examined what information was available to Dr Benny at the pre-operative surgical consult and what informed his surgical decision making.

I accept that surgery was the only definitive treatment for Mrs Mead's malignancy.

Dr Benny says his decision to proceed with the planned surgery was based on his clinical review of Mrs Mead and her pathology results, as she presented to him on 12 December 2014. However, Dr Benny did not recall having the November 2014 discharge summaries brought to his attention at the time of that consultation, and says he was not made aware of the fact or findings of the abdominal CT scan performed on 17 November 2014.

Dr Benny says the CT report suggested she was already showing features of malignant bowel obstruction so this information would have been very helpful to him and had it been brought to his attention, *...I would have, probably, addressed the two tumours differently. If the patient already had a right-sided bowel cancer causing obstruction, given the clinical picture she had, I may have operated earlier to relieve the right-sided bowel obstruction and that could have arrested some of the metabolic derangement that had happened or followed that. That – they way I would have taken it. That's the way I would have done it. I just would have done it differently.*¹

¹ T3-55, 15

Dr Benny's evidence on this point is consistent with the expert opinion of Professor Wall who favoured a two-stage surgical approach. He was concerned the bowel disturbance she experienced during the second November 2014 admission, while described as an ileus, was more likely to have been a very low grade bowel obstruction. To him the small bowel thickening demonstrated on the CT scan suggested an inflammatory process which he would have addressed with an ileostomy in the first instance. However, in expressing this opinion, Professor Wall acknowledged this was ultimately a clinical decision for the individual surgeon.

It is difficult to understand why Dr Benny and his team were not notified of, let alone involved in, Mrs Mead's admission over 13-28 November 2014, at that time. Dr Benny says he would have been happy to see Mrs Mead on the ward had he been asked to. It would certainly have made far greater sense for the surgical team already involved in Mrs Mead's care to have been allocated to her during this admission. On Dr Benny's evidence, it would have better positioned him earlier to consider his surgical approach.

This is a significant missed opportunity to have optimised Mrs Mead's care by reassessing the planned surgical approach. That said, whether earlier and staged surgical intervention would have changed the outcome for her can only be speculated upon.

Adequacy of the multidisciplinary team approach to Mrs Mead's pre-operative care

So how did this occur for a patient being managed under the auspices of a formal multidisciplinary team?

Mrs Mead's treatment plan was determined at the initial SOMDT meeting on 9 September 2014. As Counsel Assisting rightly points out, Mrs Mead's neoadjuvant therapy did not go as planned with her requiring two hospital admissions during November 2014 culminating in her being unable to finish the chemotherapy component. The second November 2014 admission involved a referral for surgical review of a possible small bowel obstruction.

According to Dr Benny, once a patient is under the care of a particular surgical team within the SOMDT, that team is consulted if there are any concerns during the period of the patient's treatment. The DDHHS SAC 1 Clinical Review did not identify this had not occurred during the November 2014 admission. Dr Benny's evidence about not having been made aware of the November 2014 admissions and CT scan emerged late during the inquest so there was no opportunity to canvass with Dr Sharma why his team did not consult Dr Benny's team when seeking surgical review during the second November admission.

The inquest considered the communication methods employed by the medical oncology, radiation oncology and surgical teams operating under the SOMDT mechanism, both generally and specific to Mrs Mead:

- Dr Sharma's usual practice is to provide a discharge letter from the medical oncology team at the completion of the neoadjuvant chemotherapy agreed by the SOMDT

- Dr Sharma's team prepared discharge summaries for both November 2014 admissions
- Dr Sharma's team did not prepare a discharge or 'last letter' to Dr Benny about Mrs Mead's neoadjuvant therapy because Mrs Mead had finished her chemotherapy treatment before her radiation therapy was completed – in Mrs Mead's case, the neoadjuvant therapy involved combined concurrent treatment by the medical oncology and radiation oncology teams
- in Dr Benny's experience, it was not unusual not to receive a discharge letter regarding neoadjuvant chemotherapy. He says the medical oncologist would usually contact him directly if there was a concern – there was no direct contact between Dr Sharma and Dr Benny about Mrs Mead during her neoadjuvant treatment phase
- the 'last letter' came from the radiation oncology team rather than from the medical oncology team – this letter was addressed to Dr Benny and described Mrs Mead as having had a rocky course with hospital admission for small bowel ileus and hypokalaemia on 15 November 2015 meaning she was given a three day treatment break for bowel rest, and was due for discharge home in the next few days
- there are Cancer Care Coordinators whose role is to keep the teams informed about what is happening for the patient, including any hospital admissions – there is no evidence this occurred in Mrs Mead's case
- Dr Benny says the whole patient chart is available in the surgical outpatients clinic for the pre-surgical consultation
- Dr Benny says he relied on his Registrars to review the patient chart and advise him of any concerns prior to him seeing the patient at the pre-surgical consult – in principle, I have no concerns about such a system being used to maximise the efficiency of a busy surgical outpatient clinic. However, Dr Benny's then Registrar was not called to give evidence so it is unknown to what extent the Registrar reviewed the chart and/or conveyed information from it to Dr Benny in preparation for the 12 December review. Without this evidence I cannot properly assess the effectiveness of the practice Dr Benny suggests operated in relation to Mrs Mead that day
- Mrs Mead's case was not presented to the SOMDT again until 24 February 2015, after the surgery.

The simple solution to the information flow about Mrs Mead's pre-operative issues would have been for Dr Benny's team to have received the referral for surgical review during her second November 2014 admission. Unfortunately, I am unable to make a finding about why this did not happen as it apparently should have under the SOMDT mechanism. Nor am I in a position to comment on whether this situation was the exception rather than the rule under the SOMDT.

The simple fact remains that the events of Mrs Mead's November 2014 admissions, together with her pathology and radiology results, are documented clearly in her chart. Irrespective of the role of Cancer Care Coordinators and formal communication by consultants (or members of their teams) about their shared patients, detailed information about Mrs Mead's pre-operative issues

was available to be read by any one of the clinicians involved in her care, consultant or otherwise.

Pre-operative management: January – February 2015

Mrs Mead was not seen again by the medical oncology team or the hospital dietitians after her discharge from hospital on 28 November.

Mrs Mead was seen by the radiation oncology team for a post-treatment review on 22 January 2015. The radiologist oncologist again wrote to Dr Benny stating *...The patient had quite a difficult time towards the end of the radiotherapy. I understand she needed an admission for small bowel ileus and hypokalemia. Both resolved. Life is slowly coming back to normal for her. She is trying to broaden her diet. The patient still does not tolerate a number of foods. She is slowly gaining weight; but certainly, the process takes longer than usual. She had a primary surgery booked for February 2015. I will leave the further follow up in the hands of the surgeon. Most likely, after the surgery, she would be indicated for adjuvant course of chemotherapy....*²

It appears Mrs Mead did not return to Toowoomba Base Hospital again until February 2015.

Pre-operative anaesthetic assessment - 10 February 2015

Mrs Mead was assessed by consultant anaesthetist Dr Anthony Thorne in the pre-admission clinic on 10 February 2015.

Dr Thorne described Mrs Mead's pre-operative assessment as relatively routine. He identified no significant risk factors save that her potassium level was low at 3.0 mmol/L, which although not of itself an absolute contraindication to anaesthesia, was borderline. His preference was for the potassium level to be normalised before proceeding to surgery. This is because low potassium has the potential to precipitate cardiac arrhythmia and muscle weakness which can interfere with muscle relaxant drugs. For this reason Dr Thorne spoke with Mrs Mead's general practitioner who recommenced her on potassium replacement therapy.

Dr Thorne acknowledged that Mrs Mead's blood test results on 10 February 2015 showed low albumin at 22g/L (normal range, 35-50), though he did not reference this in the anaesthetic record at that time. This was because from an anaesthetic perspective, low albumin does not of itself present any significant anaesthetic risk.

Dr Thorne noted that by 10 February, Mrs Mead's blood test results indicated she was not anaemic, which he explained could not have been achieved without adequate diet and return to an adequate nutritional status. By this time, all her haematology markers had normalised except for her albumin and potassium levels.

² ExB5, p1

In the following week, Mrs Mead's potassium level improved to 3.5 mmol/L, slightly below the normal range. Dr Thorne was satisfied that from an anaesthetic perspective the surgery could proceed as planned on 17 February.

At no time was the general medical team involved in Mrs Mead's pre-operative management or assessment as Dr Benny did not consider medical input was needed.

Management of Mrs Mead's pre-operative malnutrition and hypoalbuminemia

Mrs Mead was significantly malnourished and deconditioned prior to surgery. She had been eating very poorly at home, was underweight, with a 4kg weight loss over the two-and-a-half months prior to surgery and her serum albumin was low.

Mrs Mead's pathology results prior to her pre-operative anaesthetic assessment on 10 February 2015 show her albumin levels were normal when she first presented to hospital in early September 2014 (although there was a slight drop on 4 September), after which there was a significant decrease in her albumin levels in early November while she was undergoing chemoradiation therapy.

Her albumin level remained low during the second November hospital admission but was not a major focus of her management at that time, other than being monitored with dietician involvement at the request of Dr Sharma's team. Mrs Mead was to have been reviewed by a dietician in outpatients but there is no evidence she was seen by a dietician again prior to her admission for surgery on 17 February 2015.

Albumin is circulating protein produced by the liver and functions to maintain osmotic pressure within the blood circulation. Dr Thorne helpfully explained the significance of low albumin as *...one of its main functions is what's called colloid osmotic pressure, so it keeps fluids in the intravascular compartment in the veins and the arteries and the capillaries from not going into the tissues. If you've got a low albumin, that pressure – that force to keep them in the vasculature is less, so there's a tendency to leak out, and that was my – my opinion why the – Mrs Mead had mild swelling of ankles at –at pre-admission clinic, as I noted.*³

Low albumin is recognised as an independent risk factor for surgical morbidity and mortality. It is generally managed with nutritional supplementation, generally by oral intake and in very severe cases, by infusion.

Consequently, one of the questions for this inquest was whether Mrs Mead's malnutrition and low albumin had been sufficiently optimised for surgery.

Having heard the opinions of consultants Dr Benny, Dr Sharma, Dr Thorne, Dr Denman and the independent expert, Dr O'Donoghue, on this issue, I accept

³ T1-31, 26-38

the clinical consensus that Mrs Mead's low albumin was primarily due to the two gastrointestinal tumours and her body's response to them (a condition Dr Thorne described as cancer cachexia), in combination with the effects of chemoradiation therapy (including poor appetite and reduced oral intake), with removal of the tumours being the definitive treatment. I accept that even had Dr Sharma or Dr Benny referred Mrs Mead for general medical review pre-operatively, there was probably nothing the general medical team could have offered that would have improved her low albumin in a meaningful way without unnecessarily delaying her surgery.

Admission to Toowoomba Base Hospital for surgery – 17 February 2015

Mrs Mead was admitted to the Toowoomba Base Hospital on Tuesday 17 February 2015 for the surgery, nearly 12 weeks after she completed her neoadjuvant therapy.

She was admitted under Dr Benny whose surgical team comprised:

- Dr Pamela Caleo – the primary General Surgical Registrar who was completing a six month rotation at Toowoomba Hospital. She had only recently joined Dr Benny's team.
- Dr Marlon Perera – the senior Urology Registrar who was also the supplementary Surgical Registrar for Dr Benny (when available). As such, his attendance on Dr Benny's surgical ward rounds was subject to his full time commitments to the urology department. He also participated in the on-call General Surgery weekend roster as part of his accredited surgical training requirements and was on call over the period 20-22 February 2015
- Dr Dornan – another Surgical Registrar
- Dr Bronwyn Bryant – the surgical intern who was in her first rotation as an intern approximately four weeks post-university graduation. Dr Bryant was covering for another person on one of the other surgical teams and had not previously worked with Dr Caleo or Dr Perera.

Dr Bryant explained that surgical morning ward rounds are usually undertaken between 7:00am – 8:00am and completed quickly due to consultants and registrars commencing in theatre from around 8:00am. The evening ward round generally occurs between 6:00pm – 6:30pm.

It is the intern's responsibility (or that of medical students) to make the ward round entries in the patient record. The progress notes are routinely entered at the end of the ward round from notes taken by the intern or medical student during the ward round. The patient's chart is usually taken on the ward round and reviewed while the patient is being assessed. Dr Benny confirmed the ward round was usually led by one of the registrars under his supervision.

Dr Bryant explained that due to the more senior members of the surgical team being in theatre during the day, the surgical interns are responsible for managing patients on the ward until the surgical registrars return to the ward for evening ward rounds. However, the surgical registrars are available by phone and may return briefly to the ward during the day between surgeries. Consequently, in contrast to medical interns whose registrars remain on the ward during the day, surgical interns are expected to operate without direct supervision or access to immediate guidance and advice from their registrars.

On admission, Mrs Mead was noted to be independently mobile, elderly but fit and with no apparent cognitive deficit. Her weight is recorded as 47kg and she was noted as not tolerating a full diet.

Dr Bryant saw Mrs Mead at around 8:30am. Dr Bryant had not been involved in Mrs Mead's preoperative management other than to prescribe a fleet enema the previous evening. Mrs Mead's observations were stable and she was afebrile. Theatre was delayed.

Dr Caleo recalls meeting Mrs Mead that morning prior to surgery. She explained it was her usual practice to speak with the patient before surgery to explain what is planned and to answer any questions. She did not document this in the medical record (explaining this is something she generally would not do) and could not recall the details of their conversation other than she did not have any concerns about Mrs Mead at that time. She could not recall when she reviewed Mrs Mead's chart.

Dr Benny also recalls seeing Mrs Mead that morning. He says he observed reasonable peristalsis indicating she was obstructed and agreed there was a noticeable change from his assessment of her at the surgical outpatients review on 12 December 2014. He did not document his observations in the medical record though, advising that in many instances they do not document the preoperative assessment and proceed with the surgery as discussed.

The surgery

Mrs Mead arrived at the operating theatre suite at 7:31am; went to anaesthetics at 11:44am and into the operating room at 12:45pm. The surgery commenced at 1:15pm and finished at 4:45pm. She left theatre shortly after 5:00pm and arrived on the ward at around 7:00pm.

The surgical team comprised Dr Benny assisted by Dr Caleo and Dr Perera. Dr Thorne was the anaesthetist.

Mrs Mead was in surgery for three-and-a-half hours due to complications arising from the rectal tumour being more extensive than expected.

The right hemicolectomy commenced as a laparoscopic procedure but was converted to a laparotomy due to distended small bowel obstructing their vision. They undertook a right hemicolectomy first to resect the caecal mass (resecting

a section of the ascending colon) and create a side-to-side anastomosis. This is described as having gone as expected.

A gynaecology registrar was called in to theatre to examine a large pelvic mass arising from the uterus. It was thought to be a fibroid that did not require resection but rather for outpatient follow up. The existence of this mass had already been identified pre-operatively and is noted in the chart as far back as the medical oncology team's first review in early October 2014.

They then proceeded with the left anterior resection. The initial plan was to achieve good resection of tumour in the rectum but surgery revealed the tumour to be more extensive than expected with it having perforated and infiltrated the right lateral pelvic wall. Dr Benny sought a second opinion and assistance from another consultant surgeon, Dr Kumar. Both Dr Benny and Dr Kumar continued to operate with Drs Caleo and Perera performing the second assistant role. They achieved resection of the tumour and the rectum but were unable to completely remove the tumour with clear margins as originally intended. Finally a defunctioning colostomy was created at the left periumbilical region.

The inquest briefly considered the utility of pre-operative reimaging and whether this would have better informed Mrs Mead's surgical management.

While Professor Wall agreed with Dr Benny that Mrs Mead was ready for theatre when assessed on 12 December 2014, he was concerned Dr Benny could not be sure this would be the case in the next two months. Professor Wall felt given Mrs Mead had failed chemotherapy, the cancer was likely still growing and its metabolic consequences still developing. The intraoperative finding of distended small bowel confirmed this to be the case. Professor Wall favoured having a CT scan quite close to the surgery so he could advise the patient and cope with whatever was new from when they presented, and most importantly, assess the patient's prognosis. Dr Benny's evidence was pre-operative reimaging was not standard practice at Toowoomba Base Hospital and says CT scan would not have revealed the invasion of tumour to the pelvic side wall found during the surgery.

All members of the surgical team felt the surgery went as well as could be expected in the circumstances. Professor Wall described the time taken to be 'extraordinarily good' even though he felt a two-stage approach was the safest. I accept the total time in surgery was within internationally accepted time limits. As such, apart from the missed opportunity to have considered the merits of an alternative surgical approach, I am satisfied the decision to proceed to surgery at that time and the performance of the surgery itself was appropriate.

Dr Thorne also described Mrs Mead's intra-operative course as relatively stable for someone of her age and given the nature of the surgery. She had a modest but not unusual amount of pharmacological support to maintain her blood pressure.

At around 2:30pm her blood gases indicated a reduction in her potassium level to 2.6 mmol/L for which she was given an intravenous potassium chloride bolus

over an hour and a further bolus at around 4:00pm at which time her potassium level had improved slightly to 2.7mmol/L. Her potassium level had returned to 3.1mmol/L at post-surgery recovery. Dr Thorne ordered overnight intravenous fluids containing potassium.

At around 3:10pm, Mrs Mead was given 500ml of Albumex 4%. Dr Thorne explained the twofold purpose of this therapy as *...Mrs Mead had low albumin, and as I say, crystalloid fluids can leak out of the vascular compartment more readily and cause – and cause oedema, but in – also, there’s current argument in the literature at the moment that’s been present for the last four or five years about fluid restricting people having gastrointestinal surgery. There is some evidence that excess fluid inhibit the repair of the bowel and inhibit – forgetting about albumin – that they do better with a restricted fluid in – intraoperatively and postoperatively for the first 24 hours. That’s undecided. That’s still being – being debated, and there’s a couple of large studies there at the moment [indistinct] going to try and define, define the – the issue. You have anaesthetists in both camps at the – at the moment, so I – I’m having a halfway bet.*⁴ And further, *So my aim was to limit the crystalloid fluid both from an albumin point of view and from – also from a current literature point of view, and top up what I thought was a volume deficit with a – with a fluid that would stay in the intravascular component.*⁵

Mrs Mead’s pre-operative low albumin level influenced Dr Thorne’s consideration of her fluid management during surgery. He did not communicate this to the surgical team. He thought Dr Benny was well aware of the issue of low albumin. He agreed it was an issue he might normally communicate with the surgical team as an issue they need to consider in their post-operative management of the patient, but did not in this case probably because he was pre-occupied with Mrs Mead’s low potassium. I am satisfied nothing turns on Dr Thorne not having conveyed this to the surgical team.

Dr Perera completed the operation report with post-operative comments for Mrs Mead to be taken to the ward for ongoing care. Her analgesia was being delivered by a Patient Controlled Analgesic device. She had a nasogastric tube for free drainage with four-hourly aspirates, and a surgical drain in place. She had received prophylactic antibiotics during surgery and was to continue with antibiotic therapy due to the perforation.

Dr Perera also ordered deep vein thrombosis (DVT) prophylaxis 6/24 post-operatively. However, an order for Heparin was not written up until Mrs Mead was reviewed on an overnight Ward Call on 18-19 February. The Heparin was actually commenced on 19 February. None of the surgical team were able to explain how or why this delay occurred. While this was certainly not optimal clinical management, I am satisfied the delay in commencing the Heparin did not contribute to Mrs Mead’s death.

⁴ T1-39, 30 - 39

⁵ T1-40, 7-10

The significance of post-operative urine output, fluid shift and fluid balance monitoring

Much of the inquest focussed on the surgical team's management of Mrs Mead's episodic hypotension and persistent low urine output over the days following her surgery. My understanding of the significance of post-operative urine output, fluid shift and fluid balance management has been greatly assisted by the treating team and expert witnesses' explanations of the body's response to surgery, how that manifests and how it is managed.

In simplistic terms, the trauma of surgery triggers a physiological response whereby the body initially endeavours to retain water and salt, a response which lasts for a period of time after the surgery before the body starts to offload the fluid. Part of this response involves fluid shifts within the body including the shift of fluid from within the blood vessels (the intravascular space) to places outside the circulatory system (extravascular or third space loss) causing oedema and reducing the volume of blood (hypovolaemia), the latter affecting the patient's blood pressure and their ability to produce urine. It is not unexpected for a patient's albumin level to decrease as part of the body's post-operative inflammatory response. Low albumin impacts on a patient's ability to retain fluid intravascularly, making it more likely for the patient to develop oedema. In addition to fluid shifts within the body, the patient's fluid balance can be affected by blood loss, ooze and loss of fluids being drained off through nasogastric tubes and surgical drains.

Consequently, post-operative surgical management involves careful fluid balance management with there being a potentially fine balance between leaving the patient fluid deplete and fluid overloaded. As Dr Benny explained *...the way the body responds in – following surgery or trauma – so as I mentioned earlier, surgery is a form of controlled trauma – is to retain fluid in the vascular space. That's why most doctors tend to push two ways, overloading in the initial phase of fluid resuscitation, because we understand that in the initial phase the body will retain the fluid, but when it comes to the second phase of the body's response is that it will start to offload all the fluid that they originally – and that usually happens at about – after day 7. And when we go into that phase, it's very hard to catch up with the fluid management then. So most doctors – most surgeons will tend to overload the fluid towards the positive fluid balance at the initial phase of the resuscitation rather than going into a negative phase, knowing fully well that you might end up with a negative balance in the later phase of resuscitation, and once in that phase then it's very hard to resuscitate these patients accordingly.*⁶

Mrs Mead's low post-operative urine output overnight on 17-18 February

Mrs Mead arrived on the ward at 7:00pm. She had an indwelling catheter in place and was on hourly urine measures.

The inquest heard expert evidence that the generally quoted figure for hourly urine output is 0.5ml per kilogram in a patient with normal renal function. For

⁶ T3-63, 13

Mrs Mead, this equated to around 24mls per hour. However, it became clear during the inquest the surgical team were working on a lower 'acceptable' hourly urine output for Mrs Mead in the order of 15-20mls per hour. Dr Caleo explained it as, *and things vary, based on patients. So that's just a – that's an ideal number. And, as I said, that's – that's a normal adult, without any interventions. We've, I guess, we would not be surprised at a patient having a lower urinary output after a long operation. And – and with differences in fluid shifts within the body. And –and so it's not surprising to see a slightly lower urine output than the ideal number.*⁷

Once on the ward, Mrs Mead's urine measures were recorded as:

Time	Measure
7:00pm	30mls
8:00pm	50mls
9:10pm	10mls
10:00pm	7mls (bladder scan showed 13mls)
11:00pm	0mls
midnight	15mls

Nursing staff appropriately contacted Ward Call at around 10:00pm in response to her low urine output, resulting in Mrs Mead being given a bolus of 500mls of CSL (brand name for Albumin).

Day 1 Post-Op – Wednesday 18 February 2015

Mrs Mead's urine output continued to be low overnight:

Time	Measure
1:00am	6mls
2:00am	24mls
3:00am	14mls
4:00am	30mls
5:00am	15mls
6:00am	15mls
7:00am	17mls
8:00am	25mls
9:00am	15mls

Nursing staff again notified Ward Call at around 3:00am about Mrs Mead's low urine output. Her intravenous fluids were increased to six hourly (had previously been running at ten hourly). A nurse noted, *1/24 output still remains low. For team review today.*

She was seen during the surgical morning ward round at or around 9:00am. Dr Benny, Dr Caleo, Dr Perera, Dr Bryant and a medical student were present.

Dr Bryant recalls being told by the nurses prior to the ward round commencing that there had been an overnight Ward Call because Mrs Mead was

⁷ T1-103, 0-5

experiencing low urine output. She recalls being told Mrs Mead's urine output remained low that morning despite her having had fluid boluses overnight.

There is no reference in the progress note to Mrs Mead's low urine output overnight. However, having regard to the evidence of Dr Bryant and Dr Caleo, the low urine output is likely to have been discussed by the team because Dr Bryant noted a change to Mrs Mead's infusion rate from 80ml to 100ml per hour on the Intravenous and Subcutaneous Fluid Order Form.

Now knowing the surgical team were working on an acceptable urine output of 15-20mls, it is clear Mrs Mead's urine output measures were not of concern to them at that time.

The team noted her observations to be stable and she was afebrile.

The plan was for Mrs Mead's nasogastric tube to be removed and for her to start on sips of clear fluid (suggesting she was doing quite well post-operatively); to commence chest physiotherapy and incentive spirometry; to keep the surgical drain in place and to remove sequential compression devices (used to prevent deep vein thrombosis in the acute post-operative period).

Dr Thorne attended the ward at 10:05am to ensure the ward staff knew Mrs Mead's potassium level needed monitoring. Dr Bryant subsequently noted this request in the chart and wrote up an order for potassium replacement therapy.

From 9:00am, Mrs Mead's urine output was recorded as:

Time	Measure
10:00am	16mls
11:00am	20mls
11:50am	12mls
12:50pm	10mls
2:00pm	20mls
3:00pm	15mls
4:00pm	15mls
5:00pm	18mls
6:00pm	10mls

Nursing staff asked Dr Bryant to review Mrs Mead later in the day as her urine output had remained consistently low. Dr Bryant says she noted Mrs Mead was a very slight woman for whom she considered a urine output of 20ml per hour was not particularly low. Nevertheless she commenced Mrs Mead on 250mls normal saline at 5:30pm, initially at 100ml per hour and subsequently increased to 166ml per hour.

The evening ward round occurred at the usual time between 6:00pm – 6:30pm. It was attended by Dr Caleo, Dr Perera and Dr Bryant. Dr Bryant's progress note indicates they had noted Mrs Mead's low urine output during the day and the increase in fluid orders, and were happy to continue with that treatment.

The plan was for Mrs Mead to be commenced on a clear fluid diet the following morning; to continue receiving incentive spirometry; to be referred for chest physiotherapy; to be continued on intravenous fluids as charted and for her bloods to be checked in the morning.

By this time, Mrs Mead's hourly urine output had not reached above 18mls per hour since 2:00pm. Dr Caleo explained they attributed the low urine output at that time to Mrs Mead being intravascularly dry or deplete. On this basis, they considered fluid resuscitation was appropriate for her given her normal renal function.

She was noted to be feeling well, her observations were noted to be stable and she remained afebrile.

The surgical team were not concerned about the low albumin and its possible impact on Mrs Mead's recovery at this time. Dr Benny explained the rationale for this as, *not at the immediate –immediate time. There were concerns – I mean, our concern was to – my concern was that the urine output was most likely to – related to hypovolaemia rather than to the hypoalbuminemia, and then that's our understanding of low urine output following surgery. In the event that patient doesn't respond to a fluid challenge then you look at other options and that's when we would have consulted other teams for their opinion in managing this.*⁸

From 6:00pm, Mrs Mead's urine output was recorded as:

Time	Measure
7:00pm	22mls
8:00pm	11mls
9:00pm	12mls
10:00pm	10mls
11:00pm	12mls

At 9:30pm a Medical Emergency Team was called in response to a drop in Mrs Mead's blood pressure (88/55). A medical registrar, intensive care registrar and emergency registrar attended. She was noted to be asymptomatic and was written up for a bolus of 250mls of normal saline and to increase the infusion rate to 166mls/hour. Her low urine output of 10-25mls per hour was noted at this time.

Mr Mead's blood pressure improved with the fluids (105/50) but her urine output remained low. When seen again by Ward Call at around 11:00pm to assess her response to the fluid bolus, her blood pressure had increased to 115 systolic and she was noted look well. Ward Call noted her low urine output remained under 15mls and suggested continuation of her treatment as charted.

⁸ T3-59, 20

Mrs Mead's ongoing low urine output over 19-21 February
Day 2 Post-Op - Thursday 19 February

From midnight, Mrs Mead's urine output was recorded as:

Time	Measure
Midnight	9mls
1:00am	15mls
2:15am	10mls (bladder scan noted 0mls)
3:10am	11mls
4:10am	9mls
5:55am	6mls
6:30am	20mls
7:30am	None recorded
8:00am	10mls

Nursing staff notified Ward Call of Mrs Mead's low urine output after the 2:15am measure was taken.

The medical records shows the Registered Nurse caring for Mrs Mead that night, RN Therese Comber, contacted Ward Call about her on at least three occasions over a four hour period, the third contact was in response to Mrs Mead's ongoing low blood pressure at 3:52am. RN Comber explained she did not activate a Medical Emergency Team call as she was in frequent contact with the doctor concerned.

Ward Call reviewed Mrs Mead at 3:40am, noting her blood pressure had been 105-87 systolic over the previous five hours and her urine output as 10-15mls, but mostly 10mls/hour since around 8:00pm. She was noted to be asymptomatic and appeared well. The surgical drain was full of haemoserous fluid. She had some mild pitting oedema in her hands but none in the lower limbs. Her hypotension and low urine output were attributed to reduced intravascular volume post-op and she was written up for 250mls bolus of CSL (Albumin) and then to increase her intravenous rate to 166mls/hr. It was at this review that Dr Perera's order for DVT prophylaxis was first written up.

At 7:30am, Dr Bryant ordered one litre of intravenous normal saline at an infusion rate of 166ml/hr.

Mrs Mead was reviewed on the morning ward round. Dr Benny, Dr Caleo, Dr Bryant and a number of medical students were present. The progress note references the overnight MET call and Mrs Mead's urine output of ~10mls/hour. Her blood pressures was noted to be 93/49, her other observations stable and she was afebrile.

The plan was for Mrs Mead to be upgraded to clear fluids; to maintain her intravenous therapy and fluid balance aiming for a urinary output of greater than

15mls per hour. She was to be encouraged to mobilise and continue incentive spirometry and for follow up with chest physiotherapy.

The surgical team had no major concerns about Mrs Mead that morning, noting she was 'progressing well'.

From 9:00am, Mrs Mead's urine output was recorded as:

Time	Measure
9:00am	25mls
10:20am	None recorded
11:00am	8mls
Midday	10mls
1:00pm	None recorded

Dr Bryant recalls someone on the ward, probably a nurse, raised with her at some point during the day that Mrs Mead had ongoing low urine output. She did not document this in the chart and could not recall what she did in response to this information. However, she says she must have assessed Mrs Mead as being 'dry' because at around 1:00pm she ordered 500mls of normal saline at 250mls/hour and then one litre of normal saline at 200mls/ hour at 1:30pm.

Dr Bryant recalls having a telephone discussion with Dr Lindsay Haase, a Medical Registrar from the General Medicine Team some time during the day, possibly because she could not get hold of Dr Caleo. She did not make an entry in the chart about this interaction and could not recall the detail of their conversation. While Dr Haase has no recollection of speaking with Dr Bryant on this occasion he acknowledges it may have occurred because it was not uncommon for surgical interns to ask him opportunistically for advice.

The significance of this interaction lies in Dr Bryant's impression that Dr Haase had agreed to review Mrs Mead the following day, something she later conveyed to the surgical team during the evening ward round and documented in the chart.

Dr Bryant subsequently ordered 40mg of IV Frusemide (Lasix) presumably in response to advice she received from Dr Haase. Dr Caleo later reduced the Frusemide dose to 10mg because, *I was concerned that given that dose and that there was still a question about being hypovolemic clinically, that a dose of 40mg would reduce her intravascular volume even more, which, again, like I said, would effect things like her blood pressure, and ultimately, then, effecting her end-organs such as her kidneys even more so.*⁹ The IV Frusemide was given at 4:08pm.

Having since reviewed the patient record Dr Haase assumes Dr Bryant may have described features of peripheral oedema and fluid overload to him, which may have prompted him to suggest Frusemide at that time. He says if it had been brought to his attention that Mrs Mead was intravascularly dry, his

⁹ T1-113, 18-22

management might have been slightly different (namely the earlier use of Albumin and more judicious fluid administration). In so saying, Dr Haase says he would have discussed this approach with his Consultant before making any firm recommendation in that regard. Had he been asked to come to see Mrs Mead he would have been able to make a more thorough assessment of her intravascular and extravascular fluid status and would have sought consultant advice.

While some of the surgical and medical witnesses questioned why a dehydrating agent such Frusemide would be given when the clinical concern was intravascular depletion, the consensus was that a low dose of 10mg of Frusemide was not problematic as a small testing dose in the circumstances.

Dr Haase diligently kept a contemporaneous list of all the surgical patients he was asked to formally review. Mrs Mead was not on his list leading him to say with a high degree of confidence he was never formally asked to review her. He explained his usual practice when giving informal advice to interns is to end the conversation by advising that a medical review was an option and that the surgical team could request one. He thinks this was misconstrued and is why Dr Bryant subsequently referenced him in the evening ward round entry that evening.

I am satisfied that Dr Bryant did speak with Dr Haase and this conversation is what informed Dr Bryant's order for Frusemide 40mg. Further, I am satisfied this conversation did not constitute a request or agreement for a formal medical consult, and Dr Bryant was mistaken in her impression otherwise.

Dr Denman, the Medical Consultant who later became involved in Mrs Mead's care, confirmed it is a common occurrence in most hospitals for junior members of other teams to seek informal assistance or input or recommendations from medical team members on issues arising in the management of patients under their care. He reinforced that such communication ought not be discouraged as it is a necessary function of the day to day running of a busy hospital. I agree.

Over the course of the afternoon, Mrs Mead's urine output was recorded as:

Time	Measure
2:00pm	10mls
3:10pm	0mls
4:10pm	5mls
5:00pm	5mls
6:00pm	37mls

A nursing entry made at 1:15pm notes Mrs Mead continued on IV fluids for low urine output and her blood pressure remained low, though she was asymptomatic. She had mobilised to the shower with assistance and was sitting out of bed, comfortable.

Mrs Mead was reviewed on the evening ward round. Dr Caleo and Dr Bryant were present. Dr Bryant's entry in the chart noted Mrs Mead's low urine output was persisting and had been as low as 5ml per hour at times. Her observations were noted to be stable and she was afebrile. There is no reference to her blood pressure.

The plan was to continue the intravenous fluids and for Ward Call to re-check Mrs Mead in two hours and if her urine output remained low, the Frusemide was to be repeated. Further, if still low, a bladder scan was to be performed before any further doses of Frusemide were given and for the Medical Registrar to be contacted. It is in this entry that Dr Bryant noted Dr Haase's 'agreement' to review Mrs Mead the following day.

Dr Caleo recalls Dr Bryant telling her about her phone conversation with Dr Haase earlier that day including his suggestion to give 40mg of Frusemide, to potentially consider Albumin if they thought Mrs Mead required it and that he might review her.

Dr Caleo says she wanted to continue Mrs Mead's intravenous fluids as a precaution primarily due to her concern that she was intravascularly dry. While aware of the 'agreed' medical review the next day, she says she did not think it was needed at that time and wasn't expecting it to happen, *At the time I didn't think that it was necessary. I mean every single one of our post-operative patients, at some stage, has fluid replacement. Most of the time that's stopped fairly soon after their operation. But in patients that have large operations, fluid balance and managing their input and output is based on us as well. You know, that's part of our job to manage the post-operative patient. We don't rely on the medical registrars for that.*¹⁰

Mrs Mead received a further 10mg dose of IV Frusemide at 8:00pm that evening, presumably after Ward Call review though there is no medical entry in the chart of this attendance. She appears to have responded well to the Frusemide with a significant increase in her urine output into the night:

Time	Measure
7:00pm	25mls
8:10pm	100mls
9:00pm	120mls
10:00pm	45mls
11:00pm	80mls
Midnight	21mls

According to the 24 hour fluid summary, by midnight on 19 February, Mrs Mead was in a positive fluid balance of around 9.9 litres (consistent with her significant weight gain from 47kg to 56kg). When asked to consider the significance of this, each member of the surgical team indicated in essence this was but one factor in their overall clinical examination and assessment of Mrs Mead who they considered, and were treating as, intravascularly dry.

¹⁰ T1-115, 38-44

When asked to consider the significance of Mrs Mead's positive fluid balance, Dr O'Donoghue indicated he would not expect someone having this type of surgery to have a positive fluid balance of that magnitude at that stage post-operatively. He observed that increasingly positive fluid balance, certainly in intensive care, is associated with a poorer outcome, likely reflecting the severity of the underlying condition rather than necessarily being purely a complication of fluid.

Day 3 Post-Op – Friday 20 February 2015

Unfortunately, Mrs Mead's urine output measures were not recorded after midnight until 7:00am the next morning, 20 February, when the bag containing 120mls was emptied.

As well as no urine output being recorded overnight; there are no nursing progress notes recorded for shift.

RN Therese Comber was rostered on that night shift, commencing at 10:45pm. RN Comber was rostered to work with an Enrolled Nurse Natalie Tschumy that shift.

While RN Comber had cared for Mrs Mead the previous night shift, she says EN Tschumy was allocated to her this shift and consequently RN Comber was not directly involved with Mrs Mead's care that night.

RN Comber confirmed the assessment and recording of observations and urine output is within an EN's scope of practice and that if there are findings outside of the normal parameters, the EN is to consult with the RN.

RN Comber confirmed the notations on the fluid balance chart of normal saline at 2:30am and the emptying of the IDC at 7:00am were her writing. She could not recall what happened that shift but suggested EN Tschumy had not undertaken the hourly urine measures during the night and upon reviewing Mrs Mead in the morning, RN Comber made the retrospective entries on the fluid balance chart. She says she wrote on the next fluid chart *1/24 IDC measures* to remind oncoming staff that Mrs Mead was on strict hourly measures. This was because she had noticed they weren't done the night before.

EN Tschumy was not asked to provide a statement or called to give evidence to explain why the hourly urine measures were not recorded after midnight.

Regardless of how this came to happen, it hindered a proper assessment of an important aspect of Mrs Mead's post-operative recovery being actively monitored by the treating team.

Thereafter, Mrs Mead's urine output was recorded as:

Time	Measure
7:00am	120mls (with notation, 'IDC emptied')
8:00am	5mls

Mrs Mead was reviewed during the morning ward round. Dr Caleo, Dr Perera and Dr Bryant were present.

Her observations were noted to be stable and she remained afebrile. The team noted her urine output had responded well to the intravenous Frusemide 10mg overnight but had again slowed down to 5ml per hour. They also noted her surgical drain output was increasing and looked watery with a light pink tinge. On examination, she was noted to have quite a lot of subcutaneous fluid in her arms and legs with some pitting oedema. She had some bibasal soft crepitus in the lower part of her lungs. Her stoma was pink and healthy but there had been no wind or bowel output and she had sluggish bowel sounds.

The plan was for her to have a further stat doses of 10mg of IV Frusemide and to continue her hourly urine measures. Her bloods were to be checked again that day and a bowel chart was to be commenced. She was to continue with a clear fluid diet and to continue receiving incentive spirometry and chest physiotherapy.

Dr Bryant also noted, *notify any concerns, Med Reg d/w yesterday possible review today*. When asked about this at the inquest, Dr Bryant confirmed she was expecting Dr Haase to come when he could, not if he could, and she had communicated to Dr Caleo an expectation that he was coming at some stage when he could. We now know this is not the case. Dr Bryant says she knew that if the Surgical Registrar thought Mrs Mead needed urgent medical review, they could contact the Medical Registrar, Registrar to Registrar.

Mrs Mead received 10mg IV Frusemide at 9:00am which again achieved an increase in her urine output:

Time	Measure
9:00am	30mls
10:00am	80mls
11:00am	60mls
Midday	20mls
1:00pm	15mls
2:00pm	15mls

A nursing entry made at midday indicates the surgical team were notified of the drop in urine output and ordered another dose of 10mg IV Frusemide. Mrs Mead was noted to be leaking fluid subcutaneously from both arms at this time. When seen by the stoma nurse around an hour later, Mrs Mead was unable to assist with the stoma appliance change 'due to grossly oedematous hands'.

She received a further dose of 20mg of IV Frusemide at 2:15pm, followed by a further 20mg dose at an unmarked time. This achieved a significant increase in her urine output:

Time	Measure
3:00pm	245mls
4:00pm	300mls
5:05pm	190mls
6:10pm	100mls

Mrs Mead was reviewed on the evening ward round. Dr Caleo and Dr Bryant were present.

Mrs Mead's observations were noted to be stable and she remained afebrile. She was considered to have responded very well to the doses of Frusemide she received that day. Her subcutaneous fluid had reduced by that evening. There was still no stoma activity.

This was reassuring to Dr Caleo who says she was hopeful Mrs Mead was starting to turn the corner.

The plan was for continued monitoring of urine output and to consider giving her Albumin if it dropped again. Dr Bryant says she raised the Albumin with Dr Caleo who agreed it was worth considering. In anticipation of this occurring, Dr Bryant wrote up an order for 20% Albumin and consented Mrs Mead for its administration if needed. The order was subsequently struck out on the medication chart indicating the team ultimately decided not to proceed with the Albumin.

Mrs Mead was to continue with a clear fluid diet, to be encouraged to mobilise and for her potassium, phosphate and magnesium levels to be monitored over the weekend.

Thereafter Mrs Mead's urine output was recorded as:

Time	Measure
7:00pm	120mls
8:00pm	25mls
9:00pm	10mls
10:10pm	0mls
11:00pm	Not recorded
Midnight	90mls

Day 4 Post-Op - Saturday 21 February

From midnight, Mrs Mead's urine output was recorded as:

Time	Measure
1:00am	33mls
2:00am	34mls
3:00am	25mls
4:10am	12mls
5:05am	10mls
6:30am/7:30am	45mls

At some time during the early hours of 21 February (time not documented), Mrs Mead was reviewed by Ward Call Dr Ryan due to her low urine output .

Dr Ryan documented a comprehensive examination, noting Mrs Mead's observations as stable (blood pressure 140/60, heart rate 80) and she remained afebrile. Dr Ryan noted no significant cardiac or renal impairment, referencing essentially normal echocardiogram results from 26 November 2011 and essentially normal renal function on 20 February 2015. Her chest was clear. Both arms were swollen with pitting oedema and bilateral pitting oedema to the knees.

Dr Ryan's impression was Mrs Mead was intravascularly depleted with significant third spacing of fluid secondary to decreased oncotic pressure. However, noting that she was haemodynamically stable with good renal function biochemically and showing signs of good end organ perfusion, Dr Ryan was comfortable with her then current urine output.

Dr Ryan reduced her intravenous fluids from 3-4L to 2L based on her weight. Dr Ryan noted protein diet/total parenteral feeding as a 'long term fix' and recommended Albumin for persistent hypotension or elevated creatinine. She was also for a daily weight.

Mrs Mead was reviewed on the morning ward round by Dr Perera and a different surgical intern. They noted her upper and lower limbs to be 'oedematous +++', the stoma was still not working but was pink and healthy and the surgical drain still had high output. Her observations were stable and she remained afebrile. Her urine output was noted to be 'good at present'.

Her right arm was very oedematous with an area of redness above the intravenous cannula site, this prompting a decision to relocate the cannula to her left arm.

The plan was for Mrs Mead to receive another dose of 20mg IV Frusemide, continue hourly urine measurements and to review her again in the evening. Dr Perera could not recall why he ordered the Frusemide but suggested he was following the treatment plan recommended by the team. He was comfortable she was not fluid overloaded at that time because she did not have an elevated jugular venous pressure.

Ultrasound imaging of Mrs Mead's arms performed that day showed bilateral deep vein thrombosis of the cephalic veins. Imaging of the upper arms was compromised by her oedema but there were no obvious clots above the elbow region on either side. Dr Perera advised the surgical intern to seek medical advice about how to manage the bilateral upper limb DVT.

The surgical intern subsequently spoke with the on-call Medical Registrar, Dr Alexandre David. Dr David recalls being contacted by phone at around 5:00pm that day by the Surgical Intern who was seeking input regarding the management of Mrs Mead's bilateral upper limb thromboses.

Dr David did not attend to examine Mrs Mead at this time. He advised the Surgical Intern to commence Mrs Mead on therapeutic anticoagulation (Clexane 1mg/kg BD) provided there were no contraindications to do so, and recommended she discuss this with the Surgical Registrar before commencing treatment. He also recommended that Mrs Mead undergo an ultrasound of her lower limbs to exclude any lower limb DVTs. He told the Surgical Intern he would review Mrs Mead with the Medical Consultant the following day.

The Surgical Intern then discussed this with Dr Perera who agreed with this plan.

For an unknown reason, the urine measures were not documented hourly over the course of the day. Mrs Mead demonstrated a good response to the Frusemide she received at 9:00am that morning but her urine output slowed again after 12:30pm:

Time	Measure
8:30am	30mls
10:40am	350mls
12:30pm	200mls
2:00pm	40mls
4:30pm	25mls
6:00pm	70mls
8:00pm	35mls
9:10pm	25mls
10:05pm	10mls
11:00pm	45mls

Day 5 Post-Op - Sunday 22 February

From midnight, Mrs Mead's urine output was recorded as:

Time	Measure
Midnight	50mls
1:10am	38mls
2:00am	30mls
3:00am	35mls
4:00am	37mls
5:00am	31mls
6:00am	29mls
7:00am	0mls
8:00am	11mls
9:00am	11mls
10:00am	0mls
11:00am	5mls
Midday	1ml
12:50pm	'off ward -> U/S'
2:00pm	10mls
3:00pm	2mls
3:10pm	-
4:30pm	120mls
5:30pm	10mls
6:30pm	6mls
7:30pm	13mls
8:45pm	6mls
9:30pm	-
9:45pm	15mls

The observation chart shows a drop in her blood pressure after 9:00pm the previous evening, dropping to 83/52 at 11:00am, after which time it hovered in the 90s systolic until 9:00pm that evening when it was back up to 120/60.

The first entry in the progress notes on Sunday 22 February is made by the medical team comprising Dr David and thoracic physician, Dr Ross Sellars, who was assisting the on-call general physician with patient reviews that day. They attended Mrs Mead briefly at around 11:00am. They both understood their attendance at this time to be limited to following up on the advice Dr David had given the previous day regarding anticoagulation therapy – it was not a full medical review and to their knowledge, they had not been requested to undertake one at that time. They confirmed the need for Mrs Mead to have anticoagulation while she had active malignancy and requested an ultrasound scan of her lower limbs. Dr David's notation indicates their willingness to review further if requested.

As it turns out the surgical team had decided earlier that morning to request a formal medical review of Mrs Mead's fluid status; they just hadn't documented that request in her chart prior to Dr David and Dr Sellars seeing her at 11:00am.

A nursing entry made at 2:20pm includes the notation, *Obs stable. Nil c/o pain or nausea. Tolerating small amounts of FF.IDC remains insitu on 1/24 measures – very poor output – notified surg reg doing the rounds, instructions were for medical R/V. Urine output remained low with no instructions from the medical team, On ward call R/V – still awaiting intervention. Pt arms leaking serous fluid. Pt wounds + around drain site leaking serous fluid ++. Dx redressed with 2x exudrys this am. Drain bag changed @ 12mD – 600mls serous fluid discarded. Nil output in the stoma this shift.*

This nursing note is followed by a retrospective entry by the surgical team following their review of Mrs Mead at around 9:00am that morning requesting formal medical review of her fluid status. This entry is accompanied by a notation indicating it was made in the 'PM'. This means Mrs Mead was seen by Dr Sellars and Dr David earlier that day without the benefit of this information.

The surgical morning ward round was undertaken by a different Surgical Registrar, Dr Neubery, with the same surgical intern that day. Mrs Mead's observations were noted to be stable and she remained afebrile. She reported feeling well with no shortness of breath. The oedema, though reducing, was still significant. Her urine output was noted to be low at ~10ml per hour for the past two hours while on intravenous fluids at an infusion rate of 62ml per hour. She is noted to have been responsive to her last dose of Frusemide the previous morning. The stoma was still not working. There was some serous discharge from the surgical wound and 500ml serous fluid had drained between 2:00pm the previous day and 9:00am that morning.

The plan at that time was for medical review of her fluid status, to change the surgical drain bag and await the lower limb ultrasound. This is the first time a formal medical review was requested.

Mrs Mead was eventually reviewed by Dr David at 9:00pm that evening. He could not recall what time he had been contacted and asked to review her. He was asked to review her low urine output, fluid overload and fluid balance management. He undertook a full medical examination.

He recalls she was alert and reported feeling well but mentioned she was not eating very much. He noted she was not short of breath and she did not have a cough. Clinically she appeared well and was comfortable.

Dr David noted that while she had been hypotensive earlier in the day with systolic blood pressure in the '90s, she was normotensive at that time (120/60) and her observations were within normal limits – heart rate 90 and regular; respiratory rate 60 and oxygen saturation 97% on room air. She was afebrile.

Her jugular venous pressure was not elevated and her chest was clear with no crepitations.

She was fluid overloaded with pedal oedema to above the knees as well as sacral oedema. Her weight was 56kg (up from 47kg pre-operatively).

He examined her blood test results, noting her white cell count was normal, as were her major electrolytes and liver enzymes. However, she was significantly hypoalbuminaemic in that her Albumin level was unrecordably low (less than 15g/L).

He noted 'declining renal function', a notation he later explained that while the results were still within the normal range, the creatinine had risen slightly from 57 to 70 that day and her glomerular filtration rate (eGFR) was also potentially representative of a decline in renal function (74, down from 89). In other words, there was a shift in her renal function.

He noted her urine output as *>20mL today on average >40 +ve 1000mL yesterday* and documented urine output acceptable at >20mL per hour on average.

His clinical impression was that Mrs Mead was *fluid overloaded and hypoperfusing kidneys but not clinically in heart failure, ?hypoalbumaemia contributing.*

Dr David recommended a number of interventions including ceasing intravenous fluid maintenance, fluid restriction (1.5L per day), strict fluid balance monitoring, 20% Albumin, accept urine output greater than 20mls/hr, avoid boluses for urine output and to consider Albumin if needed (for hypotension, persistent low urine output). He ordered urine PCR testing and also recommended she be given a high protein diet as a means of managing the hypoalbuminaemia.

Dr David describes Mrs Mead's fluid status as complex given she was fluid overloaded and intravascularly dry. The intravascular depletion was impacting on her renal perfusion resulting in low urine output. He considered her low albumin was playing a role in this situation, and not unexpectedly so given her malignancy, malnutrition and post-surgical state. The fact she had received multiple fluid boluses of crystalloid fluid without improving her urine output suggested to him she was third spacing her fluid. With this in mind, his intention was to improve her renal perfusion by improving her intravascular volume by replacing the albumin to increase oncotic pressure and help her conserve fluid intravascularly.

Dr David explained that while theoretically it makes sense to give Albumin to a patient with low albumin, there is no convincing evidence in the clinical literature to suggest Albumin is more beneficial than another fluid, such as a crystalloid like Hartmans. He says while there was no evidence the Albumin was going to make a difference but there wasn't anything else he could think of that would be appropriate in the situation.

On this point, Dr O'Donoghue confirmed current clinical literature, citing both the SAFE¹¹ and ALBIOS¹² studies, has shown no objective benefit in the administration of Albumin in terms of reduced mortality, reducing the progression to renal failure or reducing the incidence of pulmonary oedema (considered potentially one of the complications of excess non-albumin type fluids).

There were no hourly urine measures recorded after 9:45pm that night.

The observation chart shows a drop in Mrs Mead's blood pressure over an hour after Dr David's review, decreasing to the 80s systolic by 10:00pm. A notation on the observation chart at this time indicated the Medical Registrar was at the bedside and advised 'no Code Call' but to continue the Albumin infusion and recheck Mrs Mead in an hour. Her blood pressure was back in normal range when taken again 10 minutes later.

Day 6 Post-Op – Monday 23 February 2017 - Mrs Mead is identified as critically unwell and transferred to intensive care

From midnight, Mrs Mead's urine output was recorded as:

Time	Measure
Midnight	0mls
1:00am	35mls
2:00am	0mls
3:10am	30mls
4:00am	5mls
5:00am	0mls
6:00am	25mls
8:00am	15mls
9:00am	15mls
9:40am	10mls (with notation 'IDC removed')

A nursing entry made at 4:10am indicates Ward Call were notified to review Mrs Mead for her urine output (<30ml/hr) and her low blood pressure (94/48). She was noted to be comfortable with no complaints of dizziness, headache, dry mouth, nausea or excessive thirst at that time.

She received intravenous antibiotics at 6:00am.

Medical Ward Call, Dr Manley, reviewed Mrs Mead at around 6:35am. By this time, her blood pressure had improved to 110/68 and her heart rate 85 beats per minute (up from 74). Her respiratory rate was 14 and her oxygen

¹¹ S. Finfer (Chair), R. Bellomo, N.Boyce, J. French, J. Myburgh, and R. Norton. *A Comparison of Albumin and Saline for Fluid Resuscitation in the Intensive Care Unit*, 350:2247-56, New Engl J Med 2004

¹² *Albumin Replacement in Patients with Server Sepsis or Septic Shock*, 370:1412-21, New Engl J Med 2014

saturations were 97% on room air. She was afebrile. The urine PCR test results were still pending at this time. Dr Manley's clinical impression was the low urine output was secondary to low PO (per oral) fluids and she was clinically fluid overloaded, with reference also made to her hypoalbuminemia.

The plan was to give a further stat dose of Frusemide 20mg and to monitor renal function. She was for strict fluid balance monitoring and to aim for urine output over 20ml/hour. She was to be given Albumin 20% over four hours and for the day team to consider Medical Registrar review once blood test results were available.

Dr David recalls having mentioned Mrs Mead to the incoming Medical Registrar, Dr Andrew Carr, during the medical team morning meeting. He says he told him the surgical team had asked him to formally review her the previous evening and, although he couldn't remember the specifics of their conversation, says he likely gave Dr Carr a brief overview of her status and the plan he put in place. At that time, Dr David's expectation was for his management plan to progress slowly in reversing her complex fluid status. Consequently he did not consider there any need for Dr Carr to review her urgently that day, given she would be seen by the surgical team that morning in any event.

Mrs Mead was reviewed by the surgical team on the morning ward round. Dr Benny, Dr Dornan, Dr Perera, Dr Yong, Dr Bryant and a medical student were present.

Mrs Mead was sitting up in bed and alert at this time. The only concern noted by the surgical team was a high output of haemoserous fluid in the surgical drain. There is no mention of the attendances by either Dr David or Dr Manley, the plan recommended by Dr David or Dr Manley's recommendation to consider Medical Registrar review.

The plan was for Mrs Mead to commence on a light diet, for her surgical drain to be removed and for an ultrasound of the lower limbs.

The team also ordered for the IDC to be removed. In practical terms, this meant there was now no way to accurately record Mrs Mead's hourly urine production. The IDC was removed at 9:30am.

The surgical team was asked to explain why they ordered the removal of the IDC when the medical team had recommended strict fluid balance monitoring. Dr Perera could not recall the team's reasoning. Dr Benny explained it was based on the high risk of Mrs Mead developing a catheter infection given she was going on seven days post-operative. He relied on this decision being consistent with a Royal College of Surgeons protocol which recommended the IDC should be removed as early as possible to reduce the incidence of urinary tract infection. As Mrs Mead was independently mobile and had been to the shower and back, he thought she was someone they could rely on to have the IDC taken out and output measured in a bedpan.

The reasonableness of this decision was not put to the experts for consideration.

Clearly this strategy was never going to meet the medical team's recommendation for strict fluid balance monitoring with a view to aiming for urine output to be above 20mls per hour. While I accept the general rationale behind removing IDCs as soon as possible to minimise the risk of urinary tract infection, I find Dr Benny's explanation most unconvincing in circumstances where there was an unambiguous clinical need and rationale for strict fluid balance monitoring including hourly urine measures, put in place following formal medical review. On the available evidence, I can not be satisfied the surgical team took this action having given considered thought to the medical team's recommendations.

In her statement, Dr Bryant says she had never seen a patient with such third spacing as Mrs Mead, and nor has she seen a patient like that since. She says she did not feel comfortable voicing her concerns to the team when the team's overall impression was one not of that much concern. This is understandable given her relative inexperience of four weeks as a doctor at the time she was involved in Mrs Mead's care. There is no evidence of systemic communication issues within the surgical team.

Mrs Mead was seen by the physiotherapist at 9:00am. She reported reduced mobility due to fatigue. She became dizzy when asked to stand and mobilise; this settled when she sat down. Her blood pressure was 110/70.

The 9:50am observations indicate nurses were unable to get a blood pressure reading but her other observations were all within normal range at this time.

An entry by the stoma nurse made at 11:00am notes that Mrs Mead was too sick for stoma education that day. Dr Dornan was contacted for approval to administer glycerol suppositories.

Mrs Mead was taken for an ultrasound scan of her lower limbs at 11:40am. In the early afternoon she was seen by the occupational therapist for review of a pressure area noted by the physiotherapist, and then showered with assistance.

Dr Bryant says she approached Dr Carr for assistance as she became concerned about Mrs Mead as the day progressed. She was worried about the lack of stoma activity and she did not know how to manage the third spacing. She told the court, *I think she had deteriorated from the morning ward round, but not in a great way. I think I mentioned I was already – had some concerns growing, especially that she still wasn't having any oral intake at all and we were still just giving her fluids.*¹³

Dr Carr reviewed Mrs Mead at around 3:15pm and documented a comprehensive clinical examination. He noted she was frail and looked unwell.

¹³ T1-89, 38

She was quite confused and hallucinating. Her blood pressure was 105/60 and heart rate 90, with a notation she had been tachycardic for ~48 hours. Her left arm and drain site were oozing fluid.

He queried why the IDC had been taken out noting *IDC out today ?why very poor FB? oligoaneuric today*. He also queried why she was on antibiotics noting she was afebrile and *WCC w (L) shift*.

Dr Carr considered she had delirium with possible causes including sepsis, lower respiratory tract infection, abdominal cause or urinary tract infection. He noted her 'profound hypoalbuminaemia', changing electrolytes and poor urine output. He was concerned that there had been no bowel activity for six days and noted ongoing abdominal tenderness. He recommended a delirium screen (chest x-ray, urine microscopy +/- blood count), an abdominal x-ray, electrolyte replacement and intravenous fluids (only if she was haemodynamically compromised).

Dr Carr discussed Mrs Mead's condition with Dr Denman. While Dr Denman could not recall when Dr Carr spoke to him, he does recall having attended Mrs Mead more or less straight away.

Dr Denman's entry in the chart at 5:40pm notes *this lady is seriously ill. She is shocked, delirious and has a silent abdomen*. He says he could see from standing at the foot of the bed that she was 'in trouble'.

Dr Denman immediately relayed his findings to the surgical team, suggested fluid boluses and an indwelling catheter was reinserted. He arranged for urgent ICU review and recalls the intensivist attended very promptly. Dr Benny had gone to ICU and arrived on the surgical ward with consultant intensivist, Dr Manimozhi Vellaichamy, while Dr Denman was still there.

Dr Denman told the inquest, looking at Mrs Mead then he expected she might not emerge from ICU.

Mrs Mead was admitted to ICU at around 6:00pm. She was noted to be in profound shock, pale and mottled with low haemoglobin, very dehydrated with very minimal urine output with worsening kidney function, was coagulopathic, had low blood glucose and mild metabolic acidosis but was maintaining her airway. Dr Vellaichamy's clinical impression was severe sepsis, possibly urosepsis/intra-abdominal sepsis, with multiorgan dysfunction. Mrs Mead was immediately treated with aggressive fluid resuscitation with 4% Albumin, glucose, broad spectrum antibiotics and commenced on continuous dialysis. Blood and urine cultures were sent to pathology and her electrolytes were replaced and she received a blood and plasma transfusion. Dr Vellaichamy ceased the Clexane as she considered it unnecessary given the ultrasound scan had shown only cephalic vein thrombosis below the elbow meaning Mrs Mead did not need therapeutic anticoagulation.

Mrs Mead was seen by Dr Benny and Dr Perera at 6:40pm in the ICU. They ordered a CT scan of the abdomen and pelvis which was performed at 7:45pm.

The CT scan showed grossly thickened bowel loops but no evidence of anastomotic leak or abdominal sepsis.

Efforts to insert a femoral vascath under ultrasound guidance were unsuccessful due to the femoral veins being obscured by gross oedema.

Was there a delay in diagnosing Mrs Mead's urosepsis?

The inquest examined whether Mrs Mead's urosepsis could or should have been diagnosed sooner.

Dr Benny says Mrs Mead appeared alert, was sitting up and had already been to the shower when he saw her on the morning ward round. There was no indication of deterioration or that she was already septic.

Dr Denman agreed there were no outward or clinical signs of sepsis at the surgical review that morning. He suggested Mrs Mead may have had a silent sepsis brewing that a medical consultant may not have identified at that point.

Dr Vellaichamy provided a very helpful explanation of what Dr Carr noted in relation to Mrs Mead's blood test results as *WCC w (L) shift*. While the white cell count had not risen on 22 February, there was a left shift of neutrophils identifying infection. She advised there was nothing particularly indicative that Mrs Mead was developing sepsis before 23 February - her white cell count was not elevated, she did not have a high temperature and her vital signs were reasonably stable. Dr Vellaichamy felt Mrs Mead's condition declined rapidly during the day on 23 February and this reflected her succumbing to a very aggressive infecting organism.

Dr O'Donoghue agreed that Mrs Mead's blood results on 22 February, in particular the white cell count and neutrophils, were non-specific and did not point to sepsis. He too considered the sepsis developed between the time of the surgical morning ward round and Dr Carr's mid-afternoon review, advising urinary tract sepsis can develop very quickly.

There is no evidence to suggest removal of the IDC precipitated the acute deterioration; rather, there was non-specific change indicating infection in the pathology results from 22 February as noted by Dr Carr.

I am satisfied Mrs Mead's deterioration that day was acute and there were no clinical or outward signs of sepsis at the time she was seen by the surgical team on the morning ward round. Dr Bryant is to be commended for acting on her concerns about a change in Mrs Mead's condition after that time.

Days 7 & 8 Post Op – Tuesday 24 & Wednesday 25 February 2015 – Mrs Mead's management in ICU

The surgical team reviewed Mrs Mead in ICU during the morning ward round. Dr Benny, Dr Dornan and Dr Bryant were present. She was noted to be stable and improving. The surgical plan was for her to continue to be managed as per

the ICU plan and to commence total parental nutrition and continue with a light diet.

Mrs Mead was reviewed by Dr Indranil Chatterjee, consultant intensivist, that morning. She was formally diagnosed with septic shock secondary to urosepsis after her blood and urine cultures revealed she had *Pseudomonas septicaemia*. She was noted as being *coagulopathic, acidotic, requiring dialysis for anuria, grossly fluid overloaded extravascularly and dry intravascularly, poor nutritional status, episodes of hypoglycaemia on 10% dextrose infusion*. She was cardiovascularly stable. Although she had some crepitus at the base of lungs, her blood gas levels were good on minimal oxygen support. She was afebrile. Her abdomen was soft and the stoma was working. In comparison to her condition on admission to ICU the previous evening, Mrs Mead was improving.

The plan was to reduce her oxygen requirement to nasal prongs, continue dialysis, start total parenteral nutrition, continue antibiotic therapy and monitor her bloods and coagulation profile.

Mrs Mead's condition continued to improve over the next 24 hours though she still needed dialysis as she remained anuric. When reviewed by the ICU Registrar that evening, she was noted to be grossly oedematous with ascites pleural effusions and ?pericardial effusion. The lower half of her surgical wound had dehisced with an estimated 500mL fluid leaking from the wound and drain site together with ooze from the site of the failed vascath attempt. She was grossly fluid overloaded. Her coagulopathy was resolving. She was awake and oriented, afebrile and her observations were stable.

Dr Chatterjee reviewed Mrs Mead at around 8:45am on the morning ICU round the next day, Wednesday 25 February. Mrs Mead was alert, awake, obeyed commands, was warm and well perfused, had a regular heart rate and rhythm and good blood pressure which was unsupported. Her blood gas exchange was good and she was maintaining good oxygen saturation (99%) on minimal oxygen support. Her abdomen was soft and the stoma functioning. Her ascites were clearing.

She was still anuric, grossly extravascularly fluid overloaded, her white cell count remained high but she was afebrile, her albumin level was reasonable and her creatinine was noted to be rising. She was still on dialysis.

The plan was to cease continuous dialysis, continue her on oral free fluids, administer a stat dose of Gentamicin and continue the Piptaz and increase her total parenteral nutrition to 40ml/hr. She was to be referred for renal team review and discharged back to the surgical ward.

The surgical team (Dr Caleo, Dr Perera and team) reviewed her in the ICU shortly after Dr Chatterjee, noting she was still anuric but the renal team had been notified. They were happy to receive her back on the surgical ward when she was ready.

Mrs Mead was still in ICU when seen by the physiotherapist at around 2:15pm.

A nursing note made at 2:30pm describes Mrs Mead as peripherally shut down with cold and mottled extremities, and no urine output since dialysis was ceased at 9:30am. However, when reviewed by Dr Benny and Dr Dornan at around 3:30pm, she is noted to appear comfortable but malnourished with high output from her wounds and ascites thought likely secondary to low albumin. She was to be managed as per the ICU discharge plan which was to monitor for refeeding syndrome and electrolyte replacement, close monitoring of her blood sugar level, continue intravenous antibiotics (in discussion with the Infectious Diseases team), follow up her blood cultures, free fluid diet and continue TPN at 60ml/hr (for dietician review) and ongoing review by the renal team.

Mrs Mead was back on the surgical ward by 5:00pm.

At 8:30pm, nursing staff contacted Ward Call to review Mrs Mead due to her increased respiratory rate. A nursing note made at 10:10pm indicates Mrs Mead's blood pressure was very hard to find and her extremities were very cold. She was seen at an unknown time by a Dr Hill who appears to have sought further Ward Call review, undertaken by a Dr Coupland. The time of Dr Coupland's review is not documented but it is noted Mrs Mead's blood pressure was undetectable and Mrs Mead was confused as to time and place. Dr Coupland discussed Mrs Mead with Medical Ward Call, Dr Tiarni, who agreed to review her.

There is no documentation of any subsequent medical review by Dr Tiarni or another member of the medical team.

Day 9 Post-Op – Thursday 26 February 2015 – Mrs Mead returns to ICU

The surgical team (Drs Perera, Dornan and Greenwood) reviewed Mrs Mead at around 7:40am the next morning, Thursday 26 February, noting she was very drowsy with an increased respiratory rate and heart rate (~104). Her observations were otherwise stable and she remained afebrile. Her right forearm was noted to be tender and hot but her hand was cold with a faint radial pulse. They noted her urine output overnight as ?10ml/hr. They notified Dr Benny who came to see her. She was discussed with ICU for further review, for repeat blood tests, monitor fluid output with strict fluid balance and diet as tolerated.

Mrs Mead was reviewed on the ward by ICU at around 9:00am. She was noted to look unwell. She was confused. Her blood pressure was 106/60 and pulse rate 104. She was ordered urgent bloods, for review by ICU and the renal team were notified.

The Renal Registrar, Dr Curley, reviewed Mrs Mead at around 10:30am. Dr Curley documented a comprehensive examination including the issues with Mrs Mead's post-operative urine output noting *in retrospect probably intravascularly depleted [with increased] 3rd spacing, however at the time [treated with] repeated frusemide doses*. Dr Curley noted her persistent anuria and that she had ceased dialysis at 9:00am the previous morning with minimal urine output

since then. She was noted to have severe widespread peripheral oedema in the context of low albumin, ongoing coagulopathy with rising indicators on that morning's coagulation profiles (for which she was given a stat dose of Vitamin K) and ongoing anuric renal failure with rising creatinine and potassium off continuous dialysis. Dr Curley queried the need for orthopaedic review of possible compartment syndrome of the right arm.

Dr Curley completed the entry with *overall still very unwell lady with multiorgan dysfunction, peripherally shut down. I feel she is probably too sick for HD in the dialysis unit currently, but will discuss with ICU and Nephrologist.*

Following further discussions between the ICU and Renal teams, Mrs Mead was transferred back to ICU at around 11:30am.

Dr Chatterjee subsequently explained he understood Mrs Mead was returned to ICU so she could receive continuous rather than intermittent haemodialysis, as she didn't otherwise meet the criteria for ICU admission. He accepted she was in multi-organ dysfunction by this time but remained of the view she did not need the ICU support they would normally offer to any multi-organ failure.

On examination in ICU, Mrs Mead was in shock with cold mottled extremities and was still not passing urine, with pain in her right arm (investigated by ultrasound with no abnormalities detected). She had mild tachycardia and marginally low blood pressure. No admission diagnosis is recorded in the ICU notes. She was given intravenous fluids and 20% albumin and recommenced on continuous dialysis. Her intravenous antibiotic therapy continued. Further investigations including chest x-ray, echocardiogram and ultrasound of the right arm were ordered.

Dr Danielle Wiltshire, then Resident Medical Officer in the ICU, attempted to insert a left femoral arterial line. She recalls Dr Chatterjee was present for the procedure as Mrs Mead had just been transferred back to ICU from the ward. Dr Wiltshire initially experienced difficulty advancing the needle to the correct location and then again with advancing the guidewire. She then asked Dr Chatterjee to attempt the line. He too was unsuccessful. It was decided to abandon the procedure and try again in a different location later, after investigation of the upper limb oedema and swelling and if Mrs Mead became more haemodynamically unstable.

Neither Dr Wiltshire nor Dr Chatterjee made any entry in the chart regarding their attempts at inserting the line.

Should Mrs Mead have been discharged from ICU on 25 February 2015?

The fact of Mrs Mead's return to ICU less than 24 hours after being discharged back to the surgical ward raises the question whether she should have been discharged from ICU in the first place.

Dr Chatterjee explained they would usually have a patient on continuous haemodialysis in ICU when the patient was haemodynamically unstable as this

is a slower form of dialysis than intermittent dialysis. He considered that because Mrs Mead had become haemodynamically stable, she could tolerate intermittent dialysis in the dialysis unit. In his opinion, she was clinically stable and could be managed on the ward as she no longer needed ICU monitoring and interventions.

Dr Denman and Dr O'Donoghue both agreed. Her sepsis was under control and being treated with appropriate antibiotics, and her condition was sufficiently stable off inotropes for her to be discharged to the ward. The only remaining issue was her renal failure requiring dialysis for which a plan was in place involving the renal team.

I am satisfied that at the time Dr Chatterjee saw Mrs Mead that morning, her condition was such that it was clinically appropriate for her to be discharged from ICU back to the surgical ward with renal team input.

Unfortunately the overnight Ward Call response did not achieve medical team review prior to the surgical morning ward round (documented at 7:40pm). The times of the attendances by Drs Hill and Coupland are not documented in the chart, so it is not clear what time period elapsed between Dr Tiarni's reported agreement to review Mrs Mead and the morning ward round. In any event, Dr Coupland instructed nursing staff to notify any concerns or deterioration. It appears none were; the observation chart shows improvement of her respiratory rate and no other changes triggering further escalation.

Dr O'Donoghue considered Mrs Mead had deteriorated overnight on the ward but was unable to identify from the chart, or deduce himself, the cause of her deterioration. He did not think it was a continuation of the urosepsis as this appears to have resolved prior to her discharge back to the ward. He postulated a new source of sepsis, possibly soft tissue infection of the right arm as noted on the surgical morning ward round on 21 February for which it appears Mrs Mead was commenced on flucloxacillin. However he acknowledged no evidence of a new source of sepsis was found.

Day 10 Post-Op - Friday 27 February

Notwithstanding the cause of Mrs Mead's deterioration and return to ICU, the primary issue soon became her coagulopathy following the failed arterial line insertion.

Mrs Mead started bleeding into the tissues after the attempted arterial line insertion. I am reassured by Dr O'Donoghue's advice that arterial bleeding is a recognised complication of evasive vascular access that was clearly technically very difficult to perform in this case. There is no evidence to suggest the procedure was performed other than with appropriate skill and supervision.

This bleeding resulted in a significant drop in Mrs Mead's haemoglobin (60 down from 97) which was noted overnight. The overnight intensivist noted right forearm cellulitis and a tender tense left upper thigh/groin haematoma but no other source of bleeding. The plan was to transfuse Mrs Mead but she

reportedly did not want blood transfusion at that time (for reasons she could not articulate). The alternative plan was to rediscuss the need for transfusion with her family.

The surgical team (Dr Benny, Dr Caleo, and Dr Dornan) reviewed her in ICU at around 7:50am. Mrs Mead refused examination but after further discussion with Dr Dornan agreed to have the blood transfusion.

When reviewed by the ICU team at 9:50am, Mrs Mead was alert, awake and oriented. Her haemoglobin had dropped further to 55. The plan was to transfuse three units of packed cells that day and to arrange for an ultrasound of the left groin. The ultrasound revealed a small left groin haematoma (about 30ml) which did not connect to femoral vessels. It was decided to manage the haematoma conservatively.

Dr Chatterjee and Dr Benny met with Mr Mead and the couple's adult children that afternoon. They were advised she was on maximal therapy though her overall outcome may be poor with a high chance she would die. Mr Mead told a social worker he felt his wife had 'given up'.

She was subsequently commenced on inotropic support and her dialysis was ceased given her renal function was improving though she remained anuric. When reviewed overnight, her inotrope requirements were increasing and her prognosis was considered poor. Her haemoglobin had increased to 105 after transfusion but then dropped to 69. She was given further blood transfusion.

Day 11 Post-Op – Saturday 28 February 2015

Surgical Registrar Dr Matt Lyon reviewed the haematoma overnight at the request of the ICU team and noted it had increased in volume from 30ml to 600ml with an associated drop in haemoglobin in 65 and increasing inotrope requirements. After discussing the case with consultant surgeon, Dr Antoun, and the consultant intensivist, it was agreed to continue to manage the haematoma conservatively with transfusion to correct the coagulopathy.

Dr Lyon reviewed Mrs Mead again in the morning noting the haematoma had increased in size and the haemoglobin remained low despite transfusion and fluids. After discussion with Dr Benny, it was decided to continue conservative management pending CT angiogram to investigate the cause. Mrs Mead initially refused the CT angiogram but it proceeded after her condition deteriorated and she became haemodynamically unstable at around 9:00am

Mrs Mead arrested during the CT angiogram but was resuscitated after approximately six minutes. She was intubated and ventilated. The CT angiogram showed extensive haematoma and active bleeding. After discussion with Mr Mead, she was taken to theatre urgently to treat the now rapidly expanding groin haematoma. Despite Mrs Mead losing over one litre of blood and activating the massive transfusion protocol, the surgeon was able to control the bleeding intra-operatively with a marginal improvement in her coagulation in theatre.

Mrs Mead remained coagulopathic, bleeding from the mouth and surgical sites and required ongoing massive transfusion of blood and blood products. Following discussion with Dr Benny, it was agreed that further surgery was not an option given the coagulopathy. Her prognosis was now very poor. In consultation with the family, it was decided that if Mrs Mead did not improve after transfusion then she would be transitioned to comfort cares. Mr Mead remained with her overnight.

Day 12 Post-Op – Sunday 1 March 2015 – Mrs Mead’s ongoing deterioration and death

Unfortunately, Mrs Mead continued to deteriorate. Following further discussion with Mr Mead, she was taken off inotropes and the ventilator at around 5:30am the next morning, 1 March 2015, to allow her to pass away peacefully. She died at 6:00am.

Should Mrs Mead’s bleeding have been managed more aggressively?

Dr Benny considered the coagulopathy to be a trauma-induced complication of the failed arterial line insertion, rather than a continuation of the coagulopathy that developed when Mrs Mead was admitted to ICU the first time with sepsis.

This was put to Dr O’Donoghue who considered there was bleeding clearly associated with attempted arterial line insertion followed by the significant drop in haemoglobin. However, Dr O’Donoghue was unable to say definitively whether the coagulopathy was solely related to the attempted arterial line insertion because the cause of Mrs Mead’s overnight deterioration was unclear.

On this point, I note Dr Curley’s earlier observation of the change in Mrs Mead’s coagulation profile on bloods taken on the morning of 25 February, and assessment of ‘ongoing coagulopathy’. These clinical findings suggest a process already unfolding and more likely exacerbated, rather than caused by, the attempted arterial line insertion.

Dr O’Donoghue explained the vicious cycle of uncontrolled bleeding, problems with blood clotting, increasing haemodynamic instability all making the process harder to reverse. He advised the ongoing bleeding and coagulopathy need to be corrected concurrently. He describes Mrs Mead as being very, very unwell by that stage and her condition was ‘very precarious’. While initially of the view that earlier control of the bleeding in a patient with limited physiological reserves may have been more successful, he considered the conservative approach taken, given how unwell she was at the time, was reasonable. He was unable to say whether earlier attempts to correct the problem would have made any difference to the outcome for Mrs Mead.

Having regard to Dr O’Donoghue’s opinion, I am satisfied the management of Mrs Mead’s bleeding and coagulopathy, informed by both surgical and intensive care input, was reasonable in the circumstances.

Was there a connection between the persisting low urine output and Mrs Mead's deterioration and death?

Mrs Mead was unable to overcome the coagulopathy exacerbated by complications of attempts to insert a left femoral arterial line on her admission to the ICU on 26 February 2015. The arterial line was required to facilitate intensive care monitoring of Mrs Mead's condition which had deteriorated overnight on the ward, leaving her too unwell to receive intermittent dialysis. She required dialysis for ongoing anuria, having been commenced on continuous haemodialysis after being admitted to ICU with acute urosepsis on the evening of 23 February 2015. She was anuric because she had acute kidney injury. Medical Registrar review on the evening of 22 February identified a shift in Mrs Mead's renal function (albeit still within normal parameters) on bloods collected earlier that day. This finding was made in the context of a formal medical review of Mrs Mead's fluid status which was complicated by persisting low urine output and significant fluid shift.

Dr O'Donoghue's evidence has been extremely helpful in assessing whether there may have been a connection between Mrs Mead's persisting low urine output and the acute kidney injury complicating her acute sepsis, and if so, whether there may have been a missed opportunity to identify and treat this aspect of her post-operative course sooner and perhaps have changed the outcome for Mrs Mead.

Dr O'Donoghue identified the November 2014 admissions as relevant to her post-operative care. He considered her previous acute kidney injury in the setting of dehydration and asymptomatic hypotension suggested she had reduced renal reserves. As such this information was a 'minor flag' that Mrs Mead might be susceptible to acute kidney injury in future. His report acknowledges the post-mortem finding of microscopic evidence of hypertensive changes in the kidneys with hyaline arteriosclerosis and nephrosclerosis, suggestive of pre-existing kidney disease.

He identified Mrs Mead's persisting low urine output as the most significant indicator of evolving acute kidney injury. He referred to the Kidney Disease Improving Global Outcomes clinical practice guidelines¹⁴ for acute kidney injury under which acute kidney injury is considered present if:

- Serum creatinine rises by greater than or equal to 26.5µmol/L within 48 hours
- Increase in serum creatinine greater than or equal to 1.5 times baseline in seven days
- Urine volume less than or equal to 0.5ml/kg/hr for six hours.

On Mrs Mead's weight, Dr O'Donoghue calculated a urine output of less than 24mls/hr as abnormal especially if sustained for longer than six hours. On this basis, he identified Mrs Mead's post-operative urine output as lower than the expected consecutive hourly urine output and in the range indicating stage II

¹⁴ Volume 2, Kidney International Supplements, *KDIGO Clinical Practice Guideline for Acute Kidney Injury* (2012), Issue 1 March 2012.

acute kidney injury under the KDIGO guidelines on a number of occasions prior to 20 February 2015.

As such he considered the surgical team's acceptance of 15mls/hour to be on the low side for Mrs Mead.

Turning to creatinine increments, the pathology results reported Mrs Mead's creatinine levels as:

Date & time collected	Creatinine
17 Feb @ 7:10am	58
18 Feb @ 12:32pm	63
18 Feb @ 1:52pm	58
No bloods on 19 Feb	-
20 Feb @ 8:45am	57
21 Feb @ 12:05pm	57
22 Feb @ 12:15pm	70
23 Feb @ 4:10pm	129
23 Feb @ 5:15pm	128
24 Feb @ 4:30am	138
24 Feb @ 10:00pm	87
25 Feb @ 5:00am	86
26 Feb @ 9:30am	122
27 Feb @ 4:40am	83
27 Feb @ 5:55pm	86
28 Feb @ 4:25am	127
28 Feb @ 1:50pm	129
28 Feb @ 10:17pm	132
1 Mar @ 5:30am	136

Dr O'Donoghue explained that one of the indicators of kidney injury is a rise in creatinine, which is used as a marker of glomerular filtration (kidney function). Creatinine will rise if the rate of filtration becomes low. When a person's body mass is low, their production of creatinine is low so they do not have to excrete as much, meaning it takes a long time to rise. He says this explains why Mrs Mead's creatinine was still within the normal reporting range (prior to 23 February), despite her having stage II acute kidney injury by urine output definition.

I am satisfied the clinical evidence supports Dr O'Donoghue's opinion there was a period of hours to days over which kidney injury was evolving, as evidenced by the persisting low urine output which met the criteria for stage II acute kidney injury under the KDIGO clinical practice guidelines, and then the dramatic increase in creatinine reflecting dramatic decrease in renal function associated with septic shock that ultimately brought Mrs Mead to ICU on the evening of 23 February 2015. The 'declining renal function' noted by Dr David on the evening of 22 February, albeit still within normal range, sits with this explanation. The autopsy finding of indicators of pre-existing kidney disease has also informed my conclusion on this issue.

In reaching this conclusion, I accept that the evolving kidney injury was one of a number of factors, including hypovolaemia and third space loss in the context of hypoalbumaemia, causing the low urine output.

Dr O'Donoghue agreed it was acute sepsis that made Mrs Mead critically unwell on 23 February, and would have made the evolving kidney injury worse.

The consequences of acute kidney injury, exacerbated by the sepsis, remained an issue for Mrs Mead as she required ongoing dialysis after the sepsis was brought under control. She remained anuric and was returned to ICU to resume continuous dialysis after being identified as too unwell to receive intermittent dialysis. She sustained an iatrogenic injury upon her return to ICU, the complications of which she was ultimately unable to overcome.

As such I am satisfied there is a connection between the persisting low urine output and Mrs Mead's subsequent deterioration and death. The question then becomes whether there was a missed opportunity to have identified the evolving kidney injury sooner and perhaps have changed the outcome for Mrs Mead.

The collective evidence of the surgical team shows they were not actively considering differentials for the persisting low urine output for reasons including:

- managing a post-operative patient's fluid balance is routine, described by one witness as the 'bread and butter of post-operative care'
- a post-operative patient often has low urine output in the days following surgery
- patients who develop third spacing usually self-correct and offload retained fluid up to 5-7 days post-operatively
- their experience in managing patients with low albumin
- Mrs Mead's intermittent hypotension responded to fluid challenges and small doses of Frusemide were showing some good effect
- Mrs Mead's creatinine was within normal range up until around 23 February 2015.

Both experts considered Mrs Mead's low urine output warranted a second opinion once it persisted beyond 48 hours – the problem was persisting despite repeated treatments ordered by both the surgical team and sporadic and reactive Ward Call attendances, so further investigations of the underlying cause were warranted.

Professor Wall considered ongoing low urine output for greater than 40-48 hours post-operatively should have perhaps triggered a second opinion and earlier medical review. He disagreed with the surgical team's evidence about it not being unexpected for a low urine output to persist 4-5 days post-operatively, suggesting the team needed to be considering differentials, such as an antidiuretic hormone release, in order to 'be in front' and as such the surgical team had the benefit of access to other sources of clinical opinion at Toowoomba Base Hospital.

Dr O'Donoghue felt it would have been beneficial for Mrs Mead to have been seen by a senior physician around, and certainly beyond, the 48 hour mark to reassess whether in fact her fluid balance issues was all third space loss and why that third space loss was continuing to occur. He fairly acknowledges it was difficult to identify the exact underlying cause of the low urine output and suggested it was likely multifactorial.

In Dr O'Donoghue's opinion there seemed to be an association between the intermittent hypotension and the low urine output and felt it reasonable for the surgical team to assume they may be connected. Dr Denman expressed a similar view.

While he agreed with the recognition of there being an element of hypovolaemia and third space loss, Dr O'Donoghue was concerned about the same treatment (fluid administration and subsequently Frusemide) being initiated each time for the recurring problem with the same transient or lack of effect. To his mind, a second opinion by someone senior was likely to be helpful in reconsidering the underlying cause of Mrs Mead's ongoing fluid replacement needs.

The inquest explored whether a formal medical review was indicated by the morning of 20 February 2015, particularly as Mrs Mead's urine output was noted to have slowed and she was showing signs consistent with fluid overload as the weekend approached.

Each member of the surgical team was given an opportunity to explain their assessment of Mrs Mead's clinical presentation at that time. While they acknowledged that her clinical signs, particularly the bibasal crepitations, were consistent with fluid overload, intravascular depletion was still their primary clinical concern. Dr Perera helpfully explained that a patient could have too much fluid on board but not intravascularly, and in this situation..*the third-spacing or the loss of fluid from the intravascular space is not as consequential on outcomes as the intravascular volumes. So your primary concern is making sure she's euvolumic, has appropriate fluid status intravascularly. So that's your primary concern, and that's driven by markers, clinical examination and what not.*¹⁵ Further, he stated, *that fluid in the extracellular environment doesn't affect haemodynamics, per se.*¹⁶

Dr Perera says he would not have considered a medical review at this time because *this is something we deal with very regularly, and if we got medical registrar involvement at this stage, this – that regularly, it would be not feasible. I mean, a lot of surgical patients, I couldn't tell you a number. But – end up in this sort of scenario day 2, day 3 postoperatively.*¹⁷

Dr Caleo was reassured by Mrs Mead's response to the Frusemide and the clinical examination findings that morning, and that is what influenced her management plan.

¹⁵ T2-17, 9-13

¹⁶ T2-17, 23

¹⁷ T2-19, 16

Dr Benny was not present on the morning ward round as he had a Friday scope list. While he does not recall what happened that day the evidence suggests his team kept him informed about Mrs Mead's progress. Interestingly, when asked to consider Mrs Mead's clinical presentation on the morning ward round as documented in the notes, he felt that if there was evidence she was starting to accumulate fluid at the base of her lungs (as indicated by bibasal crepitations) he would have recommended seeking a medical opinion. Further he advised *there are multiple causes for, and we cannot confidently say that one cause is the underlying low urine output. It could be multiple factors that have contributed to the lower urine output.*¹⁸ He agreed this is why it would have been prudent to bring in the medical team, for example on 20 February, to see what was going on with the low urine output. He confirmed he would have expected his Registrar would re-assess the situation later to see how it was progressing.

From the perspective of the General Medical team witnesses asked to comment on this issue (Drs Haase, David and Denman), all agreed Mrs Mead's condition was manageable by the surgical team who put worthwhile interventions in place at that time.

Dr O'Donoghue considered the pitting oedema and bibasal soft crepitations noted that morning were likely representing the same underlying process producing the very positive fluid balance and low urine output. He considered some form of medical review was required at this stage as he felt the Frusemide was, to an extent, masking the underlying issue of persisting low urine output. He explained that Frusemide, while increasing urine output, has not been shown to be associated with a reduction in progression to renal failure. He commented that while it was somewhat reassuring there was enough renal function to be able to produce urine, he wouldn't have been overly reassured by that when relying on Frusemide to produce urine output in that situation.

When asked to consider what treatment options might have been available at that time, Dr O'Donoghue suggested it may have been useful to have augmented her blood pressure – requiring admission to intensive care for inotrope support – plus or minus some ongoing fluid administration. So saying, he accepted that even had Mrs Mead been medically reviewed on 19 or 20 February, given boluses of albumin and closely monitored with ICU review, it is difficult to say what, if any, effect treatment may have had on her progress.

Dr Denman also felt it would have been nice for her to be medically reviewed on the morning of 20 February but was not critical of the surgical team not requesting a medical consult at this time and could not say whether it would have changed the outcome for Mrs Mead.

It was only when Mrs Mead was seen by a different Surgical Registrar on Sunday 22 February 2015 that active consideration was given to obtaining formal medical review of her fluid status. I can not help but observe the request was made by a Surgical Registrar not previously involved in Mrs Mead's care,

¹⁸ T3-75, 27-34

reflecting perhaps a 'fresh eyes' assessment of the ongoing fluid balance issues. This decision set in train the comprehensive medical review undertaken that night by Dr David who identified declining renal function and was the first to actively consider measures to improve Mrs Mead's renal perfusion. This outcome lends credence to the experts' view of the potential benefit in the surgical team seeking a formal second opinion about the persisting low urine output. That said, I accept the medical consensus that even had Mrs Mead been reviewed by a medical consultant sooner with more focussed investigation of what might have been underlying her inability to sustain a response to fluid therapy, and a more deliberate plan to monitor and manage it, this may not have changed the ultimate outcome for her.

There was quite some time spent on the issue of whether post-operative use of Albumin would have been beneficial in managing Mrs Mead's fluid balance issues given her hypoalbuminaemia. On the one hand, while almost every non-surgical team interaction during Mrs Mead's post-operative course generated a suggestion or recommendation to administer Albumin as part of her fluid management; the surgical approach was definitively not to. Having regard to the current clinical literature, I accept there is no clinically proven benefit in using Albumin in fluid resuscitation – it is used by some, not others and equally reasonably so. On this issue I accept Dr O'Donoghue's opinion that Mrs Mead's low albumin was really a side issue and attempts to correct this alone would not have been successful. To coin the phrase used by Counsel representing DDHSS, the significance of Mrs Mead's hypoalbuminaemia and the use of Albumin to treat it proved ultimately to be the archetypal red herring.

The surgical team's decision to remove the IDC had little if any regard for Dr David's recommendations. By the time it was reinserted following Mrs Mead's deterioration with urosepsis that day, she was anuric and very dehydrated, requiring continuous haemodialysis. Her need for haemodialysis continued until the afternoon of 27 February when her renal function had improved. Unfortunately by this time Mrs Mead's issues were overtaken by her coagulopathy and her prognosis was poor.

I agree with the observations of both Dr Denman and Dr O'Donoghue that the intervening sepsis on 23 February means we can never know whether Mrs Mead's fluid balance issues would have resolved spontaneously as Dr Benny's team, in their collective experience, were not unreasonably expecting to happen.

I acknowledge the presentation of Mrs Mead's evolving kidney injury was unusual given her normal creatinine and an anticipated period of low urine output and third space loss following major surgery. However, with the benefit of hindsight the coronial process affords, Mrs Mead's clinical course demonstrates the importance of surgical teams actively considering differentials and the benefit of second opinion as part of their routine management of the post-operative patient. For this reason, a copy of these findings will be forwarded to both the Colorectal Surgical Society of Australia and New Zealand and the Royal Australasian College of Surgeons.

Findings required by s. 45 of the Coroners Act 2003

I am required to find, as far as possible, the matters set out under section 45(2) of the *Coroners Act 2003*. Having considered all of the evidence, including the material contained in the exhibits, I am able to make the following findings:

- Identity of the deceased: The deceased person is Gwendoline Mead
- How she died: Mrs Mead died 12 days after elective surgery to treat synchronous bowel tumours. Post-operatively she experienced persisting low urine output and intermittent asymptomatic hypotension which responded transiently to repeated fluid challenges and Frusemide. By the evening of day 5 post-operatively she was diagnosed as fluid overloaded with hypoperfusing kidneys in the context of hypoalbumaemia. She became acutely unwell the following day with urosepsis and acute kidney injury requiring intensive care admission and dialysis. Her need for dialysis continued after the urosepsis was brought under control and she was discharged back to the surgical ward on day 8 post-operatively. Her condition deteriorated overnight requiring readmission to intensive care on day 9 post-operatively. The cause of her deterioration remains unknown but was quickly overtaken by coagulopathy likely exacerbated by bleeding from injury to her left femoral artery during repeated attempts to insert an arterial line to facilitate intensive care monitoring. Unfortunately she was unable to overcome the coagulopathy despite medical and surgical intervention. Following discussion with her family, she was transitioned to comfort cares allowing her to die peacefully on day 12 post-operatively.
- Place of death: Mrs Mead died at Toowoomba Base Hospital, Toowoomba in the State of Queensland
- Date of death: Mrs Mead died on 1 March 2015.
- Cause of death: Mrs Mead died from multiple organ failure due to or as a consequence of sepsis due to or as a consequence of rectal and caecal adenocarcinoma (surgically treated).

Comments and recommendations

Section 46 of the Coroners Act 2003 provides that a coroner may comment on anything connected with a death that relates to public health or safety, the

administration of justice or ways to prevent deaths from happening in similar circumstances in the future.

The inquest identified a number of missed opportunities to have optimised Mrs Mead's care. While I can not say with certainty those opportunities would have been outcome changing for Mrs Mead, I do consider they were significant in maximising the potential for better clinical outcomes.

Improved pre-operative communication within the SOMDT environment

The most significant of the missed opportunities flows from Dr Benny's team not being involved in her management during the second November 2014 admission. His involvement in investigating and managing her bowel complications at this stage of her neoadjuvant treatment would have better positioned him to reassess the planned surgical approach in light of those complications.

Unfortunately there is insufficient evidence to identify exactly how this situation arose and whether it represents a broader system failure at Toowoomba Base Hospital. However, it arose in the context of a patient whose treatment plan had already been decided by a multidisciplinary team supported by Cancer Care Coordinators. Mrs Mead was already known to be Dr Benny's patient. The fact his team was not allocated to the surgical review requested by the medical oncology team suggests to me the need for DDHHS to review the SOMDT mechanism to ensure the correct treating team is allocated to and/or notified at the time their patient requires investigation and treatment of complications emerging during and after the neoadjuvant therapy phase and prior to surgery. It is my hope the strengthening of these processes will position surgical teams to not only proactively assess and if necessary, reassess, the planned surgical approach but also maintain awareness of issues that could impact on the patient's post-operative recovery, for example, susceptibility to renal impairment.

Mrs Mead was unable to complete an aspect of her neoadjuvant therapy and as such the treatment plan developed by the SOMDT did not 'go to plan'. I note her case was not represented to the SOMDT until after the surgery. Although not explored at the inquest, I question whether there is merit in patients who can not or do not complete the planned neoadjuvant therapy being represented to the SOMDT for reconsideration prior to the planned surgery.

I recommend that DDHHS examine these aspects of its SOMDT model and formally report the outcomes of its review.

Notwithstanding potential improvements to the SOMDT model to enhance surgical team awareness of emerging pre-operative issues, it remains incumbent on senior and junior members of all teams involved in a cancer patient's pre-operative and post-operative care to actively read the patient's chart.

Improved response to multiple MET calls or escalation for recurring problems

I share Dr O'Donoghue's concern about Mrs Mead's recurring hypotension and low urine output having been managed repeatedly with the same treatments achieving the same transient or lack of response. Many of these treatments were initiated or continued by different doctors called to review the same problems after hours. Prior to Mrs Mead's acute deterioration with sepsis on the afternoon of 23 February 2015, nursing staff appropriately escalated these recurring issues to Ward Call for review on eight occasions and on one occasion, initiated a MET call. As such these issues were attended to in a sporadic and reactive way.

Dr O'Donoghue suggested a system be put in place whereby patients who have multiple MET calls for a recurring problem can be identified and referred to a senior clinician for timely review. He considered this would help commence appropriate investigations earlier and facilitate communication between senior members of the treating teams which may enable earlier escalation to more intensive treatment if appropriate. By way of example, he referred to the system implemented by the Royal Brisbane & Women's Hospital over the past 12 months whereby on weekdays there is a two hour period for the acute inpatient physician led team to review patients who have MET calls or especially multiple MET calls. He readily acknowledged this system is dependent on the availability of resources.

During the inquest, DDHHS tendered a statement from Dr Martin Byrne, then Acting Executive Director Medical Services, outlining system changes under development since Mrs Mead's death.

The DDHHS Reducing Harm Committee were actively considering permutations of the system proposed by Dr O'Donoghue to avoid prolonged abnormal indicators in patients and identify those who require review for potentially more serious conditions in circumstances where the prolonged abnormal indicators might otherwise be considered relatively minor or not clearly indicative of the potentially more serious problem. As at February 2017, the Reducing Harm Committee was grappling with how best to ascertain the optimum number of MET calls over the optimum period to identify the automatic trigger point for Code Blue or escalation having regard to the relative risk to the patient and efficient use of limited available resources. Dr Byrne assured the Committee was confident an appropriate balance could be struck so a system could be implemented in the near future but further consultation and discussion was still in train.

Dr Byrne acknowledged the secondary benefit of such a system in better managing a patient's MET calls in that identifying how many MET calls a particular patient has will also help clinicians exercise clinical judgement in calling a Code Blue or escalation even if parameters for an automatic Code Blue or escalation are not triggered. It would also allow for the exercise of clinical judgement in referring the patient for review by other teams.

The Reducing Harm Committee's work to date is very encouraging and should continue with a view to actually implementing a workable system to identify patients with persisting prolonged abnormal indicators for more timely senior review.

Dr Byrne advised that as a subset of this work, the Committee had considered the possibility of an automatic trigger requiring escalation of patients with persistent low urine output. While this is not possible within current software, I note that Toowoomba Base Hospital is listed for the introduction of electronic recording of all observations and vital signs in 2018.

Improving the management of inter-team requests for patient review

On more than one occasion during Mrs Mead's post-operative course, ward-based doctors involved in her care sought advice from or requested formal review by members of the Medical Team:

- Dr Bryant sought telephone advice from Dr Haase on 19 February 2015 which she mistakenly interpreted as his agreement to formally review Mrs Mead
- At Dr Perera's request, a different surgical intern sought telephone advice from the on-call Medical Registrar, Dr David, on the afternoon 21 February 2015 about the management of Mrs Mead's bilateral upper limb DVT – this culminated in Dr David and Dr Sellars' attendance on Mrs Mead the following morning to confirm her anticoagulation
- A different Surgical Registrar, Dr Neubery formally requested medical review of Mrs Mead's fluid status after the morning round on 22 February 2015 – this formal request was made by chart entry alone but not documented in the chart until some time after 2:20pm that afternoon meaning the Medical Team were not aware of the formal request when Dr David and Dr Sellars attended Mrs Mead at 11:00am that morning – this formal request was actioned when Dr David attended and undertook a comprehensive examination of Mrs Mead at 9:00pm that evening
- Dr Bryant approached Medical Registrar, Dr Carr for assistance on 23 February 2015 – this culminated in Medical Consultant review and transfer of Mrs Mead to the ICU that evening
- Ward Call Dr Coupland sought advice from Medical Ward Call Dr Tiarni on the night of 26 February 2015 – according to Dr Coupland's entry in the chart this culminated in Dr Tiarni's agreement to review Mrs Mead, a review that did not eventuate.

The DDHHS SAC 1 Clinical Review identified the potential for inter-team referrals to become lost when they are unable to be captured properly on a paging system or patient list that is generated daily for each team, especially when the information is written on a piece of paper or committed to memory. It recommended review of the hospital's patient flow management system (Patient Flow Manager) to assess its capability to record and action these requests.

Dr Byrne advised that DDHHS has since developed capability within Patient Flow Manager to record and action formal requests for patient review. Once

entered, the request will be forwarded to the relevant clinician via an application on their smart phone alerting them to the referral and requesting their review of the patient. The patient's name will then appear on the referrer and receiving team handover sheets as a patient requiring consult. The request will remain current in Patient Flow Manager until the review is undertaken and closed off on the system.

It was hoped to trial the system in early February 2017. Dr Byrne advised that flowing from the introduction of this system would be a further process of overseeing individual patient management by dedicated staff reviewing Patient Flow Manager for particular patients or by the introduction of automatic alert triggers where clinicians have not responded to referrals entered into the system within a defined timeframe.

Dr Byrne clarified this initiative is intended to augment, not replace, direct contact at Registrar to Registrar or Consultant to Consultant level in the day to day management of patients. Nor is it intended to discourage continued informal contact between teams for advice and recommendations which I agree is integral to the day to day running of any hospital.

I am optimistic this initiative will strengthen communication between teams about patient referrals and, had it been in place in February 2015, may have achieved more timely comprehensive medical review of Mrs Mead particularly on 22 and 25-26 February.

A role for perioperative medicine?

The inquest briefly considered the concept of a broader perioperative approach to the management and treatment of elderly patients like Mrs Mead taken in larger hospitals such as the Royal Brisbane & Women's Hospital and the Mater Hospital. It was suggested that under this approach the Medical Team would probably have been involved in Mrs Mead's management from the outset meaning she would have been on their radar at an earlier stage positioning them to have been better able to influence or guide her management throughout.

I accept that while this is an attractive ideal to strive towards in the long term, perioperative medicine is an evolving discipline and is not something that can be practically achieved in DDHHS in the shorter term due to current clinical resources and funding constraints.

Improving clinical documentation

There were numerous instances of less than optimal or absent clinical documentation over the course of Mrs Mead's final hospital admission – Dr Benny and Dr Caleo did not document their attendances on her on the morning of surgery; some Ward Call doctors did not 'time stamp' their entries and others did not make entries at all; there were no nursing entries or hourly urine measures documented during the night shift on 20-21 February and there was no documentation by the intensivists who were unable to insert the arterial line on 26 February.

I note the evidence of RN Comber that since early 2015 there has been an operational policy shift at Toowoomba Base Hospital such that nurses are now required to document each shift they have in the patient's chart – this is a change from the process of 'exceptional reporting' in place at the time of Mrs Mead's final admission.

These examples of less than optimal clinical documentation are by no means isolated – the quality of clinical documentation is a subject of concern and comment in many health care related death investigations and inquests. I can only reiterate the importance of good clinical documentation in all health care settings and encourage ongoing efforts to educate and maintain staff awareness of same.

I offer sincere condolences to Mrs Mead's family.

I close the inquest.

Ainslie Kirkegaard
Acting Coroner
Brisbane
22 June 2017