QUEENSLAND COURTS

CORONERS COURT OF QUEENSLAND

FINDINGS OF INVESTIGATION

CITATION:	**Non-inquest findings into the death of Mr B.**
TITLE OF COURT:	Coroners Court
JURISDICTION:	BRISBANE
DATE:	02nd June 2025
FILE NO(s):	2023/3671
FINDINGS OF:	Melinda Zerner, Coroner
CATCHWORDS:	CORONERS: Healthcare related death – iatrogenic death – premature death – overdose of phenol – interventional radiology – celiac plexus block – Queensland Health Medicines Advisory Committee – Royal Brisbane and Women's Hospital

Table of Contents

Introduction

1. Mr B was born on 20 January 1981 and died on 29 July 2023 at the Royal Brisbane and Women's Hospital (RBWH). He was 42 years old.

2. A doctor from the RBWH reported Mr B's death to the Coroner because his death was identified as a potential healthcare related death within the definition of a reportable death in the *Coroners Act 2003*. That is, he had received an inadvertent phenol overdose during a celiac plexus block. A procedure which had been was performed to treat the pain Mr B was suffering because of newly diagnosed pancreatic cancer.

3. The role of a Coroner is to investigate reportable deaths to establish, if possible, the cause of death and how the person died. The purpose of a coronial investigation is to establish the facts, not to cast blame or determine criminal or civil liability. An investigation is about attempting to find the root cause of the incident that precipitated the death and in appropriate circumstances to analyse systemic failures that contributed to the death and to design remedial responses.

4. In making my findings, they are based on proof of relevant facts on the balance of probabilities. I am not able to make adverse findings against, or comments about individuals, unless the evidence provides a comfortable level of satisfaction that they caused or contributed to the death.

5. A Forensic Medical Officer reviewed Mr B's clinical record and determined Mr B's cause of death was Multiple organ failure due to 'Iatrogenic phenol overdose' due to 'Metastatic pancreatic cancer'. Iatrogenic means an event caused by medical treatment. I accept the Forensic Medical Officer's opinion as the cause of Mr B's death.

6. I have found there was an error by Mr B's treating radiologist in administering an excessive dose of phenol during the celiac plexus block, and that there was a failure by the RBWH in the way in which phenol was stored and used in the radiology department. I address these issues further below.

7. I extend my condolences to Mr B's family and friends for their loss. Mr B was already facing a terrible diagnosis when his already short life expectancy was cut even shorter. The loss of someone in such circumstances is always difficult. I recognise that no words can adequately express the sorrow, or the impact Mr B's loss has had on his family and friends.

Circumstances of the Death

8. Prior to the procedure, Mr B had recently been diagnosed with extensive metastatic cancer. He had been suffering persistent epigastric pain, anorexia, nausea, and reflux without vomiting. It was thought he likely had pancreatic cancer.

9. On 18 July 2023, Mr B presented to the RBWH Emergency Department (ED) with exacerbation of epigastric pain in the context of recently diagnosed metastatic cancer. He was admitted under the hepatobiliary surgical team and referred to an interventional radiologist for a celiac plexus block to assist with his pain management.

10. On 20 July 2023, Mr B underwent the coeliac plexus block. He was accidentally administered 40ml of 80% phenol instead of the intended 40ml of 10% phenol. Mr B developed tachycardia, shock, seizure, and respiratory failure. Following acute resuscitation, he was transferred to the Intensive Care Unit (ICU) for stabilisation.

Supportive cares were commenced, and advice was sought from the Princess Alexandra Hospital (PAH) Toxicology service.

11. There were limited treatment options available but based on case reports it was recommended he be commenced on a N-Acetyl cysteine (NAC) infusion and haemodialysis. Mr B developed multi-organ failure and was critically unwell. He required invasive mechanical ventilation.

12. Mr B's family were advised of the error through the hospital's open disclosure process. There were frequent family meetings led by senior intensivists. The clinician who completed the discharge summary recorded,

> *Expert opinion was that Mr B had a prognosis of weeks to short months from his underlying cancer, with no surgical options and limited chemotherapy options, which in his current state he was not well enough to have. Clearly, the family were distressed that a procedural complication has limited the quality of time they were able to spend with Mr B. Given his clinical trajectory, they accepted that prolonging Mr B's life with ICU life sustaining therapies would not result in an outcome acceptable to Mr B, with particular concerns about ongoing pain and delirium. Therefore, life sustaining therapy was withdrawn on 29/7 and Mr B demised soon after. Opportunities for memory making were provided.*

13. There are no identified deficits in the care provided to Mr B following the inadvertent overdose of phenol. My findings therefore focus on the events which led up to the administration of the phenol.

Medical Records/Statements concerning the administration of phenol

14. A RiskMan (incident form) was completed on 20 July 2023. It notes the possibility that 40mls of undiluted phenol was injected when 5-10% is considered the usual concentration. The incident was identified as a Severity Assessment Code (SAC) 1 (the most serious type of incident).

15. A detailed statement has been received from the radiologist who performed the procedure. Regarding the error he has advised,

    a. Prior to commencing at the RBWH he had not performed a neurolysis procedure using phenol, he had only previously used ethanol.

    b. In all the hospitals he had previously practised, only ethanol was used with the dose written up in the medication chart and the pharmacist responsible for drawing the medication up, and the drawn dose being delivered to the procedural suite ready for administration.

    c. He was unaware of any formal policies or procedural guidelines for the performance of celiac neurolysis at the RBWH. He had spoken with colleagues about the use of phenol instead of ethanol.

    d. He was consistently advised that a range of phenol doses were considered acceptable depending on the circumstances of the patient. He was never advised he needed to dilute the phenol dose.

e. Prior to preforming the procedure, he read two recent procedure reports for celiac neurolysis. A dose of 12ml and 20ml were used respectively. The process of diluting the phenol was not mentioned in either case report.

f. He reviewed the Society of Interventional Radiology's Interventional Pain Management guideline for further guidance. The guideline did not recommend the use of a different dose of phenol in lieu of 95-100% ethanol.

g. He considered a total dose of 40mls of phenol would be appropriate.

h. The phenol was delivered on a tray in a one litre bottle, to be measured and drawn up by him. The nurse confirmed the bottle was within the use by date. No mention was made of the concentration. He erroneously believed the phenol bottle contained the correctly concentrated dose of phenol.

16. I have reviewed the Society of Interventional Radiology – Survival Guide Services 'Interventional Pain Management'. While there is reference to the use of 95-100% absolute ethanol, there is no dose referred to for phenol.

17. I sought information from the Royal Australian and New Zealand College of Radiologists (RANZCR). I have been advised by Dr Rattan, Dean, Faculty Clinical Radiology:

    a. *The RANZCR training program for Clinical Radiology includes some injections and biopsies which are regarded as procedural Interventional Radiology. Celiac plexus blocks whilst not specifically taught can be shown to registrars as a teaching opportunity, however generally a celiac plexus block is an advanced Interventional procedure that would be part of a post fellowship experiential training.*

    b. *RANZCR has Standards of Practice for Clinical Radiology which whilst best practice, are not mandatory in Australia and are currently under review, our standards state in relation to medications used for imaging examinations and procedures:*

        > *The provider complies with manufacturer's directions, legislation and jurisdictional requirements in relation to labelling, storage, use and disposal of medications used for imaging examinations and procedures.*

    c. *The use of medications within individual hospitals and radiology practices does not come under the remit of RANZCR. It is the responsibility of the site to ensure that they are compliant with all legislation in relation to medications and that their staff are appropriately informed and trained in their use within the site.*

18. I sought statements from the three Registered Nurses (shift coordinator, scout nurse, and sedation nurse) who assisted the radiologist with the procedure. I also sought clarification from the interventional radiologist. I make the following observations,

    a. Mr B was tachycardiac with a pulse of 120 beats per minute at the commencement of the procedure.

    b. The radiologist did not think this was particularly abnormal in the setting of a hospital patient who may be nervous and in pain. The registrar who had performed a liver biopsy the day prior had reported to the radiologist that Mr B had found the procedure extremely painful and required additional sedation.

He formed the view Mr B had a heightened pain response at the time of the procedure.

c. The nurses say they notified the radiologist a number of times that Mr B's pulse was increasing steadily. The radiologist recalls the nursing staff advising him that Mr B's pulse rate had continued to climb as he delivered the final dose of phenol he had planned. The radiologist was aware Mr B's pulse had risen to 140 beats per minute which he put down to his anxiety and nervousness and discomfort for putting the needles through his back. He says his heart rate did not increase to 160 beats per minute until the procedure was over and he was removing the needles. He does not agree there was a clear dose response to the phenol.

d. A nurse says she saw the radiologist try and speak with Mr B after removing the needles and he did not respond. The radiologist says he was trying to assess Mr B and that Mr B made a grunting sound but did not clearly respond. He was in close proximity to Mr B to hear this and any response may not have been heard by others in the room due to the noise of the CT scanner.

e. Rather than call a Code as suggested by the nurses, the radiologist asked that Mr B be rolled back onto his bed so he could assess him rather than immediately call a code. The radiologist says as they did that, Mr B grabbed his arm and opened his eyes, which he interpreted to be purposeful movement rather than a startle response. Once back on the bed Mr B deteriorated further and almost immediately commenced seizing.

f. The radiologist does not recall declining starting opioid medication reversal.

19. The shift coordinator has advised,

a. Prior to the procedure being performed on Mr B, she had limited exposure to the Celiac Plexus procedure and the use of phenol. At the time, no work guideline and/or procedure protocol was available for the use of phenol.

b. She covered for the scout nurse during her allocated break. The scout nurse was involved in the preparation and commencement of the procedure.

c. When she took over care, Mr B was positioned prone, headfirst on the CT table, with monitoring, oxygen and IV (intravenous) access attached. A sterile field was in place and the radiologist was scrubbed in. There were two Chiba needles in Mr B's lower/mid back. His vital signs were stable, but he was tachycardic at 120beats/min which she was advised by the sedation nurse was Mr B's normal baseline.

d. The radiologist requested two 10 ml syringes, drawing up needles and the phenol to be opened. She was not involved in discussion about volume or strength of phenol.

e. At the time the phenol was stored in an unlocked drug cupboard in the CT/Ultrasound prep room.

f. She was located in the control room adjacent to the CTs. The procedure nurse provided the radiologist with the bottle of phenol then returned to the control room. The bottle of phenol had been placed on a procedure trolley at the request of the radiologist to allow him ongoing access to it.

g. She observed at total of 40mls of phenol administered between the two Ciba needles between multiple scans. She observed the radiologist draw up the phenol directly from the bottle on the procedure table. She did not observe him dilute the medication. After about 20mls of administration, Mr B became tachycardic. His pulse had increased to 160 beats per minute when the needles were removed, and a dressing applied.

h. She heard the other RN ask the radiologist if they should call a medical emergency. He declined, asking that Mr B be moved on to his bed so he could be assessed. Mr B did not provide a verbal response; he was still breathing and was diaphoretic (sweating). On trying to move Mr B he startled and attempt to resist the staff. On rolling him, he commenced to tremor, his intravenous access was dislodged and due to his sweating, the ECG monitor became detached. The radiologist tried to rouse Mr B, there was no response. A RN asked if the radiologist wished to administer an opioid reversal medication. He did not. It was agreed to call for a Medical Emergency at this time.

Independent Expert Opinion

20. I sought an independent expert report from Associate Professor (Assoc Prof) Koukounaras, radiologist, on the care provided to Mr B.

21. Assoc Prof. Koukounaras has advised Coeliac Plexus Neurolysis (CNN) and Splanchnic Nerve Neurolysis (SNN) are related but distinct procedures that are recognised as options for pain relief secondary to advanced malignancy in the abdomen. He considers given Mr B's condition they were appropriate interventions. He also agrees it was appropriate for the biopsy and neurolysis procedures to be performed on separate days. He can see no evidence of a consultation by the interventional radiologist on the day prior to the procedure. He sees this as best practice but accepts that current practice in Interventional Radiology in Australia does not provide routine consultation for similar patients in most Radiology departments.

22. Mr B's elevated heart rate at the commencement of the procedure was not an absolute contraindication as there were likely several reasons for the elevated heart rate such as pain and anxiety. The patient's abnormal observations should be assessed at the bedside to establish the likely cause and whether it will affect the procedure. This highlights the importance of the pre-procedure consultation. Assoc Prof. Koukounaras says Mr B was afebrile and his blood pressure was stable. He states, I have found no other cause within the medical records and no concern was raised by the Interventional Radiology Fellow that morning. He also notes the prone positioning (laying on stomach) can exacerbate abdominal pain which can elevate the heart rate.

23. Assoc Prof. Koukounaras notes the nursing staff advised the procedure was unfamiliar to them. He says this is not surprising as it is a relatively infrequent procedure. He opines best practice is for an Interventional Radiology unit to have procedural guidelines available to all staff so they can familiarise themselves with checklists which can further improve communication and avoid errors.

24. Assoc Prof. Koukounaras says both phenol and ethanol are acceptable choices for the procedure. He states,

> *It is unclear why RBWH decided to stock high concentration phenol in Radiology and dilute it for procedures. It would be important to dilute it for procedures. It*

would be important to determine whether Ethanol or low concentration phenol was available at the hospital phenol 6% aqueous for injection is listed on the Queensland Health List of Approved Medicines. Having to dilute pharmaceuticals does introduce the risk of errors. But it is practiced within Interventional Radiology with the commonest example in my practice being the dilution of Glyceryl Trinitrate (GTN) for the treatment of vasospasm during vascular interventions. I would expect Interventional Radiologists to be familiar with the concept of diluting medications prior to use.

25. As to the Interventional Radiologist's lack of knowledge, he acknowledges while the radiologist had not used phenol before and consulted the SIR guideline prior to the procedure, the SIR guideline is not a definitive description on the use of phenol for neurolysis. He says more detailed information is easily obtained in the literature. He notes the radiologist reviewed prior cases wherein 12ml and 20ml of phenol was injected. He states, this volume is significantly higher than what one would expect to use for phenol neurolysis with low concentration phenol but would be in keeping with the volumes used for ethanol neurolysis.

26. Assoc Prof. Koukounaras says the responsibility for knowledge of the agent, its concentration, and the volume to be administered, lies with the Interventional Radiologist. Delegation can be appropriately provided if there are clear instructions from medical staff and clear protocols available. Pre-prepared medication should be clearly labelled and confirmed at the time of administration by the Interventional Radiologist or by the scout nurse under direct instruction from the Interventional Radiologist. In addition, it should be checked off against a procedure guideline so as to provide an extra level of safety. He states, "*This illustrates the importance of developing and implementing standards of practice in Interventional Radiology*".

27. Regarding Mr B's developing an elevated heart rate and calling a medical emergency, he states,

> *The patient's heart rate became elevated during the procedure, and this was reported to Dr [redacted] It did not reach the mandatory MERT response rate of >160bpm (taken from the RBWH medical records) until the end of the procedure. As the heart rate increased during the procedure, the guidelines available from RBWH would indicate that increased observation would be necessary in the absence of other haemodynamic changes with no other intervention. I accept Dr [redacted] explanation that he felt the elevation was related to the procedure. Neurolysis can be painful, thus elevating the heart rate. Dr [redacted] did not know that he was injecting a high concentration of phenol. He had checked the positions of his needles on CT and also injected contrast to confirm the position. In addition, he injected Bupivicaine without incident. Finally, he would be unaware that phenol has an immediate local anaesthetic effect[1]. It is my opinion that he believed the procedure was progressing as planned at that stage. There was a small delay in activating the MERT response at the end of the procedure. But I do not believe this affected the outcome.*
>
> *Once the phenol was injected, there was very little that could be done, other than support the patient as best as possible. Unfortunately, the degree of toxicity, together with the patient's co-morbidities, were too great for Mr B to overcome. The inadvertent use of high concentration phenol for this type of procedure has been documented previously in the scientific literature although the reasons for this error in those cases was not explained.*

28. In summary, Assoc Prof. Koukounaras believes that the procedure was indicated, and that Dr [redacted] was properly trained and competent to perform a neurolysis procedure with ethanol. He states,

> *He did not have adequate training in the use of phenol as a neurolytic. His statement indicates that he had identified this deficiency in his knowledge prior to this case. Unfortunately, he did not actively seek detailed knowledge from his colleagues or from the literature. I believe that he may have assumed that the two agents were interchangeable and that the correct dose would be prepared for him prior to injection based on his previous experiences. Finally, I believe that he may have assumed that any significant safety precautions that he needed to be aware of, such as the dilution of the phenol, would have been relayed to him beforehand by other staff within Radiology.*

29. He believes there were additional contributing factors to this outcome:

    a. The choice to stock phenol (80%) in Radiology for this procedure rather than low concentration phenol or ethanol. This increases the risk of a dosage error. I do not see any use for the undiluted phenol (80%) in Radiology. If it is to be used because there are no alternatives, it should be clearly labelled that it is to be diluted before use and education provided to relevant staff.

    b. The absence of a procedure guideline. All staff involved in the procedure were inexperienced with phenol neurolysis. This can happen from time to time. A procedure guideline would help provide certainty and confidence to all staff involved in the procedure. It would be a rapid resource to ensure correct equipment and medications are prepared.

30. The radiologist was provided a copy of the expert report. He had no comments to make in response.

The Use of Phenol at the RBWH

31. A detailed statement has been provided from the Assistant Director of the RBWH pharmacy. He has advised:

    a. The RBWH Medicines Advisory Committee (MAC) has clinical governance oversight on approving the use of phenol at the hospital.

    b. The MAC had granted the Department of Medical Imagining a 'blanket approval' to use phenol for percutaneous celiac and/or splanchnic neurolysis to treat chronic visceral abdominal pain mediated by celiac/splanchnic nerves.

    c. An approval for 80-90% phenol was made in February 2019 as the 10% product had been discontinued. The dilution procedure from the Wesley Hospital was referred for dilution process.

    d. Phenol was an impress medicine to the Medical Imaging Department. Such medications are not dispensed individually to patients.

    e. The phenol bottle is labelled as 'Phenol Liquid 80%, 100mL'. The RBWH Pharmacy is not involved in preparing any doses for individual patients nor is there any individual dispensing of the phenol product. Clinical staff were to remove the required amount of phenol from the bottle for further dilution to the required volume.

32. I attempted to locate a copy of the Wesley Hospital dilution procedure (the dilution procedure) which was referred to in the February 2019 Approval. The dilution procedure was not able to be located. It was not attached to the 2018 Application to the RBWH Medicines Advisory Committee. In the Application the author states,

> *Note that this procedure has historically been done with 10% phenol in Meglumine product until this became unavailable mid 2018. We now intend to replicate this by diluting stronger (80% or 90%) phenol solution which can be sourced by pharmacy from Wesley hospital pharmacy. We will dilute the solution to 10% strength using Visipaque contrast, following the procedures also done at Wesley Hospital.*

33. I wrote to the Wesley Pharmacy and was advised the Wesley Hospital had stopped using the Wesley Pharmacy in 2007. I wrote to the Wesley Hospital radiology practice and received a response from I-MED Radiology Network which runs the radiology services at the Wesley Hospital. Enquiries were made with an Interventional Radiologist in the practice who performs phenol injections. I have been advised,

> *The phenol we have been able to source for many years now comes at 80% strength. I understand that the interventional radiologist performing the procedures subsequently dilutes the phenol to 10% strength prior to the procedure, a practice which is based on their specialist experience and knowledge of this procedure*.

34. I sought a statement from an Interventional Radiologist who had been the Deputy Director in the Department of Medical Imaging at the RBWH from early 2018 through to mid-2021. He has advised,

    a. *Until late 2018, a 10% phenol product was available for use in a celiac plexus block procedure. This was a premixed solution of 10% phenol in Xray contrast. I am unable to recall its specific name, but I believe it was phenol 10% in Conray 280. We referred to the product as '10% phenol in Meglumine'.*

    b. *Once this product was discontinued, a solution needed to be found to this product no longer being available.*

    c. *Interventional Radiology colleagues at the Wesley Hospital had arrived at a solution which was that their pharmacy had access to a more concentrated phenol solution, which could simply be diluted in contrast, down to 10% strength, thereby replicating the previously available product. I became aware of this through Dr [redacted] who was working as an Interventional Radiologist at both the Wesley Hospital and the RBWH.*

    d. *The Interventional Radiology team at the RBWH intended to follow the same procedure as the Wesley Hospital.*

    e. *I recall that at the time the expectation of the Interventional Radiology team at the RBWH was that this was likely to be a temporary requirement. It was hoped that the previous product used, or an equivalent, would become available.*

    f. *I note that the form I provided expired in 2021 which was the same year I left RBWH, and that a subsequent similar form was presumably in effect at the time of the clinical incident.*

g. *I will add that I heard anecdotally that the same solution was also used at other hospitals in South East Queensland.*

35. Concerning the Wesley Hospital dilution protocol, he has advised he does not recall that there was a written procedure and says diluting a more concentrated solution down to 10% strength is within the skill set of any interventional radiologist. He states,

> *Any dilution procedure would have been verbally transmitted to the RBWH department, as a consultant staff member, Dr [redacted], worked in both departments. The interventional radiology community is small and techniques were often discussed and shared verbally.*

36. The radiologist was not aware of any guideline being developed at the RBWH for the dilution of phenol. On 27 February 2019, he sent an email outlining the required dilution to achieve a strength of 10.2%. He states,

> *Communicating such information by email as well as verbal discussions was the usual method of sharing such details within the department. However, the ability to calculate and make such dilutions is a familiar and fundamental skill for interventional radiologists and does not require a written procedure.*

37. The radiologist has advised there are a variety of techniques to perform a celiac block procedure which are described within peer reviewed literature. One such article was published in 2013 'Celiac Plexus Block and Neurolysis for Pancreatic Cancer'. The author of the article states,

> *For neurolytic blocks, 50-100% alcohol or phenol 10% concentration may be utilised. phenol has the advantage of being painless with a similar effectiveness; however, its duration of block is shorter. While alcohol has the advantage for duration of block, if it is injected by itself, there can be severe pain.*

38. The usual local practice at the time he was at the RBWH was to generally use approximately 10-12mls of 10% phenol on each of left and right sides. However, notes it is at the discretion of the radiologist as to how they perform the procedure. He states,

> *Speaking from my experience in working at RBWH from early 2018 to mid-2021, in any instance where a radiologist was asked to perform an unfamiliar procedure or provided with unfamiliar medication or equipment, they would generally have the following options available to them:*
>
> i. *Either to request and use that which they were accustomed to;*
>
> ii. *To decline to do the procedure;*
>
> iii. *To delay the procedure to consult the literature; or preferably and usually;*
>
> iv. *To request assistance from a colleague, in the form of anything from advice to demonstration, to supervision or direct assistance, until they were confident to operate independently.*

39. The RBWH has since advised the group approval for phenol 80-90% concentration has been cancelled and has been removed from the medicine cabinets within the

Department of Medical Imaging. Any patient requiring high concentration phenol will require individual patient approval.

Clinical Review by the RBWH

40. The RBWH completed a clinical review into Mr B's death. The author of the report has advised,

    a. The bottle of phenol had a label on it which included the name, concentration (80%) and a prompt to wear gloves. The label did not include advice regarding dilution. Potentially the bottles can be used multiple times as the volume far exceeds the amount required for one patient.

    b. At the time of the incident, it was not usual practice for medical officers to document a medication order for phenol in advance of a procedure. It was readily available in the Department so did not require a special order.

    c. The practice of not documenting the medication order is similar in other medical imaging facilities (this because the amount to be given during a nerve block is not known before the procedure).

    d. It would not be unusual for Interventional Radiologists to have a documented procedure, in the same way that a surgeon would not follow a documented protocol while undertaking surgery. Further, there was variation between the radiologists regarding their dilution methods, for example, 1ml 80% phenol with 8mls contrast in a 10ml syringe, or 3mls 80% phenol with 14mls contrast in a 20ml syringe.

41. In addition to removing phenol, requests for splanchnic nerve blocks will be flagged by the Imaging Department leadership and be considered on a case by case basis in consultation with the Pharmacy, with a plan to provide 5% pre diluted phenol if required, pending the outcome of the clinical incident analysis review. A forcing function has also been added to the electronic medical record, requiring confirmation of a second person check prior to the procedure.

42. I have been advised five other Queensland Health facilities have been advised about the event.

43. The author of the report further states,

    > *The review team considered potential contributing factors, and noted that while staff work within a team, and practitioners are responsible for their actions, it is the healthcare system which offers the safety barrier to minimise the risk of patient harm. Key safety principles were discussed around practitioner/staff, standards (medication management, procedures, work unit guidelines) and system factors.*

44. There were four caution statements with corresponding recommendations made by the clinical review team:

    > Causation Statement: *The provision of 80% phenol to DMI increased the likelihood that undiluted phenol was used which led to an adverse patient outcome.*

Recommendation 1: The RBWH investigates the provision of a pre-diluted phenol product (other than the 5% already commercially available) by an external provider, in response to feedback from RBWH Interventional Radiologists regarding preferences and evidence.

Causation Statement: The absence of a formalised department peer support process for new DMI medical staff as well as variations in medical officer practice increased the likelihood of a significant medication incident occurring, which led to an adverse patient outcome.

Recommendation 2: DMI identify high-risk interventional radiology procedures and implement a formalised and endorsed department peer support program for these, which encompasses existing as well as future DMI relevant medical officers.

Causation Statement: The provision of 80% phenol in 100ml bottle to DMI rather than the maximum volume required for neurolysis increased the likelihood that the incorrect volume and therefore dose of 80% phenol was used, which led to an adverse patient outcome.

Recommendation 3: DMI determine the maximum volume of 80% phenol required for neurolysis, and the Director of Pharmacy investigates the procurement, compounding/manufacture of single-use volume for the RBWH.

Causation Statement: The absence of a documented regulatory framework in DMI that outlines the dilution requirements and maximum volume of 80% phenol to be provided for use in neurolysis increased the likelihood that the incorrect dilution and dose was utilised which led to an adverse patient outcome.

Recommendation 4: RBWH is to develop a regulatory framework/guideline which documents the processes required for the supply and administration of phenol used for neurolysis at the RBWH.

45. There was one 'lesson learnt':

    The Time Out check in many areas of DMI is led by the nursing staff, rather than the medical officer/proceduralist. This is in contrast to usual practices in RBWH operating theatres.

Additional Information from the RBWH

46. I sought further information from the RBWH concerning the bottle of phenol. I have been advised,

    a. The RBWH pharmacy sourced the phenol 80% 100mL form Central Pharmacy.

    b. Central Pharmacy is the statewide distributor of pharmaceuticals for all Queensland Health facilities and manages the procurement of pharmaceuticals from manufacturers and other external suppliers.

    c. The RBWH did not decant the phenol into the small brown bottles or alter the packaging. How it presented to the clinician (as per the photo on page 5 of the SAC 1 report) was how it was supplied from the Central Pharmacy.

d. Central Pharmacy ordered the phenol from Beaumaris Pharmacy in Victoria. It is likely Beaumaris Pharmacy applied the label to the bottle as the details of the pharmacy are listed on the bottle.

e. The label on the bottle reads,

> LIQUID PHENOL 80% 100ML
> AVOID CONTACT WITH SKIN AND
> EYES WEAR PROTECTIVE GLVOES
> WHEN MIXING OR USING
> B80743743954 EXP 08/24
> KEEP OUT OF REACH OF CHILDREN
> BEAUMARIS PHARMACY
> M. COSGRIFF & D SYZLIT (PROPS.)
> 1A EAST CONCOURSE, BEAMARIS 3193 TEL 9589 2676

47. In addition, there is a circular label coloured purple that reads 'Hazardous Drug!'.

48. There is a second label on the bottom of the bottle that reads:

> If spilt on skin remove contaminated
> clothing, wash with soap & water, then
> swab with glycerine or PEG or meth. Spt
> KEEP OUT OF REACH OF CHILDREN
> BEAUMARIS PHARMACY
> M. COSGRIFF & D SYZLIT (PROPS.)
> 1A EAST CONCOURSE, BEAMARIS 3193 TEL 9589 2676

49. The bottle is 100mL amber/brown coloured and is designated as a POISON bottle. The word 'POISON' is vertically indented in the glass down one side of the bottle.

50. Upon receipt from Central Pharmacy, the bottle is sealed with a red plastic screw top lid with red adhesive tape applied around the side of the lid, where the lid meets the neck of the bottle.

51. I sought a statement from the interventional radiologist who worked at both the Wesley Hospital and the RBWH, referred to above. I have been advised,

a. On 19 July 2023, he supervised a liver lesion biopsy on Mr B.

b. On 20 July 2023, he was part of the medical emergency response team in the department of medical imaging in response to an alarm raised regarding Mr B.

c. He was not present during the administration of the phenol to Mr B he was performing another procedure in a different part of the department and had just finished when the alarm sounded.

d. Concerning the administration of phenol, the radiologist states,

i. *Prior to 2018 a premixed phenol in meglumine was available. Sometime during 2018 this product was no longer available for any hospital to order.*

ii. *After the premixed phenol in meglumine became unavailable in 2018, I was informed by a colleague, Dr [redacted], that the practice at the Wesley was able to source a more concentrated solutions of phenol that required dilution.*

iii. *The original solution of phenol varied between 80 and 92% and was to be diluted with aqueous contrast media to a final concentration of approximately 10%.*

iv. *This was discussed amongst interventional radiologists at the Wesley but no formal written protocol of the requirement to dilute or how to dilute a 10% was thought necessary as it was believed to be within the skillset of a trained interventional radiologist. Further, it is customary that if an unfamiliar device or preparation going to be used, the performing physician would seek advice of a colleague who had done it before, have them assist/supervise if necessary or decline to do the procedure and find someone else who was more comfortable to do the procedure.*

v. *Given my position at both the RBWH and the Wesley, I had the same discussion I had at the Wesley with my fellow interventional radiologists at the RBWH at the time about sourcing a more concentrated solution of phenol that required dilution.*

vi. *Again, no written protocol for dilution was thought necessary at RBWH as it was within the skillset of the interventional radiologist and fellows, and all employed at RBWH at the time knew the phenol solution needed to be diluted.*

vii. *There is not a prescribed dose of 10% phenol for coeliac plexus/splanchnic nerve block or other neurolysis procedure.*

viii. *The amount of 10% phenol administered is based on anatomical distribution of the opacified solution in the target range.*

ix. *In my experience, it was rare to administer greater than 20ml of 10% and the usual amount I used was between 6 and 16ml in a splanchnic nerve block.*

x. *For the purposes of this statement, coeliac plexus and greater splanchnic nerve neurolysis are essentially synonymous. The efficacy of various concentration in the literature (articles by Bahn et al and Kambadakone et al) varies (as much as between 3 and 20%).*

xi. *During the transition/before an 80% solution was available, some premixed 5% phenol in almond oil and 6% in aqueous solution were trialled at RBWH but were anecdotally ineffective in a small number of cases.*

xii. *The interventional radiologists at RBWH had all reviewed the literature referencing the variability of techniques and concentrations between 3 and 20%* (references omitted) *had been described. Based on previous experience using the premixed 10% in meglumine, it was thought appropriate to dilute to a similar concentration as had been previously used with good effect and safety.*

xiii. *Following this incident 80% phenol was withdrawn and approval for its use was revoked.*

xiv. *Since this incident occurred, I understand a detailed analysis was performed at RBWH looking for system errors that may have contributed to the outcome in this case.*

xv. *A peer support programme for procedures that were deemed to carry a potentially high risk application of therapeutics was introduced for newly commencing consultants so that local procedures and protocols could be introduced to a new staff member.*

xvi. *Given the variable frequency of such procedures, a set number of cases rather than a period of time to familiarise new employees was deemed preferrable.*

xvii. *A compounding pharmacy who could supply 10% phenol in aqueous solution was found, and a maximum dose of 20ml of 10% phenol is dispensed per case according to a prescription supplied.*

xviii. *Unused phenol is discarded according to an agreed process with pharmacy.*

xix. *I have discussed these processes with colleagues at the Wesley and other hospitals in Queensland where to my knowledge a coeliac plexus/splanchnic nerve block may be performed by interventional radiologists and locally with chronic pain physicians who perform this and similar procedures.*

Therapeutic Goods Administration

52. The Department of Health and Aged Care have provided information concerning the application of the *Therapeutic Goods Act 1989* (Cth) (TGA).

    a. The TGA was adopted by Queensland through the *Therapeutic Goods Act 2019*. The adoption of the Act was intended to provide a uniform system for the regulation of therapeutic goods.

    b. There are exempt goods under the TGA. Relevant to the use of phenol in a hospital setting are Item 6A of Schedule 5 and Item 5 of Schedule 5A of the *Therapeutic Goods Regulations 1990*. The effect of the two items in the regulations is that therapeutic goods made by a hospital, or a contractor fall outside the registration and listing regime of Part 3-2 of the TGA.

    c. Additionally, in Queensland the List of Approved Medicines which is a list of medicines that can be used in Queensland public hospitals and institutions is maintained by the Queensland Health Medicines Advisory Committee. Phenol is contained in the list.

    d. The TGA also provides a framework for the Scheduling of substances under the Standard for the Uniform Scheduling of Drugs and Poisons.

e. Within the Poisons Standards are ten schedules. Phenol is listed in Schedules 2, 4, 5, and 6. This appears to relate to the topical use of phenol.

53. I note the phenol listed in the Queensland Approved Medicines list is for injection and the current strength is 5% in Oil 5ml and 6%, 10 ml (aqueous).

Response from Queensland Health Medicines Advisory Committee

54. I wrote to QMHAC regarding the availability of phenol products on the Queensland Health List of Approved Medicines (LAM). I have been advised,

> *QHMAC is a peak expert advisory group comprising senior medical practitioners from a range of specialties, nursing and pharmacy representatives that maintains the LAM. The LAM is the official statewide formulary – a limited list of medicines and other therapeutic agents approved for use in Queensland Health public hospitals and facilities.*

55. I have been advised a phenol 80% product has never been listed on the LAM. No submissions were forwarded from the RBWH or any other party for its consideration of this product. It is a non-marketed medicine, which is not registered with the TGA.

56. The usual process would have been to request a change to the LAM, and for a Queensland Health clinician to complete a LAM submission. Once completed, the submission is first assessed by the local hospital Medicines Advisory Committee (MAC) or equivalent, prior to being forwarded to the Queensland Health Medicines Advisory Committee (QHMAC) for statewide consideration. The Director, Medication Services Queensland has advised the advantages of submitting LAM applications to QHMAC include,

- *Consideration and view of the safety, effectiveness, cost effectiveness, equity of access, implementation and implications of LAM listing the requested item/s compared with existing LAM products by clinicians from a broad range of medical specialities.*
- *Facilitating an increased level of local scrutiny for IPAs, should an item not be added to the LAM.*
- *Reviewing LAM listings in response to advice received that products have been discontinued.*

57. If there is a clinical need to access a medicine not included on the LAM for an individual patient, a clinician can seek individual patient approval (IPA) via their local hospital approval process. The Director of Medication Services Queensland states, "*QHMAC is not responsible for these local clinical decisions and does not have visibility of local IPAs or other patient group (blanket) approvals in place at sites*".

58. I have reviewed the Queensland Health, 'Management and governance of individual patient approvals for medicines and other therapeutic goods. Under the heading, 'Patient group ('blanket') approvals, the author states,

> *Patient group approvals are strongly discouraged. There use can cause disruption to the management of patients when transferred between health care facilities, leading to financial, clinical and administrative issues at the receiving hospital, and they do not reflect the QH intent of equity of access. For these reasons, HHSs are encouraged to forward submissions for patient group approvals to QHMAC for consideration.*

59. A Patient Safety Notice (PSN) 'Eliminate phenol 80%' was issued by the Medication Safety Team, Medication Services Queensland in May 2024. This prompted a review of all LAM listings pertaining to phenol. This resulted in removing phenol 10% (as no longer manufactured, changing the 6% solution (there had been a change in the product stocked), and maintaining the 5% listing. A cautionary note was also added to the LAM regarding the use of concentrated phenol. I have been advised,

> *It is not common practice to add cautionary notes to non-LAM items. Given the serious risk of harm, however, it was agreed that, in this instance, a note may be another mechanism to prompt review by someone checking the LAM prior to sourcing a product with very infrequent use. The cautionary note was inserted effective 1 July 2024.*

60. I sought clarification from the Director, Medication Services Queensland as to whether the blanket approval by the RBWH MAC was appropriate for the 80% phenol. I have been advised,

> *In general, patient group ('blanket') approvals are discouraged by QHMAC. However, there are local clinical circumstances where blanket approvals may be appropriate. A submission to add a medicine on the LAM that is not approved by QHMAC does not necessarily mean that the use of the medicine is not appropriate in the clinical circumstances outlined in the submission. It may be the case that QHMAC considers the use appropriate, but that the medicine is not suitable for statewide listing as it may encourage wider use that is not cost-effective. For example, a particular hospital may have a niche use for a higher cost medicine that such a medicine is better managed locally by the hospital via local clinical governance processes (such as a blanket approval) instead of being listed on the LAM for statewide use. Ultimately local MACs decide on the appropriateness of the medicines used in their facilities.*

61. I asked if under the current arrangement, the circumstances regarding phenol could happen again. I was advised that the LAM is a limited list of medicines and other therapeutic agents with evidence of safety and cost effectiveness, approved for use in Queensland Health public hospitals and facilities. The Director states,

> *It is important to note that the LAM is not a regulatory tool, and just because a medicine is not listed on the LAM does not mean it cannot be prescribed or used in Queensland public hospitals and facilities. There may be clinical scenarios where the use of a non-LAM medicine is an appropriate therapeutic option for a patient. At a local level, hospital MACs (or equivalent) are responsible for maintaining clinical governance processes to guide this clinical decision making by prescribers.*

Clinical Excellence Queensland

62. I sought a statement from Clinical Excellence Queensland concerning the steps, if any, that have been taken to attempt to avoid a similar error occurring again since the incident occurred. I have been advised,

    a. On 18 October 2023, the RBWH notified Patient Safety and Quality a Clinical Incident Analysis (CIA) report for Mr B had been completed. The RiskMan was provided. A Copy of the CIA was provided on 1 November 2023.

    b. Medication Services Queensland (MSQ), Queensland Health, received notification of the incident on 21 July 2023.

c. In response to the incident, MSQ developed a Patient Safety Notice (PSN) Eliminate phenol 80%. The PSN was published on 7 May 2024 and circulated statewide.

d. The purpose of the PSN was to inform Hospital and Health Services (HHSs) of the necessity to stop purchasing, prescribing, dispensing and administration of 80% phenol. The PSN identified eight actions required by HHSs, these are:

    i. *Disseminate this Patient Safety Notice to all relevant clinical staff.*

    ii. *It is strongly recommenced, wherever possible 80% phenol is eliminated from use for the reasons listed in this notice.*

    iii. *Identify all areas where phenol 80% solution is used in your service and review procedures and guidelines to substitute a safer and more suitable alternative wherever possible.*

    iv. *Ensure clinical areas are informed of how to obtain agreed safer alternatives and then remove phenol 80% from all storage areas and stop using this product in all clinical areas.*

    v. *Ensure electronic prescribing systems identify undiluted phenol 80% and follow all recommendations.*

    vi. *Record any suspected adverse or near miss events in RiskMan and follow local procedures for reporting to the Therapeutic Goods Administration. Revisit this notice after any incidents.*

    vii. *Table this patient safety communique at the appropriate Medication Advisory Committee or equivalent for consideration. Consider using the template position statement that is attached to this PSN.*

63. Additional measures which have been taken include,
    a. On 16 July 2024, MSQ advised the PSN was also shared on an alert's portal for access by other jurisdictions and a template for a position statement was included as an addition.

    b. Correspondence being sent to the following groups to raise concerns about the use of concentrated phenol products:

        i. Health Services Medication Expert Advisory Group (HSMEAG) via the Australian Commission on Safety and Quality in Health Care (ACSQHC) – out of session notice circulated regarding safety concerns of undiluted phenol 80%.

        ii. Council of Australia Therapeutic Advisory Group (CATAG).

        iii. Royal Australian and New Zealand College of Radiologists (RANZCR) via ASCQHC – response indicated there was no requirement for continued use of appropriately diluted phenol in conjunction with contrast media, that there are alternatives but if phenol is to be used there must be local practices specifying dilution and instructions.

iv. *Australian and New Zealand College of Anaesthetists (ANZCA) – response indicated support for recommendations in the PSH.*

v. *Society of Interventional Radiology (authors from University of Pennsylvania) – suggested an amendment to the published document Interventional Pain Management. The essentials of interventional pain management procedures noting it did not mention strength or volume of phenol in recommendations* (no response had been received as of 2 August 2024).

vi. *Queensland Department of Health Environment, Land and Water branch – requested advice on safe disposal of phenol 80% solutions.*

vii. *Work Safe – requested advice on safe disposal of phenol 80% solutions.*

Conclusion

64. After considering the material obtained during the coronial investigation, I consider I have sufficient information to make the necessary findings required by s45(2) of the *Coroners Act 2003*, in relation to Mr B's death.

65. Very sadly Mr B had received a devastating diagnosis of metastatic pancreatic cancer. His shortened life expectancy was shortened even further by the tragic error which occurred when trying to alleviate Mr B's significant pain. This resulted in Mr B being injected with an excessive (which turned out to be fatal) dose of phenol.

66. Mr B's premature death was entirely preventable. There were several omissions in the care he was provided. Despite the systems issues regarding the stocking of the higher dose of phenol in the radiology clinic, the primary responsibility was that of the radiologist. It is a fundamental principle to check that the dose of any medication administered to a patient is within the therapeutic guidelines. This did not occur. I am satisfied, the radiologist has reflected on his error.

67. I note five other Queensland Health facilities had been advised about this event following the clinical review by the RBWH. I am not sure why there was not a broader awareness campaign at that time. After liaising with Clinical Excellence Queensland, I am now satisfied a more robust process has been undertaken to raise awareness of this risk with clinicians throughout Queensland and beyond. I am hopeful through this awareness campaign such a tragic clinical error will not occur again.

68. I have balanced the public interest of holding an Inquest (formal court hearing) against the consequences of re-traumatising Mr B's family, including his young son, and the clinicians involved in this case by participating in a public hearing. This decision had been made on the basis, Mr B's family have agreed for these findings to be published on the Coroners Court of Queensland website, and because of the comprehensive measures which have occurred to try and avoid such a tragic clinical error from occurring again.

69. In addition to publishing these findings, a copy of the findings will be distributed widely, including to the RBWH, Clinical Excellence Queensland, the Office of the Health Ombudsman, and the Royal Australian and New Zealand College of Radiologists.

70. I again extend my condolences to Mr B's family and friends for their loss.

I close the investigations.

Melinda Zerner
Coroner

02 June 2025