Royal Free London
NHS Foundation Trust

PFD Response using a systems-based review

Name: John Tompkins

MRN: [redacted]

Date of Birth: 11 September 1950

Date of Death: 25 July 2024 (73 years old)

Inquest heard on 6 December 2024

PFD report issued on 11 February 2025

PFD response due on 8 April 2025

A note of acknowledgement

We acknowledge and appreciate the diligent efforts of the staff who supported this patient safety investigation. Their commitment to patient safety and willingness to improve to prevent future safety events, are highly commendable.

The staff's participation in the multidisciplinary team meetings and their extended support in conducting observational studies in busy lists, have been invaluable to the investigation process. The collaborative approach taken by the learning response team, has been pivotal in identifying the factors that contributed to the event.

Led by a Learning Response Lead trained to conduct investigations for learning, the team has adhered to the highest standards. Their dedication to identifying actionable insights and implementing safety improvement plans, based on the findings, demonstrates a strong commitment to enhancing the quality of care provided to patients.

In conclusion, the collective efforts of all involved, have significantly contributed to the success of this PFD Response, paving the way for meaningful improvements.

Executive summary

Incident overview

A 73 year old patient with liver cirrhosis, who developed hepatocellular carcinoma (HCC) was admitted to the Royal Free Hospital on 10th July 2024 for elective Trans Arterial Embolisation (TAE) and Portal Vein Embolisation (PVE) in preparation for surgical liver resection. The Cancer Multi-Disciplinary Team (MDT) recommended sequential TAE and PVE, but combined TAE and PVE were performed at the same time on 11/07/2024. The letter written by the referring hepatobiliary (HPB) consultant to the GP indicated the intention for the procedures to be staged sequentially. However, the term "sequentially" was not documented in any of the clinical notes after the HPB consultant made the documentation on the electronic patient record (Cerner) on 28/05/2024. As such, the patient had the procedures both booked for and performed on the same day/same sitting. Consent was obtained for both procedures, but the material risks of combining them were not discussed with the patient, nor was it articulated that the combination being performed together was new.

Post-operatively, on 13 July, the patient developed acute liver failure related to to liver ischemia and inadequate function of the non-embolised liver. The patient was admitted to ITU on 14 July. Despite maximal medical care, he developed respiratory failure and hepatic encephalopathy secondary to acute liver failure, leading to multi-organ failure. The HPB MDT determined that recovery was not possible. With the family's consent, life-sustaining therapies were withdrawn, and the patient passed away on 25 July 2024.

Summary of key findings

- Individual requests were made for TAE and PVE using the electronic patient record (Cerner). It neither specified the sequence of the procedure nor the interval between them, despite the referring HPB consultant mentioning sequential TAE and PVE. The requests appeared on the digital radiology information system (CRIS) as a single event with two procedures because both involved the liver.
- The patient was booked for both procedures as combined under general anaesthetic (GA).
- There is a note on CRIS - discussed with the interventional radiology (IR) consultant on 24/6/2024 and agreed. Vetting was done informally in passing with the radiologist.
- Vetting is done by the radiologists and is a thorough and personalised review of the booking. Radiologists meticulously review patient documentation, including previous notes, images, and clinical presentations, to determine the appropriateness and urgency of the procedure.
- There were communications from the hepatobiliary (HPB, referring team) specialist nurse and radiology manager as to whether both procedures would be done together. Neither were aware that the procedures needed to be performed and booked sequentially.
- There was an assumption that it is widely known that both procedures need to be done sequentially with a period in between the two bookings. This was not known to all staff as some staff were new, did not have the organisational memory and there was no SOP relating to the booking. As a confounder, it is relatively common for a different combined procedure, that of portal vein embolisation (PVE) and hepatic vein (HE) embolisation to be performed either during the same sitting or more usually the next day. It is quite rare for both procedures to be done together even sequentially.

- The investigation noted that a concern was raised on the day of the briefing, when the IR consultant encountered the patient booked for both TAE and PVE in one sitting, in contrary to the expected PVE only under GA. Attempts to reach the referring HPB consultant failed as he was on annual leave. Other HPB surgical consultants were not contacted as it was felt they would be unaware of the details of the case, so unlikely to be prepared to make / change management decision
- Although notes were again reviewed, the more recent entries did not refer to the procedure as a sequential.
- The very experienced IR consultant was aware of a small study that provided limited evidence that the procedures could be safely performed together and decided to proceed. He did not register that the combination was considered "novel" and required specific granting through the Trusts novel procedure process, nor was there an attempt to seek advice from the clinical or medical director. The decision was influenced by awareness of the pressures of admission, other patients waiting for procedures and potential delays that could ensue to this patient's surgery.
- The workflow and processes in IRCU are fluid and dynamic on the day to accommodate both emergency and scheduled cases in order of priority. This would have added to the complexity, cognition and sensemaking on the day that may have led to the decision to undertake the TAE and PVE as a combined procedure.
- The specialist registrar (ST4) did not appreciate or discuss that this particular combined procedure was being performed for the the first time at RFH. The specialist registrar was new to interventional radiology at the time, and this was not flagged as a novel procedure. The IR consultant discussed the procedure with the patient after consenting. As far as the IR consultant could recollect, the additional risk of a combined procedure was not discussed with the patient.
- The nursing team and radiographers who were in the procedure room were unaware of these discussions at the briefing and proceeded with additional safety checks using the already obtained consent for TAE and PVE. The finalised list is available on the digital record on the shared drive.
- Following the death of the patient, the team did not report the safety event as they considered it was a complication of the procedure, not recognising it as a complication of the increased risk of the simultaneous procedure.

Summary of areas for improvement and safety actions

- Issues in vetting and scheduling process: vetting was performed but without clear documentation or consultation with the relevant parties.
- The dynamic nature of operations and processes in IRCU added to the complexity and sensemaking on the day leading to a decision to proceed with a combined procedure.
- Two individual procedure requests on Cerner appeared as a single event on CRIS, creating ambiguity.
- The ambiguity between sequential and simultaneous was not articulated as it was assumed this was a norm and would be understood by all stakeholders including the radiologist. The Cerner system currently does not aid booking of sequential procedures. Additionally, to request a HVE the HPB team had to use the TAE request process on Cerner as a specific option for HV, as it is not available is the current build of the system. To mitigate, the HPB

team specify within the clinical information that a HVE is the procedure required. This could add further ambiguity.

- There were no cues or triggers to prompt staff to consider this an unusual event that would require further exploration from booking.

Contents

1. Background and context

To gain a comprehensive understanding to enable a PFD response, it was essential to consider the broader context within which it occurred. This includes examining relevant medical conditions and procedures, as well as the national and local policies in place at the time. By providing detailed background information, this section aims to set the stage for the subsequent analysis and findings.

1.1 Diagnosis and Treatments:

Hepatocellular carcinoma (HCC) is a type of liver cancer that starts in the cells of the liver. It is very serious and can be life-threatening. The main causes of HCC include infection with hepatitis B or hepatitis C and having liver cirrhosis, which is a condition where the liver becomes scarred and damaged over time.

For individuals diagnosed HCC, there are several treatment options available that can help manage the disease and improve quality of life. Before considering liver resection, it is essential to explore other therapeutic procedures such as Trans-Arterial Embolisation (TAE) and Portal Vein Embolisation (PVE).

Trans-Arterial Embolisation (TAE) is a minimally invasive procedure used to treat liver tumours by cutting off their blood supply. During TAE, an interventional radiologist inserts a catheter into the hepatic artery **under local anaesthesia** and injects embolic agents to block the blood flow to the tumour. This deprivation of nutrients and oxygen can cause the tumour to shrink or die. TAE is particularly useful for patients who are not candidates for surgery or those with multiple liver tumours.

TAE can be beneficial before Portal Vein Embolisation (PVE) and liver resection in several ways. Firstly, it can reduce tumour size and make subsequent procedures, such as PVE and liver resection, more effective and safer. Secondly, by decreasing the tumour burden, TAE can help improve liver function and overall patient health, thereby enhancing their suitability for further treatments. The combined approach of TAE followed by PVE can stimulate liver regeneration, ensuring adequate liver volume for safe resection and improving postoperative outcomes.

Portal Vein Embolisation (PVE) is another innovative procedure that can be considered before liver resection. PVE involves the embolisation of branches of the portal vein under general anaesthesia to redirect blood flow. By selectively blocking parts of the portal vein, PVE stimulates the growth and regeneration of the liver tissue in the remaining sections. This technique is beneficial for patients who have insufficient liver volume for safe resection. By enhancing liver growth, PVE can increase the chances of a successful liver resection and improve postoperative liver function.

Sequential TAE followed by PVE procedures are in clinical practice infrequent and when performed the interval between the procedures is typically few weeks to allow sufficient time for the liver to adapt and recover, optimising the effectiveness of the subsequent PVE.

1.2 Interventional Radiology and Cardiology Unit (IRCU)

The IRCU at Royal Free London NHS Foundation Trust (RFL) carries out a wide range of procedures receiving patients form all clinical/medical specialities throughout the Trust. Working closely with hepato-biliary and liver transplant teams the suite performs several procedures relating to these specialities. The procedures include hepatic angiogram, trans-jugular liver biopsy, cholangiography, Trans-Arterial Embolisation (TAE), Portal Vein Embolisation (PVE), and biliary drainage.

The interventional radiology (IR) department at Royal Free London NHS Foundation Trust conducts a variety of minimally invasive image-guided diagnostic and therapeutic procedures for patients throughout the Trust. The interventional suite covers 2800 procedures per year and covers inpatients, outpatients, private patients, A&E patients, emergency out of hours patients and day-case patients. The suite comprises three interventional rooms equipped with three vascular single-plane Siemens angiography units as well as an Ultrasound Interventional room.

Figure 1 IRCU at RFL

1.3 Guidance

The PFD response considered a number of procedures that were related to the investigation (Appendix 2):

- National Safety Standards for Invasive Procedures (NatSSIPs)
- Royal Free Consent Policy
- Royal Free New Interventional Procedures (NIPs) policy

1.4 Definitions of "MDT" Use in the report

The terms "MDT" is referred to in various places in the document. There are three occasions where an MDT is used. There was cancer multidisciplinary team meeting (MDT). This happened prior to the referral that was made. As part of the investigation, an MDT learning was facilitated. This is referred to as "investigation MDT" in the report. The investigation MDT was attended by the team that was involved in the procedure. An earlier MDT learning response was also undertaken as part of the response to the prevention of prevention of future death in January 2025.

2. PFD response approach

2.1 Investigation team

Role	Job title	Dept/directorate and organisation
Investigation commissioner/convenor	Interim Director of Nursing	Chase Farm Hospital Unit
	Interim Medical Director	
Investigation lead:	Head of Quality Governance and patient Experience Patient Safety Specialist	
Investigation Team	Interim Quality governance managers	
	Quality governance manager	
	Consultant Interventional Radiologist, Radiology Clinical Governance Lead	
	Interim Matron Radiology	

2.2 Investigation Commissioning and Terms of Reference

Following the death of the patient, immediate review at the HPB and Radiology Mortality & Morbidity (M&M) were carried out. The inquest was heard on 6 December 2024. Clinical staff gave evidence at the inquest and were supported by the Counsel. The Trust submitted further evidence in writing about what actions the Trust would take to improve safety and made submission against a Prevention of future death (PFD) on 14 January 2025. An MDT was undertaken to inform the response. The coroner has informed that there remain areas of concern giving rise to the risk of

future deaths, hence a PFD was issued on the Trust on 12 February 2025. The safety event was reported via Trust's safety events reporting system (DCIQ) on 24/02/2025.

The risks that need to be addressed set out in the PFD report are:

- Limited internal review of the incident following the inquest on performing the two procedures at the same time
- The Trust seemingly did not consider the NatSSIPS2 standards either when undertaking the procedures, nor in detail as part of its review following the inquest.

The team discussed the patient safety event at the PSERP meeting on 25 February 2025, which is held every Tuesday. The panel includes the Interim Medical Director (Group Clinical Services and Chase Farm Hospital, GCS & CFH), Interim Directo of Nursing (Group Clinical Services and chase Farm Hospital), Radiology Governance Clinical Lead, Deputy Director of Safety and Risk (RFL), Head of Quality Governance and Patient experience (GCS & CFH), Head of Patient Safety and Risk (Royal Free London, RFL), and other panel members of the unit, where this was declared to be investigated as Patient Safety Incident investigation (PSII) under the Patient Safety Incident Response Framework (PSIRF).

This PFD response covers the delivery of care and any deviation from the standard of care provided during the radiology procedure encounter, focusing on the processes around information provision, consent-seeking, and adherence to NatSSIPs2. It aims to address the concerns raised by the coroner and the family, as mentioned in the PFD report. The investigation will thoroughly examine the decision-making process surrounding the elective IRCU procedures (TAE and PVE) and scrutinise the internal reviews conducted post-inquest.

It will also involve identifying any systemic issues that may have contributed to the safety event and proposing actionable recommendations to prevent future occurrences. The scope will not include any investigation around the post-operative care provided at the ITU, as this falls outside the agreed boundaries of this inquiry.

2.3 Family Concerns

The family raised a number of concerns that were shared by the coroner in the PFD report (Appendix 1).

Attempts have been made to answer the family's questions through the thorough investigation and can be found in Section 9 of the report.

3. PFD Investigation response process

3.1 Documentation Reviews

Relevant documents, such as Electronic Patient Records (EPR – Cerner), CRIS and PACS (Radiology departmental specific electronic records), staff rosters, Trust Policies and guidelines, IRCU Standard Operating Procedures (SOPs), IR LocSSIPs, IR Care pathways and email communication between the staff were reviewed as part of the investigation process to gather information. These documents offered objective record of the events and vital aspects of developing insightful improvement recommendations to make the care evidence based. The documentation timeline was produced (Appendix 1)

3.2 Interviews

Recollection of event meetings were conducted with key participants such as nurses, radiographers, interventional radiologists, referring HPB consultant and Clinical Nurse Specialist, nurse managers and admin staff to obtain firsthand accounts of the safety event. These meetings provided valuable insights into the perceptions and experiences of those directly affected.

Staff said that they were confident in speaking up and raising any safety concerns they experience in their day-to-day operations. Furthermore, participants were encouraged to share their thoughts on systemic issues and potential improvements within the IRCU.

In addition to recollection of event meetings, the investigation team also observed the actual work processes as done. This included shadowing the staff during their routines and identifying any discrepancies between documented procedures and actual practices. These observations were crucial in understanding the complexities of the work environment and the real-world challenges faced by the team.

3.3 Post Safety Event MDT Learning Response

An in-depth review of the processes and input from different disciplines were carried out during the MDT learning response on 20/03/2025 with the presence of three of the IRCU nurses, two radiographers, two radiologists, and the HPB CNS. The team involvement and participation were remarkable and throughout the session psychological safety and well-being of staff were ensured.

The meeting was supported by review of timelines, observations and observations undertaken in advance of meeting. The facilitator reviewed the patient pathway and individual contributions to care delivery, identifying areas for improvement and ensuring a thorough understanding of the events.

Investigatory MDT discussion added more information about the patient pathway in IRCU reinforcing the complexity and dynamic processes within the department, working environment and suggestions and recommendations for improvement.

Although the individual patient flow and processes discussed have a defined pathway, the workflow within the IRCU is flexible and complex. The vetting of procedures includes reviews to ensure that what is requested includes the right information, some following discussions are changed to

another procedure, some are rejected. There is no specific protocol for vetting, but some cases will have their own procedural protocol which will be taken into consideration. Despite the team brief done in the morning the list is subject to changes as requests are being received throughout the day with some being emergency.

The team's workload and the pressure of utilising the right resources are challenging mostly due to flexibility in scheduling on the day. The interventional suite covers 2800 procedures per year and covers inpatients, outpatients, private patients, A&E patients, emergency out of hours patients and day-case patients.

The IRCU team typically performs 0-5 elective procedures planned that are scheduled and admitted in the ward expressly for IR procedures in each day. In addition, there are 5–15 inpatients and emergencies. A total of fifteen procedures per day, five in each room. All patients are reviewed together during the morning team brief and allocated based on the availability. No individual room list is printed however a local SOP guides states that a list should be printed and displayed in each procedure room. There is an electronic live list.

As the patient was admitted, the ward staff followed their routine process of preparing the patient for a PVE, which was confirmed by the documentation by the anaesthetic team. It was not known that the patient was scheduled for a combined procedure.

The IR consultant stated in the Investigatory MDT that he discovered an uncertainty to the booking of the case a combined TAE and PVE, under PVE general anaesthesia list. The decision was either cancelling the procedure, to send the patient home and reschedule to the next available slot which would have likely incurred a delay that may have been significant or to do TAE under local which would mean cancelling the anaesthetic or to do both. It was known to the IR consultant that limited evidence did exist to the use of a combined procedure as per the study mentioned during the inquest.

The impression from the Investigatory MDT discussions were that there was pressure to begin procedures promptly leaving the team with limited time to review past notes thoroughly. In this case, the term "sequentially" was not documented in any notes after the HPB consultant made the documentation on Cerner on 28/05/2024. Reviewing notes from two months prior would be time-consuming for the team and delay a start of any procedures. This level of retrospective review is unlikely to be practically applicable in practice. The notes were reviewed as part of the confirmation of the procedure at the team brief, but the more recent entries in the electronic notes, did not refer to a sequential procedure.

The referring HPB consultant was contacted but was on annual leave. Considerations on contacting other members of the team or the on-call registrar was not pursued at that point. It was felt that other members of the team may or may not be aware of the case, especially as it is not common to undertake both TAE and PVE albeit sequentially. The IR consultant felt that other HPB consultants may have been unaware of the details of the case so unlikely to be prepared to make or change management decision.

There was pressure on the decision making and the impact of sending the patient back would mean a delay in his treatment. The patient was already waiting in the IRCU recovery room as he was scheduled as the first patient on the list.

Staff felt safe to raise concerns, unfortunately this procedure did not trigger major concerns. Undertaking a combined TAE and PVE procedure was not as obvious to all staff as a deviation to normal practice. Some staff recognised that TAE and PVE were only performed as individual procedures, which may be due to both procedures done for the same patient even sequentially was very rare. They did not feel there was a need to challenge as they trusted the knowledge and skills of the IR consultant and assumed any issues were resolved at the team brief.

The briefing does not include the entire nursing and radiographer team as the rest of the members need to prepare the rooms while the full list is being discussed. Not all staff were aware of the conversations and decisions made at the briefing. Despite a list being used to go through procedures, this list is subject to change following discussions. The record of the briefing is made on the electronic whiteboard in the radiology office, which is a live document.

Figure 2 Recovery Bay in IRCU

From the discussions, it appears that the recovery bay is a hub of activity as day patients are admitted, patients are consented, and patients are received following the procedure. IRCU workflow is more fluid and dynamic.

3. 4 Observational Study at IRCU

This section details the existing workflow and patient care process under investigation, referencing the Interventional Radiology Standard Operating Procedures, LocSSIPs/NatSSIPs, Image-Guided Surgery Care Pathway, and the LocSSIPs Checklist. An observational study was carried out on

14/03/2025 as part of the investigation process. The study was undertaken by the quality governance manager and Interim matron for radiology.

LocSSIPs for interventional radiology was developed by a multidisciplinary group of clinical practitioners. The document lays out the minimum standards of safety and care that should be applied to all interventional radiology invasive procedures performed within the radiology departments of the RFL Trust group of hospitals. The scope of this document sets out the minimum standards of safety and care to prevent never events during the invasive procedure by good practice in various aspects such as scheduling, workforce, handover, team briefing, consent and site marking, equipment check, sign-in and time out, sign-out, prevention of retained foreign objects, debrief and documentation. This is audited monthly and presented at Divisional Safety Board Meeting.

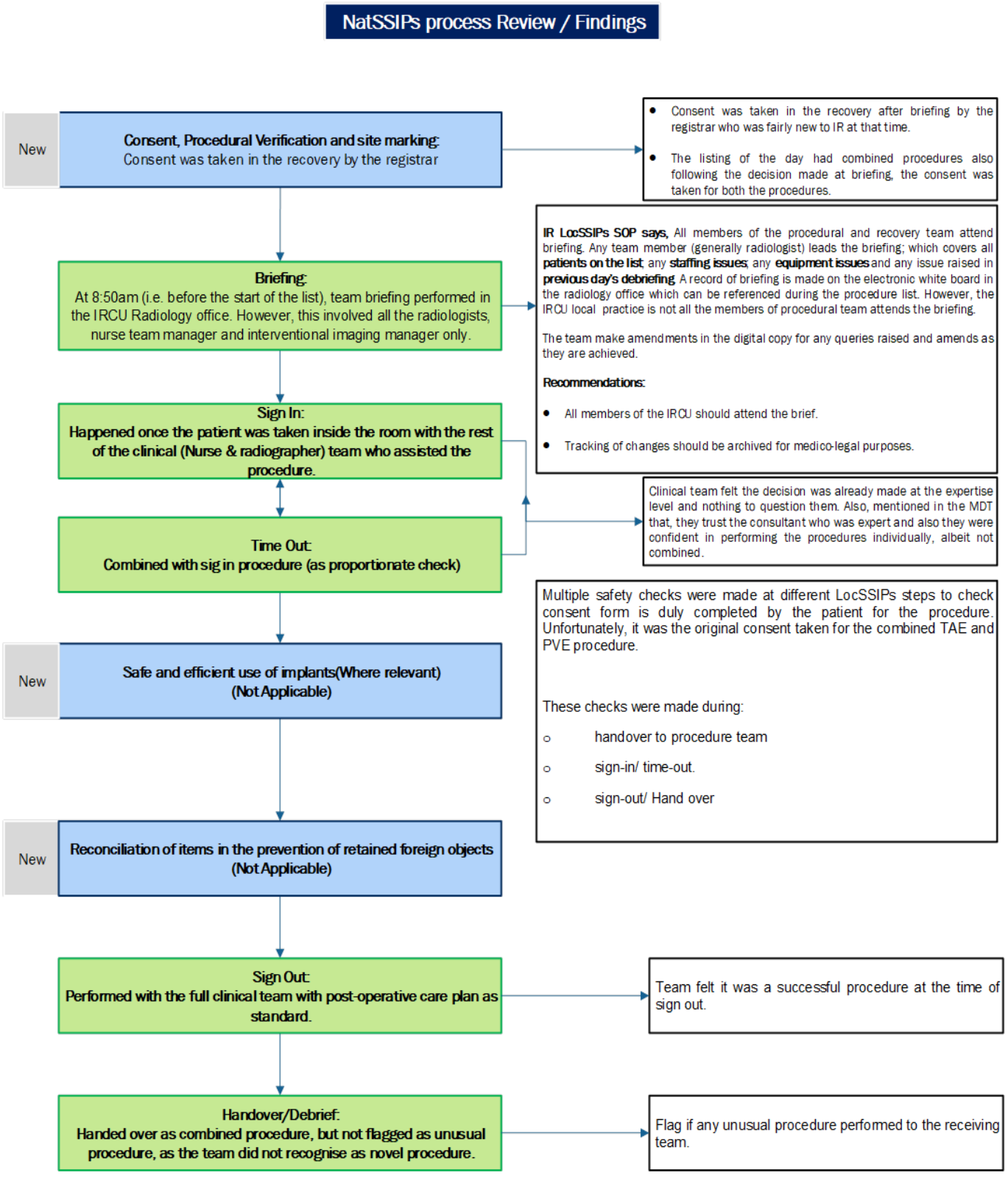


Figure 3 NatSSIPs2 process map

IRCU procedure rooms does not have anaesthetic room attached or holding bays for patients to wait for their procedures. Day patients and inpatients who are awaiting consenting are brought to the recovery bay.

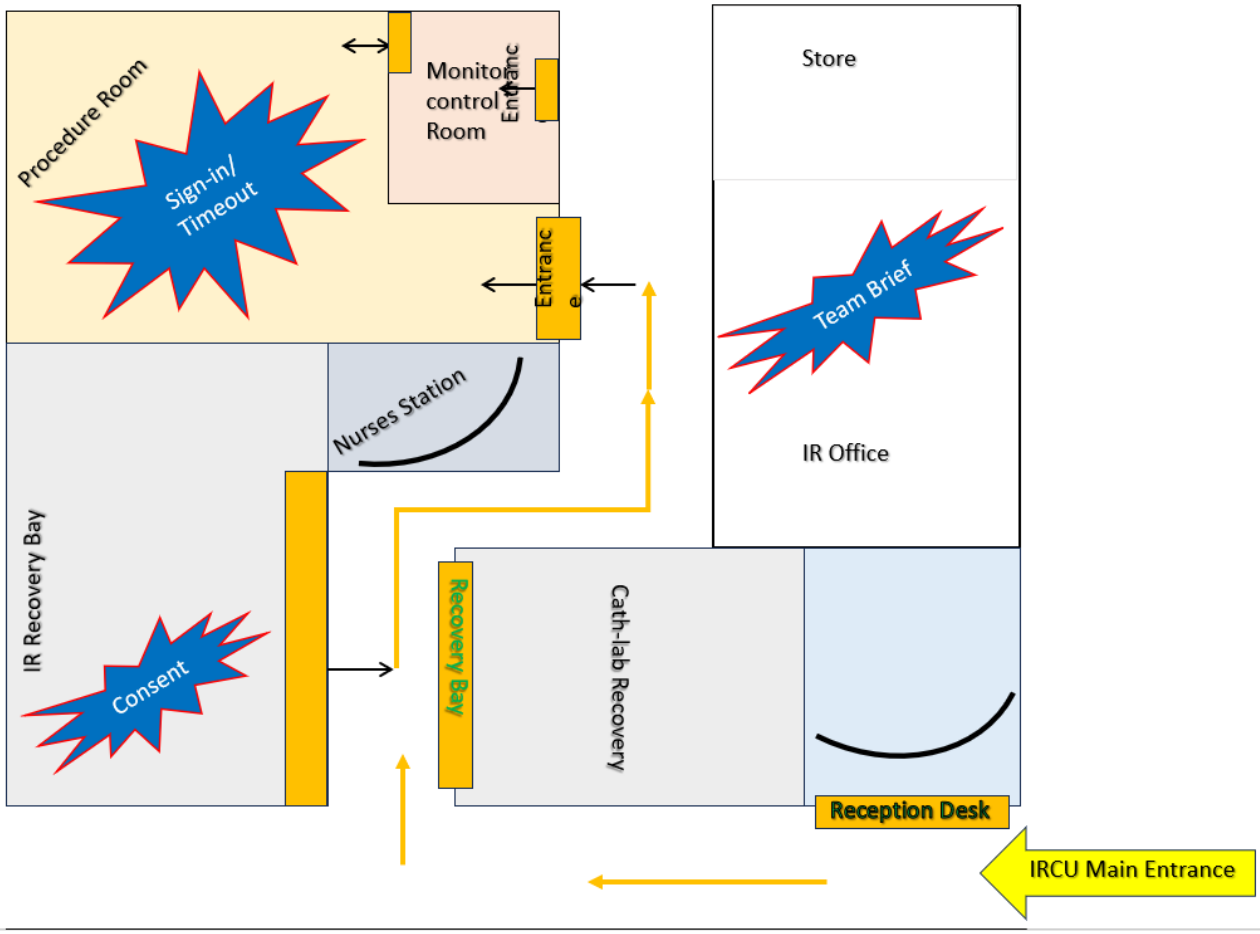


Figure 4 Mapping safety checks with location

Once the patient is verified with the consent and site/side marking by the recovery/receiving nurse the patient is taken directly to the procedure room, where the consent and full patient identification is carried out again by the full procedural team. This satisfies the statutory requirement of sign-in and timeout, which were performed together as a proportionate safety check for the procedure. This happens before transferring the patient on to the table. Figure 4 shows the locations of various mandated safety checks.

The IRCU receives interventional Radiological procedures requests from multiple specialities. This must go through the vetting process before scheduling and listing as emergency or elective procedures according to the clinical presentations and urgency. Figure 5 - Hierarchical Task Analysis, shows the pathway of IRCU procedures from referral to discharge/escalation process. For all tasks outlined in the HTA, NatSSIPs and LocSSIPs protocols are adhered to ensure safer procedures and prevent never events.

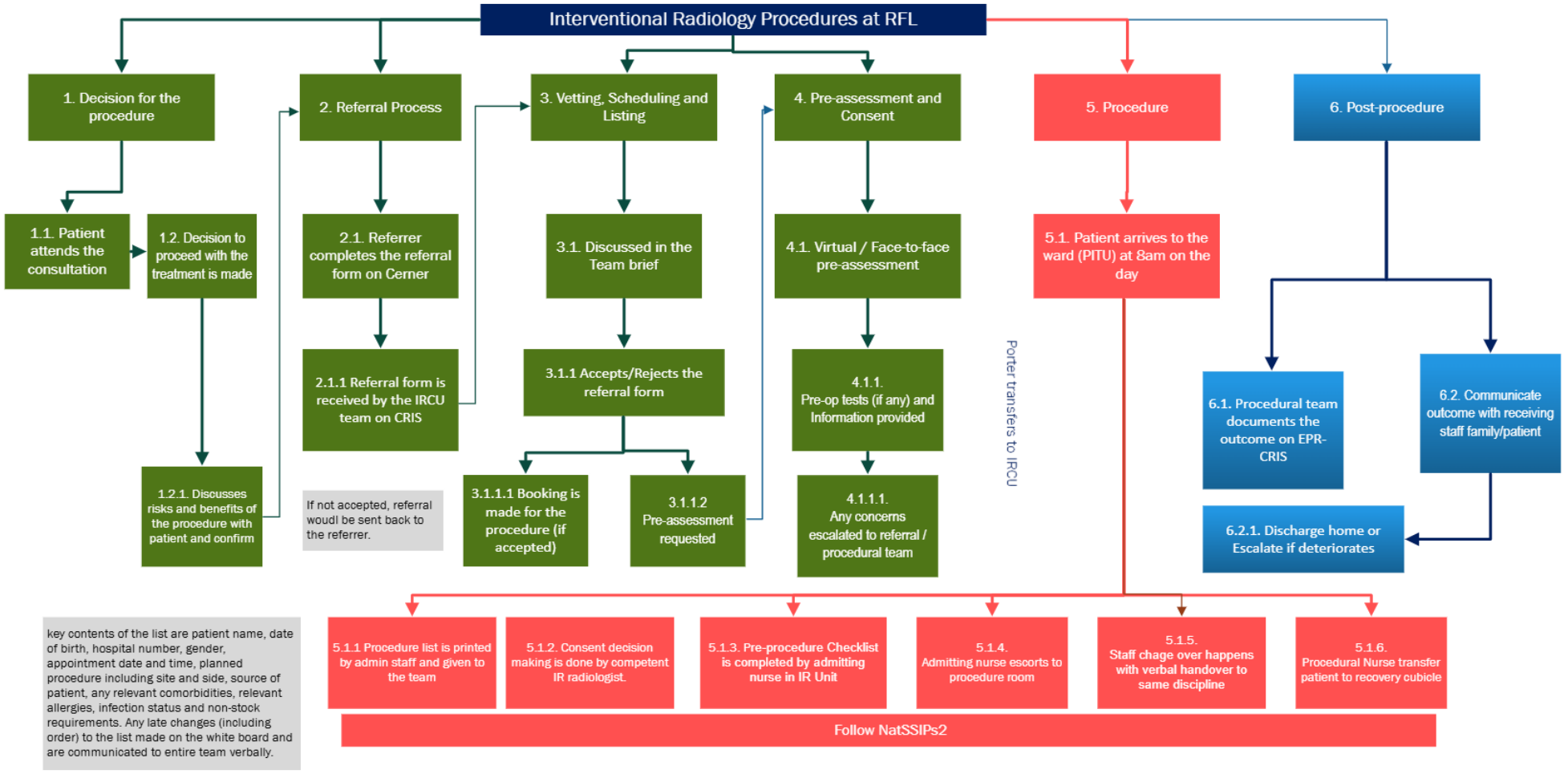


Figure 5 IRCU procedures pathway

3.4.1 Referral, Vetting and Scheduling (Work as prescribed versus Work as Observed)

The IRCU team receives referrals only from within the Trust. Direct access for GPs is not available at this facility. All requests for IRCU procedures must be entered on Cerner/CRIS prior to treatment within the IRCU facility. Once the referral is made, the referring team contacts the IRCU to inform the referral. This is scheduled for the next team brief for discussion unless the case is an emergency. Elective cases are booked onto the next available session. Emergency and out of hours requests are consulted with the on-call radiologist and decision is made. This process is referred to vetting. Vetting for all interventional radiology procedures must be performed by the radiologists, however, this case was discussed by the radiographer with the IR consultant informally.

Standard or no protocol required vetting is a process typically handled by admin and clerical staff, who schedule patients for interventional radiology procedures based on predefined criteria that do not necessitate a detailed review of patient-specific clinical information. This method relies on general guidelines and does not involve a comprehensive assessment of each individual case.

Vetting by radiologists, on the other hand, is a more thorough and personalised approach. Radiologists meticulously review patient documentation, including previous notes, images, and clinical presentations, to determine the appropriateness and urgency of the procedure. This ensures that each case is evaluated based on its unique clinical context, allowing for tailored decisions that prioritise patient safety and the optimal timing of interventions. Listing only happens if the radiologist and radiographer manger approve. A further discussion with the referring team may take place to clarify issues otherwise the request is cancelled.

Figure 6 details the vetting and scheduling process as prescribed before booking IRCU procedures. The level of review depends on each case, the complexity and the amount of information provided by the referring team.

Work-as-prescribed is the formalisation, specification and design of work. It is the work that people ‘should do’, especially according to policies, procedures, rules. Work-as-prescribed is intended to define and direct how work ought to be done to achieve its objectives, and often why it ought to be done this way. Work-as-prescribed takes a number of forms, including laws, regulations, rules, procedures, checklists, standards, job descriptions, management systems.

No matter what the level of granularity, procedures, standards and regulations lack the detail, richness and subtlety of actual work, including the many interdependencies and conditions. The Catch-22 of work-as-prescribed is that the more specified the work is, the more incorrect is it likely to become in messy work situations.

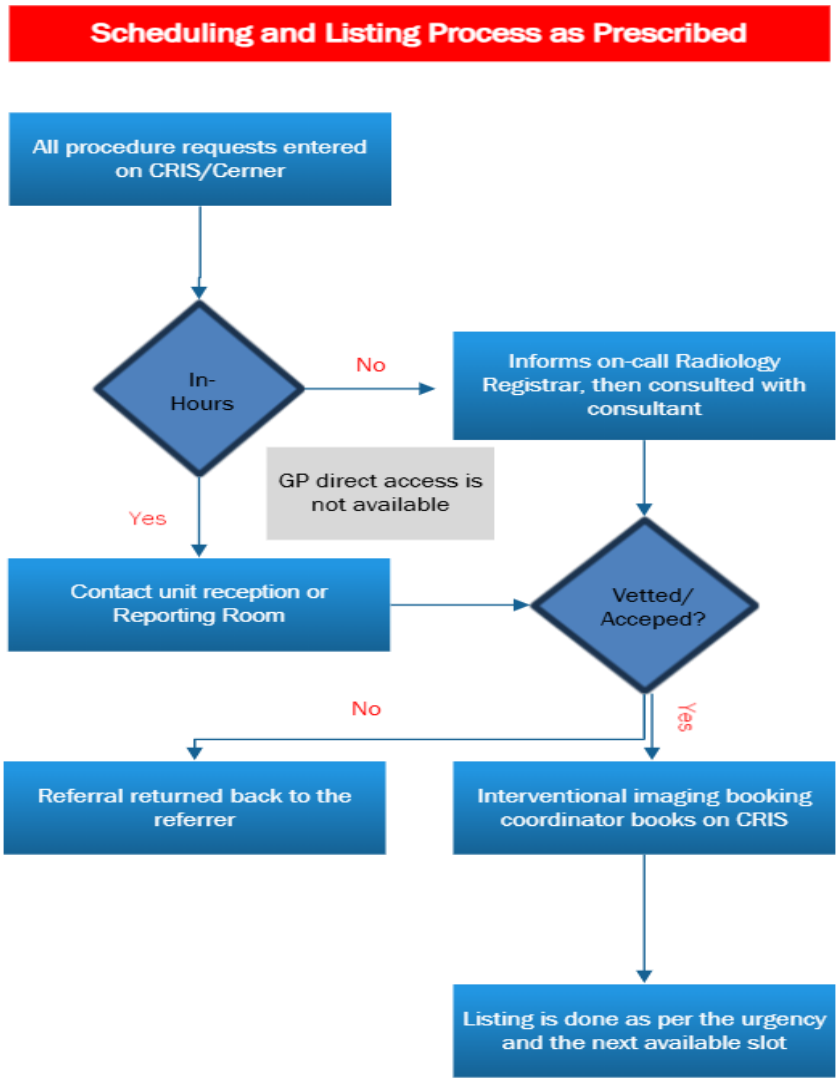


Figure 6 Vetting and scheduling as Prescribed

The vetting and scheduling were done for the procedure under investigation (Figure 7). Work-as-observed involves attending to, monitoring and perceiving the work of others, formally or informally, and the interpretation and direct description of what is observed by the observer. Not all aspects of work-as-done can be observed and so work-as-observed will never be complete.

On the day of the procedure, the list was printed by admin staff and handed over to the procedural team. The list includes elective procedures for review, new referrals for vetting, and emergency procedures under patients for discussion. A digital copy is shown on the board and accessible via MS Teams as a live, shared document. Any late changes including order of the list and further queries and concerns are documented and communicated to the entire team. The scheduling of the list depends on the expected workload and taking into consideration of other factors that include

- Team briefing and debriefing, and other key safety steps in LocSSIPs

- Reviewing previous notes and images
- Patient positioning and preparation
- Preparation of all necessary equipment and instrumentation

Any complications from procedure

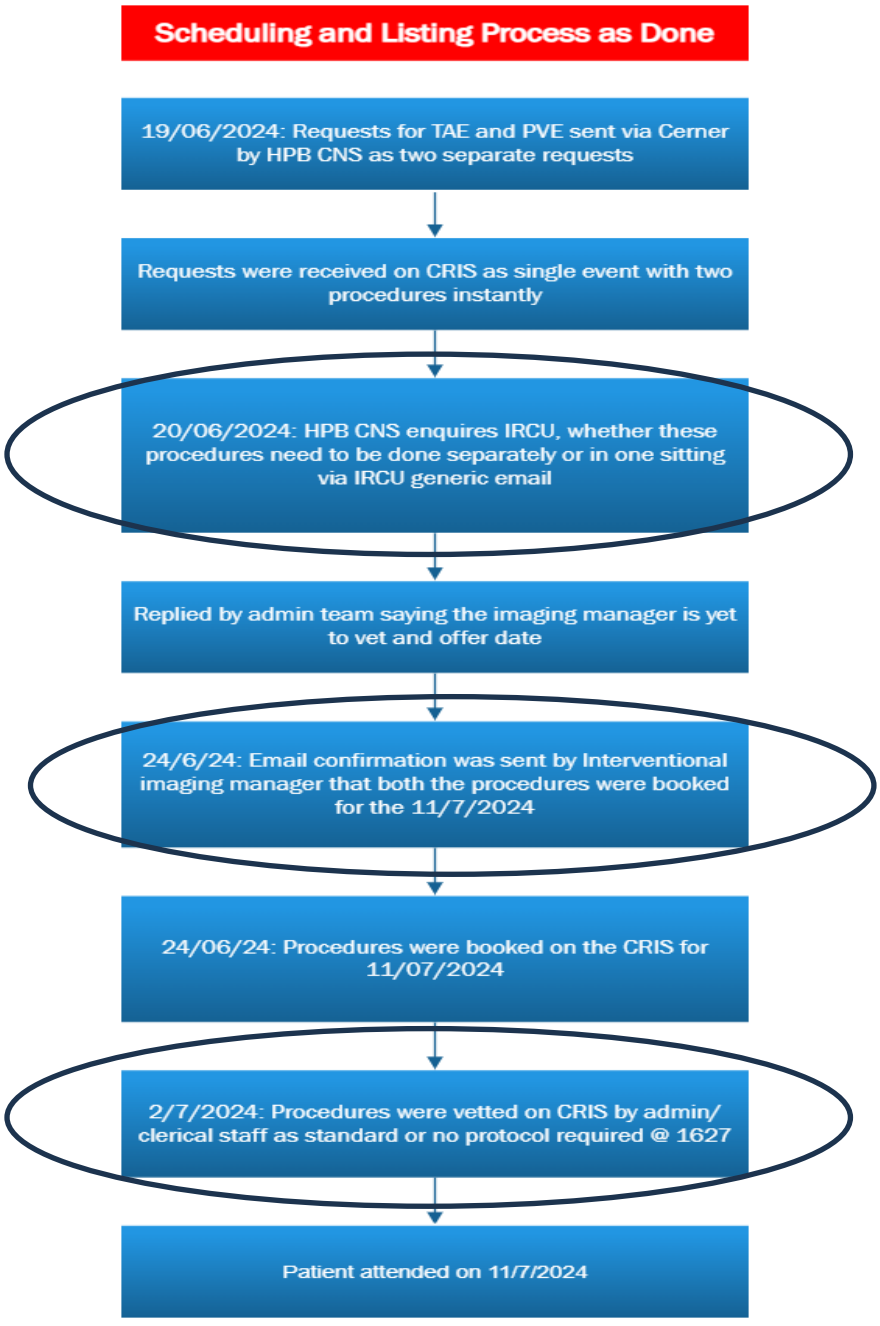


Figure 7 Vetting and Scheduling of the procedure

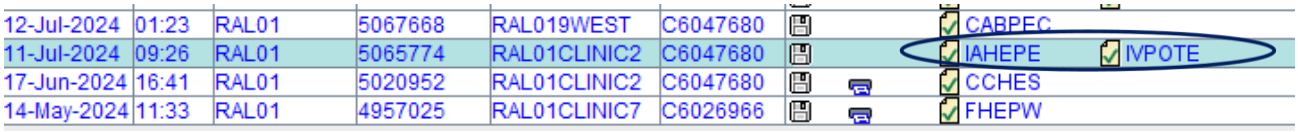
On 18/06/2024, the Cancer MDT discussion and outcome agreed to proceed with TAE and PVE sequentially. The Cancer MDT outcome was to proceed with TAE and right portal vein embolisation and not to consider SIRT (Selective Internal Radiation Therapy).

Two separate electronic request forms for TAE and PVE were submitted via Cerner by the referring team. Both requests were recorded on CRIS (Treating department patient record) as a single event involving two procedures. The individual requests did not specify the order in which the procedures should be performed or the interval between them.

On the 20/06/2024, patient was called and information leaflets sent by the HPB CNS. The specialist nurses routinely contact patients to update them of the cancer MDT outcomes and treatment plans.

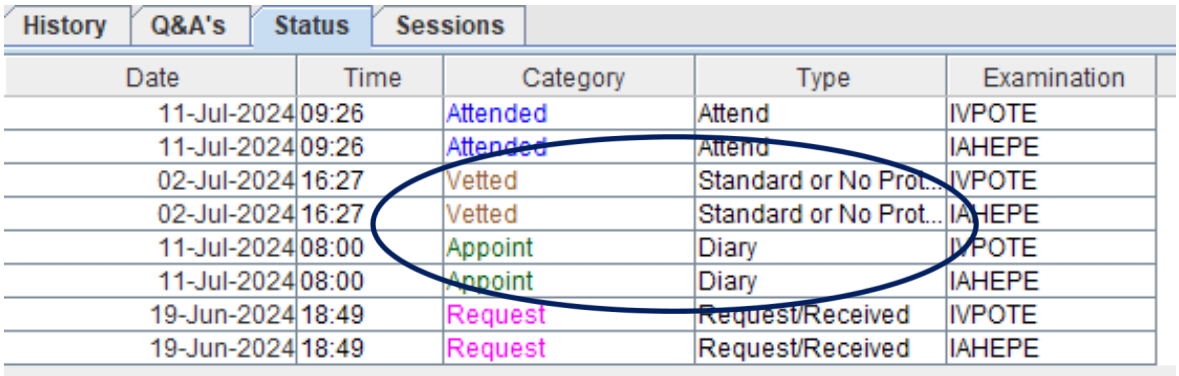
The HPB CNS enquired if the procedure should be done on the same day or if to be booked separately on 20/06/2024. On 24/06/2024, there was an email confirmation sent that both procedures were booked for 11/07/2024. As the HPB Specialist nurse is the link to all parties like the patient, the interventional radiology team and the HPB team, it would be expected that a challenge or guidance of the intention for both procedures to be communicated and a challenge to the booking for both procedures. It may have been that the discussion at cancer MDT on whether to proceed with TAE and PVE or SIRT caused the attention to be drawn away for the sequential procedure which would have been considered as a norm.

Few screenshots from CRIS for visualisation are shown in *Figure 8 and Figure 9.*



12-Jul-2024	01:23	RAL01	5067668	RAL019WEST	C6047680		CABPEC	
11-Jul-2024	09:26	RAL01	5065774	RAL01CLINIC2	C6047680		IAHEPE	IVPOTE
17-Jun-2024	16:41	RAL01	5020952	RAL01CLINIC2	C6047680		CCHES	
14-May-2024	11:33	RAL01	4957025	RAL01CLINIC7	C6026966		FHEPW	

Figure 8 Visualising procedure requests from CRIS



History | Q&A's | Status | Sessions

Date	Time	Category	Type	Examination
11-Jul-2024	09:26	Attended	Attend	IVPOTE
11-Jul-2024	09:26	Attended	Attend	IAHEPE
02-Jul-2024	16:27	Vetted	Standard or No Prot...	IVPOTE
02-Jul-2024	16:27	Vetted	Standard or No Prot...	IAHEPE
11-Jul-2024	08:00	Appoint	Diary	IVPOTE
11-Jul-2024	08:00	Appoint	Diary	IAHEPE
19-Jun-2024	18:49	Request	Request/Received	IVPOTE
19-Jun-2024	18:49	Request	Request/Received	IAHEPE

Figure 9Vetting steps from CRIS

Upon reviewing the vetting process, it appears to be conducted informally within the context of discussing the day's procedures, typically during the morning senior team briefing. This focus on immediate procedures may detract from effectively vetting upcoming procedures.

Subsequent to these discussions, the Radiographer Manager registered the procedure as vetted and scheduled in the next available slot on CRIS. However, as illustrated below figure, documentation remains unclear, impeding understanding by others. For instance, “ok w/ ND” signifies a discussion with the IR consultant’s initial ND. Those discussions were an informal confirmation.

It is essential to develop and implement a more robust vetting process with clear documentation standards to improve clarity and efficacy for future procedures.

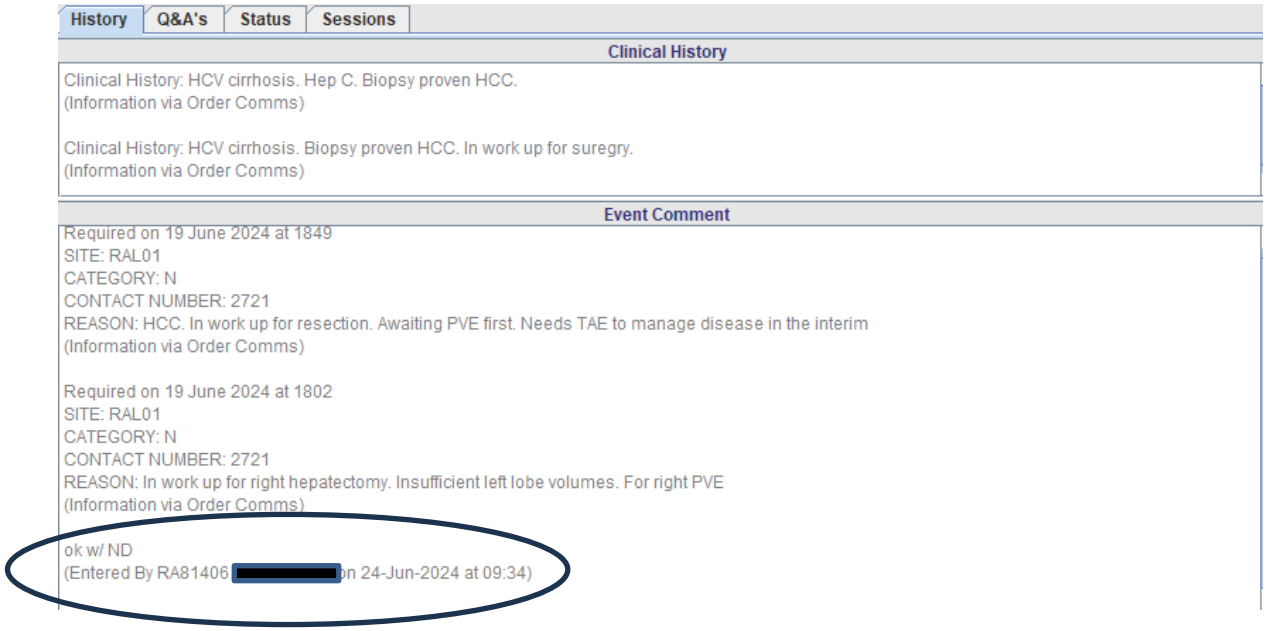


Fig 10 Evidence of the Informal vetting

During our review in IR, we observed that the Cerner system currently does not support linked procedure requests. Additionally, the HPB team requires an option for HVE requests, which is not available. To request HVE, they are using TAE (Hepatic Artery Embolisation) request and adding a clinical note indicating hepatic vein, which may introduce unnecessary complexity to the procedure requesting process. There are limitations with the current system which includes use of the national codes for procedures.

3.4.2 Listing / Vetting Process on the day in IRCU

A full list of elective patients for IRCU procedures is listed in the digital copy by the radiographer in-charge of the day, for which the entire IRCU team has access to. Along with the elective list, the list of patients who were added since the last brief for vetting, and also to be performed as an emergency were all included. This group of patients are classified under the heading ‘patients for discussion’. The compiled list is shared on Teams as a live document for the IRCU team to view. Once the radiographer prepared the list, this is verified by the registrar to be discussed in the presence of the IR consultant during the morning brief. The consensus decision is made either to

be done as an emergency or as part of vetting to accept the requests received to be booked for procedures in the future days.

As such, on the day of the observational study, there were 5 elective patients, followed by 6 emergency patients were discussed during the brief. The team had access to both Cerner and CRIS during the briefing. Registrar presented individual patients looking at both CRIS and Cerner for discussion and decision making.

During the post incident investigation MDT, the team stated that they feel this is considered as an exhaustive list to include the full team in discussion during the morning brief. Also, for the fact that the nursing team needs to prepare the rooms and equipment for the start of the list on-time. Hence, only senior members of the day are included in the morning brief. Ideally, the nurse manager or a representative for the nursing manager, the interventional radiology manager (radiographer) or a representative radiographer of the day, and all radiologists discuss the full list.

However, on the day of the observational study, while doing the morning brief, there was an emergency call that needed the radiographer to attend to the emergency. The morning brief was carried out without the radiographer representative. The radiologist and the nurse manager proceeded with the brief upon the team agreement to proceed without the radiographer.

3.4.3 Consent

According to the local SOP, all patients must have a valid consent form completed prior to entering the procedure room. The patient is consented in the IRCU recovery area prior to entering the procedure room. Consent form 1 must be completed for all responsive adults. In IRCU multiple safety checks are made at different LocSSIPs steps to check consent form is duly completed by the patient or their care giver before the procedure is started. The checks in various stages must comprise the validity of the consent form. The checks were performed during the sign in and timeout using the 'Interventional Radiology/ Image Guided surgery care pathway & LocSSIPs' checklist at the time of the patient had procedure. These checks are made during:

- ✓ Team brief
- ✓ Handover to procedure team
- ✓ Sign-in/time-out.
- ✓ Sign-out

In this instance, treatment plan was initially discussed by the HPB consultant at the time of consultation on 28/5/2024. Following the HPB - MDT outcome on 20/6/2024, CNS mailed information leaflet to patient address (TAE & PVE) and discussed the outcome with patient via telephone. The final written confirmation was obtained in the IRCU recovery. Following the team brief the IR registrar consented the patient using consent. The registrar confirmed that the increased risk combining the procedures done together was not discussed. The IR consultant, as far that he could recall, the increased risk of performing both TAE and PVE simultaneously was not discussed with the patient.

See Appendix 3: **LocSSIPs** for completed LocSSIPs for this patient journey and see Appendix 4 Consent form **Signed** for the patient under the investigation.

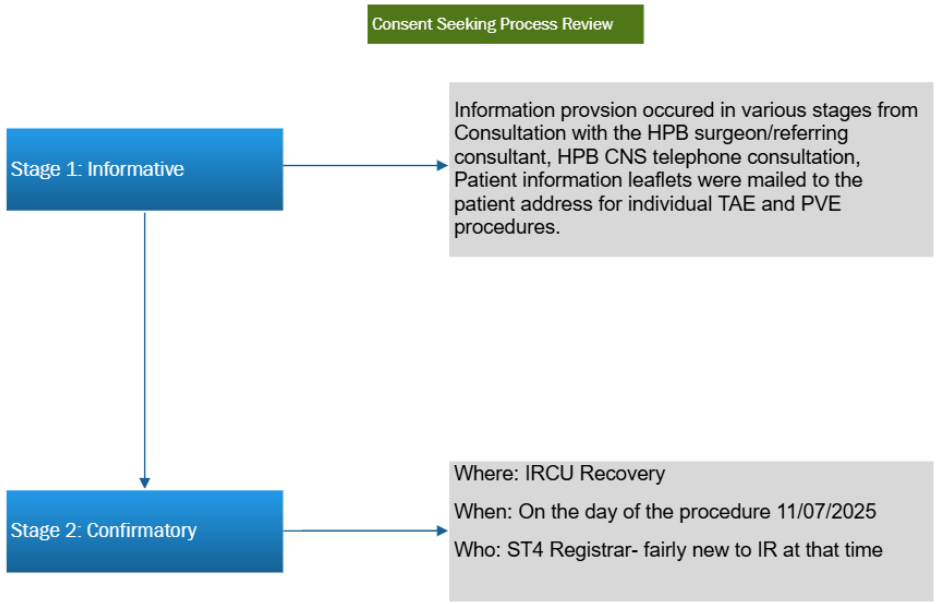


Figure 11 Consent process review

The patient received patient information leaflets for individual procedures. The ST4 Registrar joined trust in August 2022 and started working in imaging radiology around November 2023. When consenting the patient, the registrar did so on the basis of the discussion in the team brief.

3.5 AcciMap

The Accimap models the socio-technical context to identify the combination of events and decisions. It is useful tool to use to highlight the complexity and interlinked processes.. It emphasises the involvement of each level in safety management through laws, rules, and instructions. For systems to function safely, decisions made at high levels should cascade down and be reflected in the decisions and actions occurring at lower levels of the system. Conversely, information at the lower levels (e.g. staff, work, equipment) regarding the system's status must travel up the hierarchy to inform the decisions and actions occurring at the higher levels. Without this so-called 'vertical integration stems', there can be a loss of communication and connection of the processes risking failure in the system.

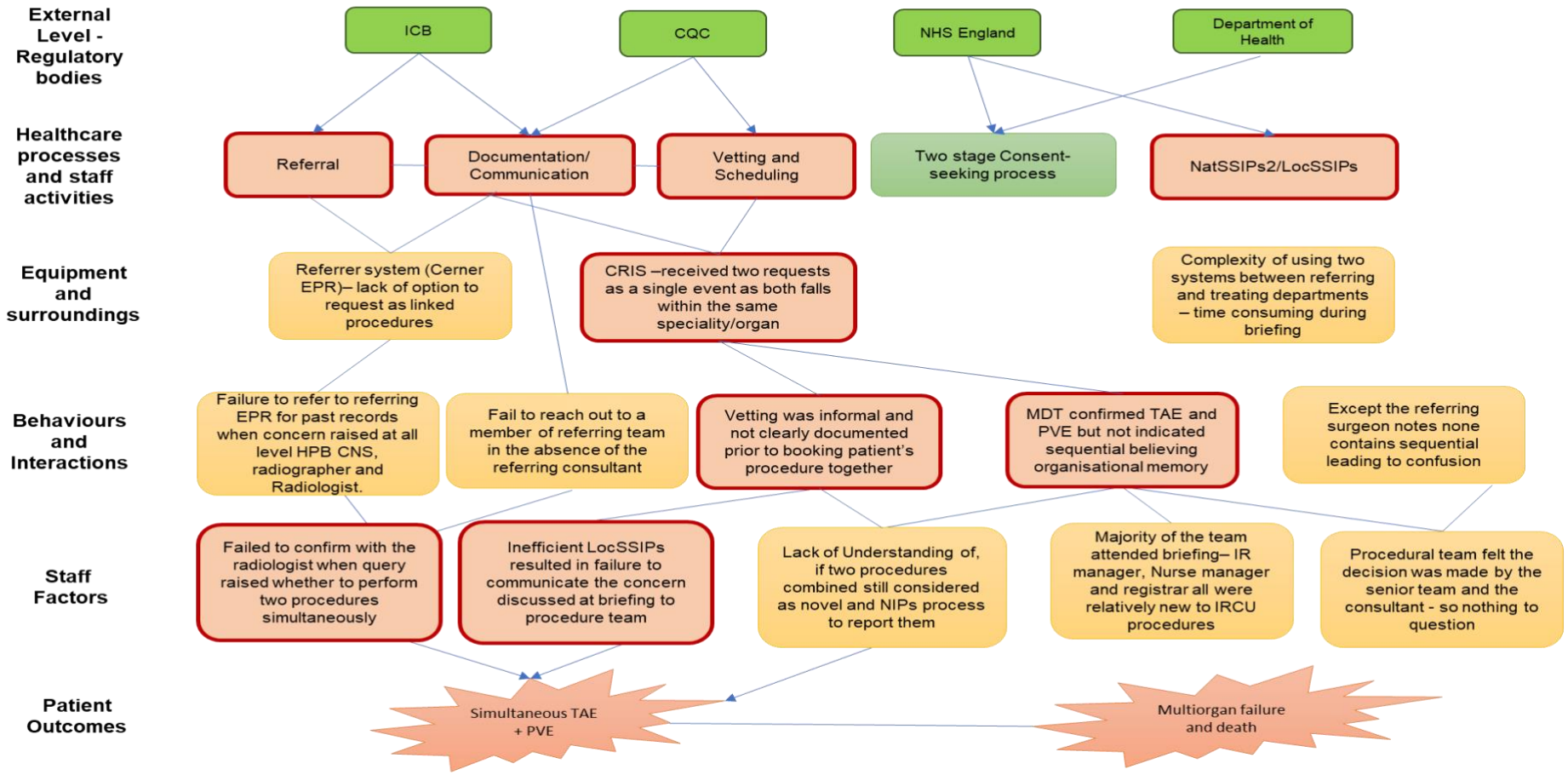


Figure 12 AcciMap

In the context of a patient safety event, this approach can be illustrated by examining the different levels of influence and how they interact.

At the organisational level, there is a need for more comprehensive Standard Operating Procedures (SOPs) for Interventional Radiology and Cardiology Units (IRCU). Current SOP does not reflect the complex operations within IRCU. There is a need to balance adaptability with guidance to bridge the gap in organisational memory for less frequently performed procedures. This case may have not have triggered any warning that this is the first time that both procedures were being done together and that it would require it to be treated as a novel or new interventional procedure therefore requiring formal committee ratification as a new interventional procedure (NIP). Empowering staff of required processes may have allowed a safe challenge. Any concerns or deviations from the process needs to be escalated using the Trust's Datix system. The hospital unit has regular conversations of all categories of cases at the PSERP.

The lack of involvement of the entire clinical team in the briefing may mean important discussions and clarifications may be missed. In this instance there were discussions, and the outcome was to proceed to doing both cases at the same time. The team confirmed in the MDT that they were unaware of concerns discussed at the team brief.

The team in attendance of the team brief included the IR manager and the registrar, both of whom were between 4-8 months into their role and new in Interventional Radiology (IR) department respectively. Additionally, the nurse manager was on leave and an acting nurse manager attended the briefing.

The IR Manager began working for the Trust in January 2023 as a rotating radiographer, and in March 2024 took on the position of IR manager. The IR manager had only been in this position for three months before the event and was not familiar with sequential TAE and PVE requests.

There is an expectation that all LocSSIPS will be reviewed and developed into a proportionate NatSSIPs2 eight steps. Most specialties are expected to continue to use their LocSSIPs during this transition. The auditing tool has been built to the standards set out in NatSSIPs2 and focuses on the qualitative aspects. This auditing tool went live with testing in December 2024.

The NatSSIPs2 has evolved to there being less emphasis on tick boxes or rare ‘Never Events’ and now include cautions, priorities and a clear concept of proportionate check based on risk.

Key Enhancements in the updated NatSSIPs2:

- Improved clarity on the roles and responsibilities of healthcare professionals during invasive procedures.
- Integration of 'systems thinking' and 'human factors' knowledge to address the complexity of invasive procedure work.
- Updated checklists and tools to support the effective implementation of safety standards.
- Emphasis on developing a team culture that promotes safety and mutual support.
- Proportionate checks to ensure that safety measures are appropriate to the risks involved in each invasive procedure.

The Trust's NatSSIPs steering group

The group is responsible for ensuring the effective implementation of these guidelines. Their role includes:

- Provision of assurance to the Trust Executive Board on effective safety standards for invasive procedures.
- Oversight and reporting on robust safety standards across the Trust.
- Development of trust-wide guidance and embedded practice of NatSSIPs2 safety standards.
- Creation of template checklists, tools, and supporting documentation for Local standards (LocSSIPs).
- Updating existing WHO Five steps to safer surgery with the 'NatSSIPs2 Eight' for relevant patients.
- Organisational ratification of policies and procedures proportionate to risk, recognising the difference between major and minor procedures.
- Ensuring appropriate checks to reduce risks, provide clarity, and set expectations.
- Identifying and ensuring adequately resourced leadership for sustained implementation of NatSSIPs2.

4. SEIPS

The Systems Engineering Initiative for Patient Safety (SEIPS) model is an innovative approach that integrates human factors and socio-technical context analysis to enhance patient safety. It recognises that healthcare systems are complex and interconnected, requiring a thorough examination of both human and organisational elements. By focusing on the interactions between people, technology, tasks, and the environment, the SEIPS model provides a comprehensive framework for identifying potential safety risks and implementing effective interventions. This model aligns well with the principles of human factors engineering, which emphasise designing systems that support human performance and minimise errors. Through its holistic perspective, SEIPS facilitates a deeper understanding of the underlying causes of adverse events and promotes a culture of continuous improvement within healthcare organisations. Patient safety events result from multiple interactions between work system factors.

Integrating the SEIPS model into safety investigations allows healthcare organisations to foster a blame-free culture, where staff feel supported and empowered to report errors without fear of retribution. This culture of openness and transparency is crucial for the continuous enhancement

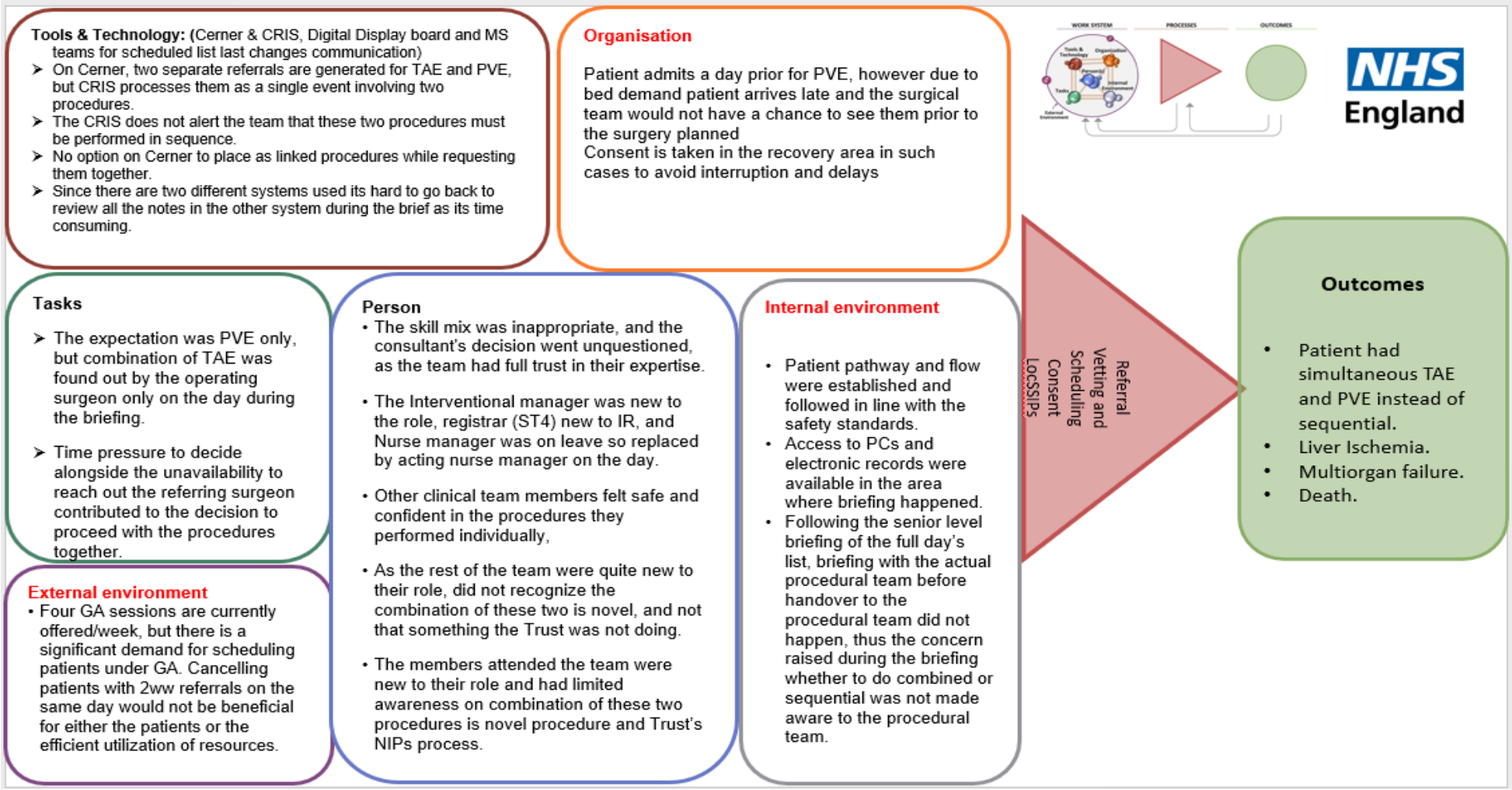


Figure 13 2 SEIPS model in patient safety event

5. Findings

This section summarises the findings from the investigation of the patient's journey during the IR procedure at RFL by referencing SOPs, patient data, observational studies, and recollection of event meetings with healthcare professionals directly or indirectly involved in care delivery. The goal is to understand the factors influencing decision-making and actions in a healthcare setting and identify areas for improvement to prevent future safety events.

The analysis conducted using SEIPS and AcciMap tools identified some areas requiring further attention for improvement. These findings are organised into three sections for clarity: before, during, and after the IRCU procedure.

Before Procedure:

Vetting, Scheduling, and Listing:

- Two separate electronic request forms for TAE and PVE were submitted via Cerner by the referring team. Both requests were recorded on CRIS (Treating department patient record) as a single event involving two procedures.
- The individual requests did not specify the order in which the procedures should be performed or the interval between them.
- One day after the requests were made on Cerner, an enquiry was raised via email by the specialist nurse regarding whether these procedures should be performed together or separately. This was with the IR team not the referring HPB consultant. Had the question been addressed to the referring HPB consultant, the intention to undertake the procedure as a sequential would have been clear.
- The IR manager confirmed with the referring team and more specifically with the HPB specialist nurse, that both procedures were scheduled for the same time.
- Documentation shows vetting was done informally before booking the patient for the next available GA slot on CRIS.
- There is no track record of briefing documents discussed during the morning team brief, which raised the concern again whether to proceed with both the procedures, given the use and update of digital records.
- The IRCU team performs both schedule and more urgent inpatient cases which makes up a greater proportion of the case load. The impact being that the team brief in the morning can be lengthy with vetting new cases.
- During our review in IR, we observed that the Cerner system currently does not support linked procedure requests. Additionally, the HPB team requires an option for HVE requests, which is not available. To request HVE, they are using TAE (Hepatic Artery Embolisation) request and adding a clinical more indication hepatic vein, which may introduce unnecessary complexity to the procedure requesting process. This adjustment highlights areas for improvement process. Also, given the fact that inefficient vetting procedure in IRCU pose significant risk to patient safety.

Information provision/1st stage of consent process:

- On 20 June 2024 at 13:45, the CNS contacted the patient to review the MDT outcome regarding the proposed TAE and PVE procedures. It was discussed and noted that the patient was informed. However, at 13:53 on the same day, the CNS emailed the IRCU manager to inquire if these procedures should be performed in one sitting or sequentially. There is no evidence that this has been communicated to the patient regarding whether the two procedures would be combined or sequential and the associated material risks.
- The Cancer MDT outcome did not include the term "sequential," leading the nurse to request TAE and PVE without specifying the order as per the cancer MDT outcome.
- The CNS did not consult the HPB consultant about the sequence of the procedures.
- Patient information leaflets for TAE and PVE were sent on 20/06/2024, intended for individual procedures to be performed sequentially as TAE and PVE at the Trust.
- The information leaflets are outdated; TAE (review date April 2017) and PVE (review date June 2018).
- Ward admission a day prior to the elective IRCU procedure on 10/07/2024 was documented as an elective admission for right TAE and PVE. This followed the organisational memory pathway of PVE only admission flow.

<u>On the day of the procedure</u>

Briefing/Confirmatory consent:

- On the day of briefing, the IR consultant was under the impression that this patient required a PVE as would have been expected as this was a general anaesthetic list (GA). In the team brief and review of the notes it was found that the first procedure of TAE, was not done and that a combined TAE and PVE was scheduled under GA session. The question of whether to perform these procedures simultaneously or sequentially arose during the briefing.
- The IR consultant attempted to contact the referring HPB consultant but was unable to reach them as the referring HPB consultant was on AL. Other HPB surgical consultants were not contacted as it was felt they would be unaware of the details of the case so unlikely to be prepared to make or change management decision.
- Upon reviewing the patient notes the sequential procedure was requested by the HPB consultant on 28/05/2024 on Cerner, but none of the following documents denotes the sequential procedure leading to ambiguity.
- Whilst the team did review the notes, they did not go back to the initial discussions around the sequential procedure being documented. It was expected that the decisions from the cancer MDT would be communicated by the team and therefore discussion was on how to balance the request of the combined procedure with the norms.
- The registrar (ST4), who was relatively new to Interventional Radiology at that time, obtained written consent in IRCU recovery following the senior IR consultant's decision to perform both procedures together. The registrar was not familiar with the combined procedure and did not recognise that the combined procedure was not the normal process, therefore this was not discussed with the patient as a novel procedure and the material risk involved with

the combined procedure. As far as the IR consultant can recollect, the additional risk of a combined procedure was not discussed with the patient.

- According to the registrar, the IR consultant spoke to the patient following the consent obtained by the registrar. However, it cannot be confirmed whether the material risks associated with this dual procedure were discussed, as this was not documented on the consent form. The IR consultant, as far as can be recollected, the additional risk of a combined procedure was not discussed with the patient.
- The nurse manager was on leave, and the morning briefing was attended by the covering senior nurse at that time. Additionally, the radiographer (Interventional Radiology Manager) was relatively new to the role.
- None of the team recognised that the combination of these two procedures had not been performed at the Trust or in the UK and should follow the new interventional procedures (NIPs) policy as it is considered as novel procedure. Staff were familiar with both procedures performed individually. In addition, it is relatively common for a combined portal vein embolisation (PVE) and hepatic vein (HVE) embolisation to be performed either during the same sitting or more usually the next day.

Procedure Room:

- The team brief did not include all staff there was no subsequent pre-procedural brief with the team that was not present at the morning brief like the nurses and radiographers regarding individual case. It is of note that proportionate checks are done, a team brief separate to the morning brief is undertaken before the patient is brought into the procedure room.
- The list updates are available in the digital record and can be accessed through the shared drive.
- During the safety event MDT learning response review, the procedure team indicated that they trusted the decisions made by the IR consultant who is very experienced. There were no triggers to raise concerns, therefore subsequent checks were done for a combined procedure as the patient was consented as such.
- Although the procedural team possessed the expertise to perform both procedures individually, they did not recognise that combining them would constitute a novel procedure, necessitating adherence to the NIPs policy. The pressures on the day prompted the decision making and there were no further escalations once the decision was made.
- The procedure team confirmed the expected procedure and the actual procedure during the combined sign-in and time-out safety check, with prior consent obtained for both TAE and PVE at the time of briefing.
- Upon sign-out, the team considered the procedure successful, documented the standard post-operative care plan, and did not flag it as a novel procedure subsequently.

Handover/Debrief:

- Discussions from the team brief were not communicated to the team that were absent from the team brief senior brief. Therefore, the discussion around the combination vs sequential of TAE and PVE was not flagged to the post-operative care team.

- LocSSIPs post-procedure handover process was based on the procedure performed and was not significant. Hence, followed standard post-operative care plan.

Post-operative care/Escalation process

- The complications followed by the procedure was considered as normal complication of the procedure, hence it was not reported as a safety event.
- After the patient's death, the IRCU mortality and morbidity review decided not to perform TAE and PVE simultaneously. This decision is undocumented with no follow up minutes or actions.
- The IR consultant presented the case study for shared learning in the HPB review meeting.

6. Discussion

Research on sensemaking processes identified action-meaning creation processes in which actors respond to change in their environment to give meaning to what has happened, thus reducing uncertainty and enabling action (e.g. Weick, 1988, 1993). Through these diagnostic processes actors construct plausible interpretations of uncertain situations, so that these plausible interpretations are sufficient to sustain action (Weick, 2005). This process involves enactment in which actors take notice of a change in their environment, and bracket elements from their environment that relate to the change. These action-meaning creation cycles occur dynamically and repeatedly as actors construct plausible interpretations that they continuously enact and modify (Maitlis and Christianson, 2013).

Through the use of existing shared meaning structures that have been created and modified through past experience, knowledge or sensemaking, actors can retrospectively create plausible meaning for what has happened in their environment to enable them to take action based on this plausible meaning.

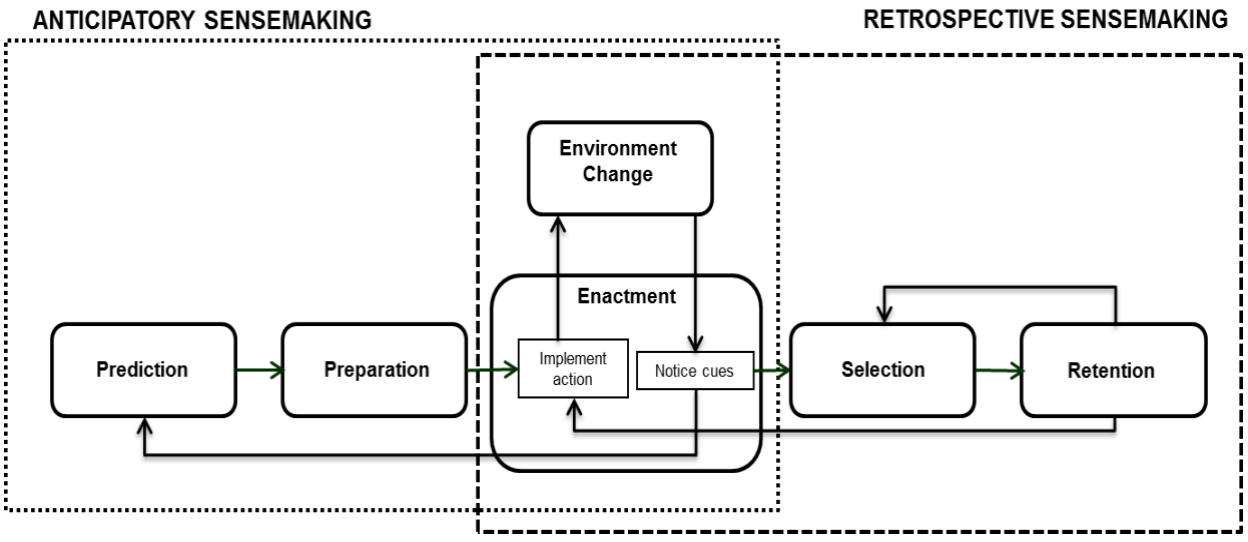


Fig 14 Model of anticipatory and retrospective sensemaking processes (Runswick, 2017)

Conditions that allow for sensemaking or attention to these cues are varied. Ambiguity and uncertainty prompt attention and triggers sensemaking. Ambiguity calls for more information, more careful scanning ad discovery.

For people within the organisation to take note of the environment is dependent on the information load, complexity and turbulence. As information load increases people take measures to manage by:

- omissions
- greater tolerance of
- queuing filtering and abstraction
- chunking

Large portions of information are neglected in the efforts to manage information load. The similar is true of complexity. Perrow (1984) warns that the warnings of unimaginable events cannot be seen, because it cannot be believed.

To enable actions staff need to identify cues to prompt sensemaking. Not all staff had the organisational memory or awareness that the booking of both procedures was novel. In addition, it is relatively common for a combined portal vein embolisation (PVE) and hepatic vein (HE) embolisation to be performed either during the same sitting or more usually the next day. During the review in IR, it was observed that the Cerner system currently does not support linked procedure requests. Additionally, the HPB team requires an option for HVE requests, which is not available. To request HVE, they are using TAE (Hepatic Artery Embolisation) request and adding a clinical more indication hepatic vein. There are more nuanced adaptations that makes the combined procedure less novel and seen as a result of multiple scenarios.

Social context is important for sensemaking. there were several staff who were new and did not recognise the norm for undertaking these procedures and hence it did not create a situation that need further enquiry, additional information and a challenge. for staff who were aware of the practice to undertake the procedures separately, there were unaware of the background conversations that took place in the morning team brief and would have expected this to be resolved and would have trusted the decision made by the consultant who was experienced and knowledgeable in this area.

There was incomplete information and the sensemaking could have been extended to look at the source of the decision. On the observational study, there were 5 cases scheduled in advance as elective cases with an additional 6 cases added as emergency for discussion. The information load and complexity lead to a premature end to the sensemaking and resolution by coming up with a plausible solution to undertake the two procedures together.

When dealing with multiple levels of arousal like trying to vet the additional 6 cases on the day would mean that staff may narrow and focus their attention on aspects of the situation that is judged most important. Attention is drawn away from the periphery which decreases the understanding of context which is the core in sensemaking.

An emergent finding was that the staff sensed a ‘need to do something’ with this need being perceived as a sense of responsibility to protect people, property or the organisation, and/or an

obligation to provide a key business service or product. This sense of a ‘need to do something’ was an underlying generative mechanism for the sensemaking processes.

The adaptability and flexibility within the IRCU using available rooms and resources play crucial in preventing delays and cancelations. The morning team brief is conducted within the senior team including radiologists, nurse manager and interventional radiology manager. The team discusses the complete elective list scheduled for the day as well as any emergencies that arose since the previous briefing that need to be addressed under the emergency list. For instance, on the day of the observational study, they discussed a total of 12 patients, highlighting the scope and scale of their daily operations.

During these briefings, they have access to both the Cerner and CRIS systems. However, the IR MDT suggested that going back to old notes for every single patient is not feasible. Therefore, once the list is confirmed, if any queries arise, they directly contact the referring team if necessary.

It was noted that involving the whole team in the briefing hinders team performance as they also need to prepare their rooms during this process. After the briefing, the communication board is updated, which everyone has access to, ensuring that the information is disseminated.

The incomplete documentation on procedural requests based on the referrer's notes, and the continued omission of the word "sequential" in following documentation, led to ambiguity for the entire team. The process of confirming with the treating team rather than the referring team or referring back to the referrer notes caused additional confusion.

The limited availability of GA slots and the patient awaiting the procedure in IRCU recovery pressures the entire team to make a quick decision.

The investigation process involved thorough vetting and analysis, ensuring every detail was scrutinised without placing undue blame on any individual. The review highlighted lapses in communication and procedural clarity among the team. The compassionate element was evident as the healthcare professionals involved were treated with dignity and respect, their concerns acknowledged, and their insights valued.

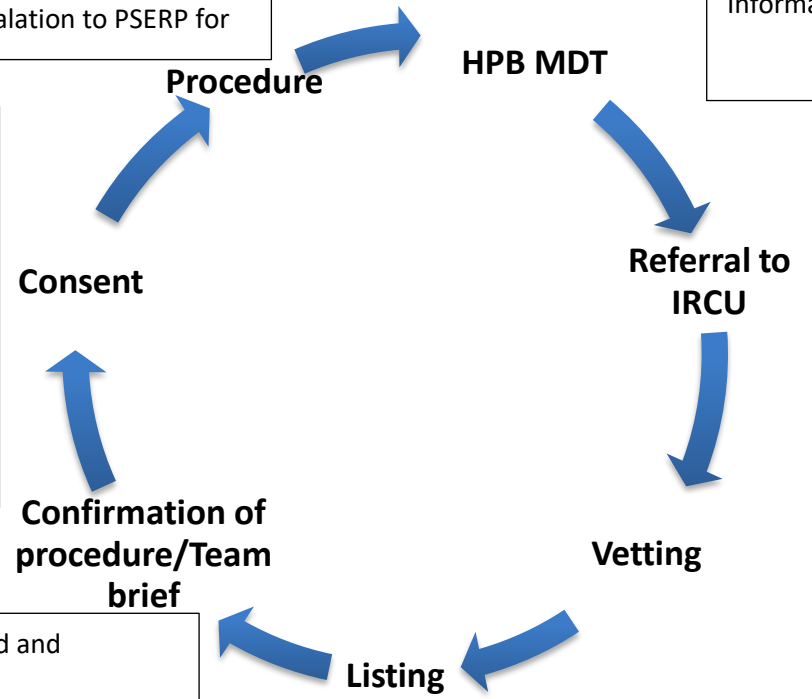
. There are various ways that one may arrive to a decision and the interpretation of the cues:

- Staff distort and filter the signal from the noise. Sensemaking would be about the pragmatics, coherence, reasonableness, invention
- Most organisational actions are time sensitive and there is speed-accuracy trade off. The list needs to get started; patient would have their treatment delay if they were rescheduled.
- Efforts to link the present cue with similar interpreted cues from the past. The connection with the study gave support that the procedure could be done together. For other staff the links with this set of procedure familiar to them as they have done them on numerous occasions previously albeit as individual procedures.
- Stimuli that are filtered out are often those that detract from an energetic motivated response. Even though there was an option to send the patient back to be rebooked this would not have been an adaptive response requiring something that needs to be done to rectify the situation.
- It was impossible to know if this would be an accurate decision

Accuracy is not essential in plausible reasoning, it is more about plausibility, coherence and reasonableness. Large portions of information are neglected in the efforts to manage information load.

7. Summary and Recommendations

This document lists the key findings, areas for improvement, and recommended safety actions from the recent investigation. Through a detailed analysis, several issues were identified that require attention to ensure enhanced patient safety and streamlined procedural workflows. The proposed safety actions aim to address these challenges effectively, promoting a culture of accountability, communication, and continuous improvement within the healthcare system.



- Proportionality considered and pre- procedure team brief follows the morning brief
- Minute and actions of MM and feeding into the overall governance structure
- Reporting discrepancies and escalation to PSERP for

The initial intention for a sequential procedure seemed to have been dropped off in the more recent entries. The last MDT was discussions around TAE/PVE or SIRT. Reliance on the specialist nurse to be point of communication between patients and IRCU. Information sent to patient about separate procedures.

- Two stages consenting, first stage undertaken by the referral team.
- Second stage consent done in the recovery area where patients are received prior the procedures
- Vetting and review on the day may mean changes to the consent – will patients have enough time to reflect, ask questions

Communications happened between radiology manager and specialist nurse. Confirmation of booking sent back to the team
Limitations on how CRIS manage the referrals, vetting was not completed before booking the patient for the next available GA slot on CRIS. The changes on CRIS can be confusing.

- Multiple requests with the same specialty/same organ and those requiring single reporting from Cerner are listed as a single event on CRIS.
- To request HVE, they are using TAE (Hepatic Artery Embolisation) request and adding a clinical more indication hepatic vein.
- Vetting is quite ambiguous and can be used interchangeably for confirming the procedure and reviewing the clinical merits
- Vetting for emergency for on the day bookings is incorporated with the team brief. May provide false assurance of team brief meeting NatSSIPs 2 requirements
- vetting is performed by IRCU team members on CRIS on behalf of the radiologist
- Can be quite an informal process with no blocked time to review and agree the running list

- Combined versus sequential procedures and intervals of waiting between procedures, not so common – procedure protocol for these
- No “Golden Patient” first patient ready to go identified.
- Emergencies take precedence over other bookings

- Team brief discusses both scheduled and emergency cases
- Assumption that vetting has occurred for the scheduled cases as would have been expected, confirmation of these cases
- Not all staff present at these meetings to qualify as a team brief meeting -NatSSIPs, more vetting may take place that may take more time of the team preparing for the procedures
- Final list following discussions not shared but available on the shared folder- unable to audit or go back as it is a live document that is continually being updated.
- Issues or concerns need to be addressed to the referring clinician, if not available then the on call- follow an escalation process

Recommendations

- Ensuring robust communication from the HPB and cancer MDT on specific procedural requirements and recommendations such as sequential procedures and referral - what information is required on referral to limit the look back and correctly inform as to procedure required & why.
- Escalation process from IR to referring teams to clarify procedural details in cases of uncertainty.
- Protocols for rare or specific requirements for cases to be booked.
- Review booking process and options on CRIS and Cerner.
- Formal process of Vetting and Listing.
- List briefing versus team briefing, possible safety huddle before a case.
- Development of approved NatSSIPs 2 template document.
- Induction for new staff.
- Procedure lists for procedure rooms to allow conversations and planning.
- First patient ready to go.
- Consenting: to consider validity for any changes on the day.
- Develop MM review process & discussion outcome documentation.

8. PFD Discussion

The risks that need to be addressed are set out in the PFD report are:

- Limited internal review of the incident following the inquest on performing the two procedures at the same time
- Trust seemingly did not consider the NatSSIPS2 standards either when undertaking the procedures, nor in detail as part of its review following the inquest.

8.1 Limited internal review of the incident following the inquest on performing the two procedures at the same time

As the acute liver failure was a rare but known complication, this did not serve as a trigger to complete a datix that would have a prompted further review. The first CT scan was to evaluate the cause of severe pain and specifically to rule out bleeding, bile leak, visceral perforation and contralateral vascular thrombosis etc. No such complications were identified on the scan. The second CT scan was to evaluate any technical complications to explain the deranged liver function. There were no technical issues identified on CT scan. However, the progressive worsening of liver function and other clinical features supported the diagnosis of acute liver failure, which is a known, but rare complication of the procedure.

The novel procedure may not have been highlighted for the people involved for various reasons:

- Both TAE and PVE procedures are done separately and seeing them together would not have been a trigger.
- it was observed that the Cerner system currently does not support linked procedure requests.
- Additionally, the HPB team requires an option for HVE requests, which is not available as a distinct category on the electronic patient record. To request HVE, they are using TAE (Hepatic Artery Embolisation) request and adding a clinical note indicating hepatic vein.

There are more nuanced adaptations that makes the combined procedures appear as less novel and therefore limiting escalations. This system wide investigation has made these more apparent with the accompanying increased awareness, procedure protocols and system changes to mitigate the consequences.

The safety event was discussed at two Mortality and Morbidity (MM) reviews. The patient was discussed on 26 September 2024 at the HPB Thursday morning M&M meeting. All the Intensivists are on the invite for that meeting and includes all staff working in the perioperative pathways. There were some important points about how procedures are requested and consent for by HPB and in IR. The main liver critical care outcome was to continue to develop the PHLF pathway to manage liver failure post-surgery/intervention.

Discussions at the radiology MM included discussions around the evidence for doing the TAE and PVE as a combined procedure. The conclusion was not to undertake both procedures simultaneously.

Following the inquest and request from the coroner to respond to a prevention of prevention of future deaths, the learning responses available in the time scale require were explored. The learning response that was undertaken was a multidisciplinary team meeting MDT with the scope of the MDT and the learning response scope and the terms of reference were limited to the questions raised by the coroner:

1. What constitutes a novel intervention that needs to go to the committee to be considered
2. Consent - JT was consented for a procedure he did not have.
3. Procedure requesting process and how that can avoid confusion around sequential procedures.

The health unit was able to undertake this extensive investigation in a very tight timeline due to additional capacity, with an additional interim band 7 quality manager and interim matron for radiology who were able to set up the investigatory MDT, interviews and observational studies.

Following the learning from this safety event, all inquest will be brought to the patient safety Incident response panel (PSERP). There needs to be consideration as a trust if wider investigations are required and if PFD’s would be part of the PSIRF policy and plan.

8.2 Trust seemingly did not consider the NatSSIPS2 standards either when undertaking the procedures, nor in detail as part of its review following the inquest.

8.2.1 Organisational Standards

The organisational standards are clear expectations of what Trusts and external bodies should do to support teams to deliver safe invasive care.

a. Communication

The communication from the cancer MDT was based on the presumption that everyone would be aware that the norm of the standard approach for treating HCC when augmenting the liver prior to resection, is sequential embolization of tumour and ipsilateral (same side) portal vein. The term "sequentially" was not documented in any notes after the consultant made the documentation on Cerner on 28/05/2024 Consent was obtained for both the procedures, but the material risks of combining them were not discussed with the patient.

Communication between the IR manager and the CNS confirmed the combined procedure.

b. Knowledge and Understanding

It was presumed that all staff would be aware that both TAE and PVE were not performed together as a norm and that the combined procedures of TAE and PVE was not done together at the same time at the trust. It is rare for both procedures to be done together even sequentially. Some of the staff were new, did not have the organisational memory and there was no SOP relating to the booking of these procedures. As a confounder, it is relatively common for a different combined procedure, that of portal vein embolisation (PVE) and hepatic vein (HE) embolisation to be performed either during the same sitting or more usually the next day.

c. Systems

Individual requests were made for TAE and PVE using the electronic patient record (Cerner). The requests appeared on the digital radiology information system (CRIS) as a single event with two procedures because both involved the liver.

Additionally, the HPB team requires an option for HVE requests, which is not available. To request HVE (Hepatic Artery Embolisation), they are using TAE request and adding a clinical more indication hepatic vein.

d. Vetting and Scheduling

There is a note on CRIS - discussed with a consultant on 24/6 and agreed. (Figure 10). Vetting was done informally in passing with the radiologist. Concerns raised on the day of briefing when the consultant encountered the patient booked for both TAE and PVE in one sitting, in contrary to the expected PVE only under GA slot.

8.2.2 Sequential Standards

The sequential standards are the procedural steps that should be taken where appropriate by individuals and teams, for every patient undergoing an invasive procedure.

a. Consenting

The trust carries out 2 stage consenting**.** The procedures are subject to changes following the vetting process. These changes are communicated with the referring team. The referring team are responsible to ensuring that the initial information is updated.

On this occasion the patient was in the recovery room when the team brief highlighted that the TAE was not done which led to the discussions to proceed to a both procedures to be done.

The consent taken and the registrar confirmed that they did not explain that this would be the first time that both procedures would be done at the same at the trust. They did say that the IR consultant saw the patient again after they had taken the consent. As far as the IR consultant can recollect, the additional risk of a combined procedure was not discussed with the patient. Even if this was discussed, it would have been good practice to allow the patient to reflect on the conversations.

The decision made by the IR consultant to proceed with the combined procedure was not escalated to senior staff.

b. Briefing

The briefing did take place but did not include all members of the staff. The record of the briefing is made on the electronic whiteboard in the radiology office.

The briefing includes confirmation of cases already booked on the list and vetting of any new cases that are added to the list. There are usually more cases booked on the day and the discussions can be extensive.

c. Sign In, Time Out and Time Out

The procedure undertaken was according to the team brief and consent. The LoccSSIPs checklist was completed (Appendix 4).

Radiology is in the process of developing NatSSIPS 2 guidance following the National Guidance. The trust has a NATSSIPS 2 steering group, the group has made significant changes in developing the audit tool to support qualitative, peer review audits. A training programme is being developed to address human factors and team working.

9. Family questions

The family raised several concerns that were shared by the coroner. These have served as a guide during this investigation and a summary complied below for ease.

1. Why combined procedure shouldn't have been performed		
1	Booking of the procedures simultaneously was an error so anaesthetists booked also was an error	The investigation revealed that two procedure requests were received as single event on CRIS and informal vetting and conversations with the specialist nurse took place following the scheduling for the PVE and TAE to be done as a combined procedure. This was very rare to undertake PVE and TAE together albeit sequentially. On the morning at the team brief, the IR consultant was expecting to do the TAE but found out that the PVE was not done and that the patient was booked for a combined procedure. The surgeon tried calling the HPB consultant. On the day, time pressure and resource utilisation and attempts to prevent delay to patient's treatment and possible liver resection influenced the decision to proceed with the combined procedure, considering potential treatment delays for the patient if cancelled and rescheduled.
2	Referring surgeon was on AL, could have contacted other surgeons	Post incident MDT review recommended contacting the on-call surgeon when the original referrer is unavailable. There was a feeling that as this was a rare request, it would not be so apparent to others. In addition, the more recent entries in the notes omitted "sequential". It was assumed that everyone involved would understand that the norm for these procedures was sequential. The IR consultant felt that other HPB consultants may have been unaware of the details of the case so unlikely to be prepared to make or change management decision.
3	Never performed this combined procedure historically in the NHS	The combined procedure in one sitting was not performed at the Royal free hospital previously, it is not known if it has not been completed in the other trusts. There were several reasons that this was not identified as novel: • Booking system- on CRIS it appeared in the same • Multiple requests with the same specialty/same organ and those requiring single reporting from Cerner are listed as a single event on CRIS. • To request HVE, they are using TAE (Hepatic Artery Embolisation) request and adding a clinical more indication hepatic vein.

		• Communications happened between radiology manager and specialist nurse. Confirmation of booking of both procedures at the same time, sent back to the team
4	Unclear if the consultant radiologist aware of the study before the procedure or referred to it retrospectively	Consultant radiologist confirmed that decision made to do a combined procedure was based on knowledge of the study where it was done as a combined procedure.
5	Davies never performed this procedure combined before	The decision was made within the complex environment on the day and although having a vast experience of both performing both procedures, he had not performed combined them together.
6	PVE+HV embolisations does not carry the same level of risk as TACE+PVE so cannot be justified	It is understood that they are a different set of procedures. In terms of human factors, cognition biasness and sensemaking, since vein embolisations have occurred at the same time was more difficult to pick up the cues and recognise the combined TAE/PVE as a novel procedure and therefore may have a higher risk.
2. NatSSIPs2 contradictions		
1	Team brief - Surgical team was not involved	IRCU standard practice is conducting morning briefing at the start of the list with radiologists, the radiographer manager, and the nurse manager present. On the procedure day, all these individuals attended. However, an improvement opportunity has been identified to incorporate the procedural team (nurses and radiographers) into NatSSIPs2 development. It is not the practice to include the surgical team in the team brief. The surgical team team do not have a practical role in performing these procedures, requiring training and qualification as an interventional radiologist. Any issues and concerns are raised through the referral, vetting and confirmation of bookings. On this occasion there was an informal vetting, but communications were with the specialist nurse and radiology coordinator.
2	Team brief - Patient was on table before team brief	The investigation found out that the patient was in recovery when the team brief was conducted. The recovery room has multiple functions which includes receiving patients and consenting.

3	Team brief - Questioned the combined procedure by the member of the team but not datixed	There were concerns raised at the team brief which concluded that a combined procedure would be undertaken. There were no triggers that this met Trust requirements as a novel procedure, due to various reasons such as staff had experience of doing these separately, some staff were new, more recent documentation did not refer to a sequential procedure, and sequential procedures are performed together for hepatic venous embolisation along with PVE. The patient was subsequently consented, and the consultant then went and spoke to the patient following the team brief.
4	Sign In - Discrepancy of unusual procedure was not resolved and signed in despite not being urgent	The procedural team (nurse and radiographer) who were involved in the sign In and Time Out were not aware of the discussions happened in the team brief. Therefore, at this point it was agreed and proceeded with the combined procedure to which the consent was taken.
5	Sign In - No further effort to contact another team member when unable to contact the referring consultant	The consultant and review of the notes took place at the team brief, unfortunately none of the recent documentation mentioned “sequential”. Upon failing to contact the referring consultant, the team felt that other members may not have been able to give more details. There is an assumption that all staff would be aware that the procedures combine would be novel. Eventually it was agreed to proceed to the combined procedures at the team brief.
6	Time Out - Despite the discrepancy the procedure went ahead	It was agreed to proceed to the combined procedures at the team brief and consented for the same. The team was unable to recognise the discrepancy as the procedure performed was confirmed against the written consent.
7	Time Out - Not reported as safety event	It was agreed to proceed to the combined procedures at the team brief and consented for the same. The team was unable to recognise the discrepancy as the procedure performed was confirmed against the written consent.
8	Time Out- Discrepancy between the consent form and the procedure expected	It was agreed to proceed to the combined procedures at the team brief and consented for the same. The team was unable to recognise the discrepancy as the procedure performed was confirmed against the written consent.

9	Time Out - Caution moments during Multiple procedures and multiple teams	No change over of the whole team during the procedure except for their break It was agreed to proceed to the combined procedures at the team brief. The referral and vetting process should allow for team communications.
10	Handover - Dual procedure performed was not flagged to the ward	The handover was the two procedures performed together documented on CRIS as agreed at the team brief. The procedure went as planned as per the team at this stage.
11	Handover - Not flagged that the TRUST had never done this before simultaneously	The handover was the two procedures performed together documented on CRIS, as was planned at the team brief.
12	Handover - Patient was not given the full disclosure of combined procedure	The patient was consented for the combined procedure. The procedure performed based on the booked and obtained consent was discussed with patient and the post-operative team. The team's oversight in recognising the novelty of the procedure resulted in its failure to be flagged as such, leading to the implementation of standard post-operative care.
13	Handover - No safety event reported	It was agreed to proceed to the combined procedures at the team brief and no cues in the system as it was novel thus the team did not report as safety event.
2. Consent invalid		
1	Patient record shows explanation around hepatectomy but none about the TACE and PVE simultaneous or combines	HPB consultant documented the plan for SIRT or TAE and PVE to be finalised at MDT. Upon MDT decision, individual patient information leaflets for TAE and PVE were mailed to patient home address. The specialist nurse called the patient to discuss the outcomes from the Cancer MDT, confirming that the outcome was to proceed with the TAE and PVE. The patient was consented in the recovery room on the day of the procedure.
2	Patient was not given the critical information of the dual procedures weighs higher risk and never performed before in the NHS	The registrar confirms that she did not discuss the higher risk of a combined procedure but consented the patient for both procedures. The consultant radiologist spoke to the patient following the consent. However, there is no documentation of the discussion. As far as the IR consultant can recollect, the additional risk of a combined procedure was not discussed with the patient.

3	Dual procedure was performed based on the feeling that patient's good liver function tests and the patient was not informed that the radiologist is performing this dual procedure in his first time	The combined procedure was considered at the team brief and there were concerns about cancelling the procedure and delaying the patient's treatment. As outlined in the report there was complex socio-technical system where the consultant had to make a decision.
4	Patient was not made aware of that the discrepancy between the planned and expected in the consent	The patient was consented following the team brief based on the decision made at team brief and the booked procedure of combined TAE and PVE.
5	Patient was not made aware that their treatment is experimental based on the small study caried out on 13 patients in China	No documentation of this.
6	Risk of death nor severe liver parenchymal necrosis were not discussed	The risks of necrosis are in the TAE patient information leaflet. **Risks and side-effects** TAE is a safe medical procedure. It is normal to feel tired, flu-like and weak for about one week afterwards (post embolisation syndrome). This will pass with simple painkillers and rest. You may have some pain in the right side and right shoulder; this is normal and will pass. There is a risk of developing infection in the dead tumour tissue. You will be given antibiotics to minimise this risk. In about 1% of cases the infection will be serious and necessitate a further procedure to treat the infection. In patients with liver disease the embolisation can result in temporary damage to liver function very rarely this can be serious and require a prolonged stay in hospital. Rarely the particles used to block the tumour can travel to the wrong place and damage healthy tissue. The specialist will try to avoid this but if this happens it can lead to pain and other problems. Sometimes the procedure fails or tumour recurs, in this case you may be offered further treatments. It is acknowledged that despite being unlikely, death constitutes the most serious harm and as such needs to be included in future consents for procedures that may result in liver failure, thereby acknowledging the limited surgical (transplantation) and medical treatments in such cases

7	Dual procedure was performed based on the feeling that patient's good liver function tests and the patient was not informed that the radiologist is performing this dual procedure in his first time dual procedure conversation was made with patient on the operating table	Consent was taken in IRCU recovery prior to moving to procedure room and following a team brief. The decision to proceed with the combined procedure was complicated and it is acknowledged that there is no documented evidence of consent being fully comprehensive to allow an informed decision by the patient.
8	Consent was taken by registrar	It is acceptable practice as per the RFL consent policy. The IR consultant also saw patient once the consent was completed.
9	Patient was on the table	Patient was in recovery room and was not moved to the procedure room prior to taking the consent. This is the local practice of IRCU taking consent in IRCU recovery room.
10	Initial conversation by nurse	Consent-seeking is a two-stage process. Information provision stage started as soon as the decision was made, and this was discussed by the consultant with the care plan options of SIRT or TAE and PVE sequential. Followed by MDT discussion, the HPB CNS provided further information on the outcome of proceeding with TAE and PVE.

10. Development of action plans

The investigation panel met to discuss the improvements required. The Hierarchy of controls was used as a guide.

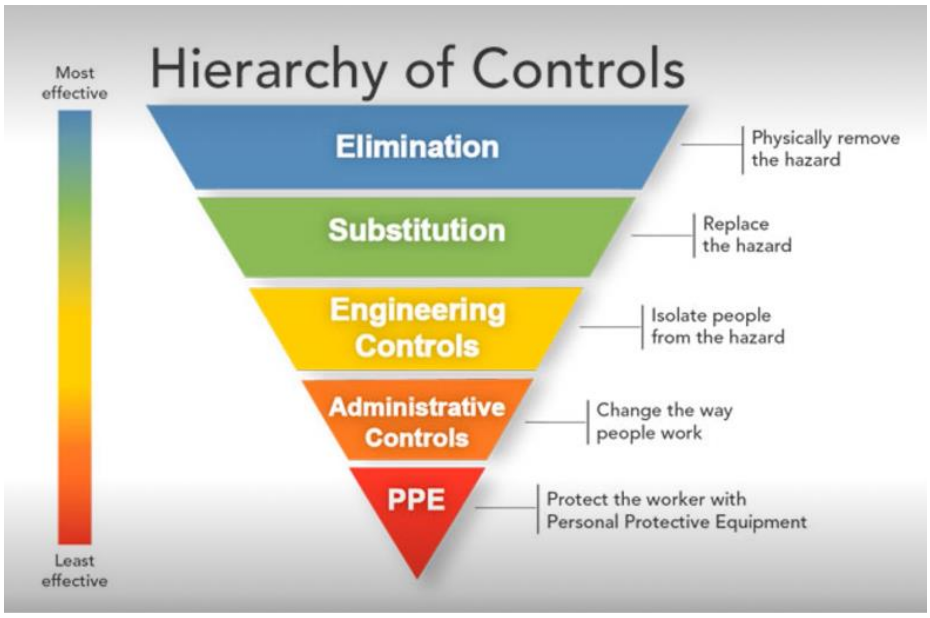


Fig 14 Hierarchy of Controls

Review of policies, protocols and standard operating procedures

These administrative processes and procedures are essential to ensure the so-called engineering control works as intended. One of the technical findings of the U.S. Chemical Safety Board's investigation into the 2010 blowout and explosion on the Deepwater Horizon oil rig in the Gulf of Mexico demonstrates the reliance upon administrative controls to ensure the effectiveness of engineered controls.

The Investigation panel recommends a review of policies, protocols and standard operating procedures that needs ratification which include:

- IRCU SOP
- TAE patient information leaflet
- PVE patient information leaflet
- Consent policy
- Transition of IRCU LocSSIPs to NatSSIPs

IRCU list planning

Mistakes are more likely if staff need to rush while working and/or are anxious due to potentially unachievable workload. The recommendation that IRCU list planning, vetting scheduling and confirmation takes these issues into account, with sufficient additional time allocated to these activities.

Adequate time should be scheduled for a comprehensive team brief at the start of a IR list with the whole team present, enabling staff to share their `mental models´ Adequate time should also be scheduled at the end of the list for a team debrief involving the whole IR team. This allows staff to reflect together on what went well, discuss practical ways of improving the working environment and practices and provides a system for escalating concerns. If performed well, these debriefs can improve team morale, improve interpersonal relationships.

Cognitive aids

Cognitive aids are tools designed to guide workers while they are performing a task, or group of tasks, with the aim of reducing errors while improving speed and utility. The use of validated human factors principles should be used when designing cognitive aids,

Non-technical skills (NTS) are cognitive, social and personal skills that complement technical skills, and contribute to safe and efficient task performance.

The TDODAR decision making model is a model that is predominantly used in aviation. It helps pilots make decisions in threatening situations. The TDODAR decision making model offers an instrument to give structure and discipline to the decision-making process.

Mortality and Morbidity Meetings

Encourage human factors approach to learning from incidents that are discussed. Include `learning from when things go well´ in M and M meetings, developing a Safety II approach. Review the governance process of these meetings.

Systems

To review Cerner and CRIS systems seem to be quite difficult to navigate. System should be designed to ensure ease of booking, and the ability to separate requests.

Escalation

Senior level decisions were made that were not escalated. This is an opportunity to discuss risks and options.

11. Safety action summary table

Area for Improvement:								
	Safety action description ***(SMART)***	**Safety action owner**	**Target date for implementation**	**Date Implemented**	**Tool/measure**	**Measurement frequency**	**Responsibility for monitoring/ oversight**	**Planned review date**
1.	Update and ratify current IRCU SOP which should include the current list of IR procedures performed at the Trust– V2 (review date – Oct 2018)	Radiology Clinical Governance Lead	31 Oct 2025		Updated and ratified IRCU SOP – V3	Annually	Radiology Governance/ GCS DQSB	Annually or sooner if changes
2.	Review and update patient information leaflet current version1 - TAE and the information should contain the material risk involved with the procedure.	HPB and Radiology team	30 May 2025		Updated TAE patient information leaflet version2.	n/a	HPB team Governance/HPB, IR local governance meetings	3 yearly or sooner if changes
3.	Review and update current patient information leaflet PVE (v1) and the information should contain the material risk involved with the procedure.	HPB and Radiology team	30 May 2025		Updated PVE patient information leaflet version2.	n/a	HPB team Governance/HPB, IR local governance meetings	3 yearly or sooner if changes
4.	Update Trust's current Consent policy (V6.1)	Group Chief Nurse	31 Oct 2025		Updated version of consent policy	Annually	Trust Quality Group	3 yearly or sooner if changes

5.	Transform IRCU LOCSSIPs SOP to NatSSIPs2 SOP with department specific standardised approach for consent taking and briefing model to include onward communication from senior team brief.	Radiology Matron, IR clinical lead	31 Oct 2025		NatSSIPs2 document for IRCU ratified by CPPS	Monthly NatSSIPs audit	Radiology Governance/ GCS DQSB	3 yearly or sooner if changes identified.
6.	Review and update Vetting, scheduling and listing process of IRCU and perform audit.	Radiology Clinical governance lead and IR manager	31 Oct 2025		Written standardised and efficient vetting, scheduling and listing process written in SOP and ratified.	Annual review of SOP. 6 monthly audits.	IR manager/ Radiology Governance/ GCS DQSB	Annual review of SOP. 6 monthly audits.
7.	Develop M&M meetings ToR which includes action plan trackers and governance escalation pathways.	Radiology Clinical Governance Lead	30 June 2025		M&M ToR written document	Quarterly	Radiology Governance/ GCS DQSB	Quarterly
8.	Provide human factors training to mitigate high tempo, high complexity decision.	Radiology governance lead	31 Oct 2025		Training sessions conducted	Annually	IRCU Matron and Radiographer Manager	Annually
9.	Explore options with Cerner team to implement linked procedure request system for combined procedures & provide specific option to request HVE	HPB consultant and EPR team	31 Dec 2025		Options to request linked procedure available on EPR	n/a	Cerner team	n/a
10.	Develop guidelines for two procedure requests for HPB CNS which includes the minimum information required in the requests	HPB and IRCU team	31 May 2025		Written guideline for procedure requests	Annually	HPB team and IRCU team	3 years or sooner if new combined

								procedure to be introduced.
11.	Complete NIPs if combined TAE and PVE is indicated and agreed	IR clinical lead	Ongoing		NIP approval	If required	Radiology Governance/ GCS DQSB	As required
12.	Agree escalation pathway for shared decision and risk management making on more complex cases.	IR clinical lead	9 June 2025		Written SOP	Review of safety events	Radiology Governance/ GCS DQSB	3 yearly or sooner if changes identified.
13.	Review the IRCU workload to ensure protected time for vetting new cases and reviewing of notes	IR manager	Ongoing		Audit	Radiology Board	Radiology Board	Quarterly

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13. Appendix

Appendix 1: Relevant documentations from EPR

MDT for Cancer	09/Feb/2021 00:00:0...
HCC	Contributor_system, R...

Outcome: MRI with contrast. If patient is allergic, the patient could have primovist.

Comparison:
MRI liver 10/3/2021
CT liver 7/1/2021

Impression:
1) Suboptimal study (inadequate arterial phase) with poor conspicuity of the lesion in segment VI. Consider further evaluation with MRI.
2) Chronic liver disease without evidence of portal hypertension.

MDT for Cancer	02/Apr/2024 00:00:0...
HCC	Contributor_system, R...

Outcome: Review in the joint HCC clinic to assess fitness for resection vs ablation. Would require Wedge pressure and ICG and liver volumes 1-4. Potential candidate for PRIMER-1. Requires CT chest to complete staging.

15-Feb-2024 12:39 CCHAP CT Thorax abdomen and pelvis RAJ_R15113688502

Impression:
1) Suboptimal study (inadequate arterial phase) with poor conspicuity of the lesion in segment VI. Consider further evaluation with MRI.
2) Chronic liver disease without evidence of portal hypertension.

MDT for Cancer	09/Apr/2024 00:00:0...
HCC	Contributor_system, R...

Plan: Rollover with 15/02/2024 CT imaging.

MDT for Cancer	16/Apr/2024 00:00:0...
HCC	Contributor_system, R...

Outcome: Continue work-up for resection and Primer-1

Outpatient GP Letters	22/Apr/2024 20:14:0...
HCC Clinic Letter	[redacted]

We will review [redacted] n our surgical clinic after these tests.

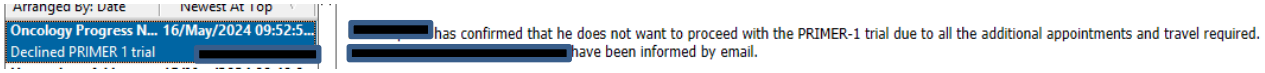
I have requested an HVPG test and the ICG will be arranged on the same day (usually a Monday)

I have sent him to the POA clinic after today's consult to see the anaesthetic team

He will be seen by the oncology team today to discuss the PRIMER-1 trial.

Coding Summary	14/May/2024 16:02:3...
Coding Summary	

```
PROCEDURES:
J11.7          Transjugular intrahepatic
               pressure measurements of
               hepatic vein
Y78.3          Arteriotomy approach to organ
               using image guidance with
               ultrasound
```



MDT for Cancer	21/May/2024 00:00:0..
HCC	Contributor_system, R...

Outcome: Continue surgical workup. MRI liver requested in Basildon. To be reviewed in the HCC MDT once completed.

HPB Surgery GP Lett...	28/May/2024 09:49:3...
HPB Outpatient Letter ...	

His wedge pressures (4mmHg gradient) and ICG tests are favourable and a surveillance gastroscopy did not reveal any varices. His case was discussed at MDT and surgery was recommended as an option. I note he has seen the anaesthetic department and has been deemed OK to proceed.

Although this has been discussed as an option with him in the past, I went through the rationale of surgery and the benefits/risks involved. I highlighted the risks of bleeding, infection, clots, bile leak, post op liver insufficiency, recurrence and the small risk of death associated with a hepatectomy.

He was keen to proceed so CNS Keating will provide some further information material and we will schedule a provisional date for surgery.

03-Jun-2024 11:35	MLIVEC	MRI Liver with contrast	RAJ_R15142183401

```
Conclusion:

Findings suggest multifocal HCCs in the right lobe where on the arterial
phase the largest lesion is in segment V which show subtle increase in
size as compared to the study of 04-05-2024. Within segment VI two
adjacent enhancing nodules can be further  seen .
```

MDT for Cancer	11/Jun/2024 00:00:0...
HCC	Contributor_system, R...

Outcome: Technically resectable - would require right hepatectomy. Need liver volumes 1-4 and up-to-date CT chest. For surgical triage.

Outpatient GP Letters	14/Jun/2024 10:32:5...

Plan
Need tumour control and volume augmentation of left side aand plan a right hepatectomy with FLR volume >40%
Options,
1) SIRT
2) TAE + Right PVE, sequentially

CT Thorax	17/Jun/2024 16:41:0...
CCHES	Contributor_system, R...

Opinion:
Minor inflammatory change in the left lower lobe.
No evidence of thoracic metastases.

MDT for Cancer	18/Jun/2024 00:00:0...
HCC	Contributor_system, R...

Outcome: For TAE and PVE. SIRT MDT discussion no longer required.

General Clinical Note	20/Jun/2024 13:45:0...
HPB CNS telephone call	[redacted]

I called John to update him about the plan following MDT this week, after also discussing with Mr Iype.
John was already aware that it was a possibility between SIRT or TAE, and PVE. I informed him that the plan is for TAE and PVE, which he has agreed to.
I have posted him some patient information leaflets today (he does not use email) and we will let him know when the admission for these is booked for.
He has our contact details if he has any questions in the meantime.

Progress Note	10/Jul/2024 22:51:04...
HPB admission	[redacted]

Elective admission for Right PVE

Plan and requested actions
- NBM from 2 am onwards
- IV fluids at 6am
- Bloods including FBC, CRP, U&E, LFts, Clotting screen with INR
- For IRCU procedure tomorrow.

Anaesthetics - Intravenous cannulation

Progress Note	10/Jul/2024 23:38:25...
Anaesthetics - US guid...	[redacted]

Indication - pre-procedural, admission for right PVE

Embolisation hepatic ...	11/Jul/2024 09:26:00...
IAHEPE	Contributor_system, R...

IAHEPE
Clinical Indication: HCC. In work up for resection. Awaiting PVE first. Needs TAE to manage disease in the interim In work up for right hepatectomy. Insufficient left lobe volumes. For right PVE Clinical History: HCV cirrhosis. Hep C. Biopsy proven HCC.

Findings:
TAE:
Written consent obtained. General anaesthetic. Aseptic technique.
1% lidocaine.

PVE:
Written consent obtained. Aseptic technique. WHO checklist.
1% lidocaine.

No immediate complications.

Postprocedure care, including six hourly bedrest with half hourly pulse and blood pressure recorded in the notes.

Study Date: 11/07/2024

Arranged By: Date Newest At Top

Nursing Procedure N...	11/Jul/2024 09:52:05...
IRCU- op notes	[redacted]

INTERVENTIONAL RADIOLOGY NURSES RECORD

Date of procedure: 11/07/2024
Time started: 09:25H
Time finish: 12:45H

Procedure performed: 1) **HEPATIC ARTERY ANGIOGRAPHY + EMBOLISATION**
2) **PORTAL VEIN EMBOLISATION**

PERI-PROCEDURE NURSES NOTES

consent form signed; positioned comfortably on the table
and vital signs monitored and recorded by anaesthetics team.
handed over theatre recovery.

Hepatology Progress ... 16/Jul/2024 10:43:39...
Liver SpR Review [redacted]

This admission
Admitted 10/7/24 for HA embolisation (TAE) and PV embolisation (PVE)
Difficult pain control post operatively
CT 12/7/24 - no acute bleeding with post embolisation appearances
Noted 13/7/24 with worsening LFTs. Seen by Dr Hassan from liver on 13/7/24 and plan given
CT 13/7/24 - reported as stable appearnces of the liver post TAE/PVE
Desaturated on 14/7/24, with difficult pain control, worsneed lactate 9 and raised RR and HR
Transferred to ICU 15/7/24. Noted to have progressive HE

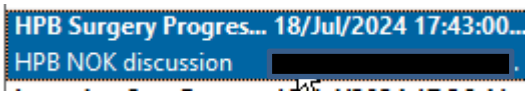
Clinical impression
ACLF on background of cirrhosis, decompensated post recent TAE and PVE
Grade III = HE, intubated, coagulopathic

Critical Care Family C... 16/Jul/2024 15:00:00...
Critical Care Family C... [redacted]

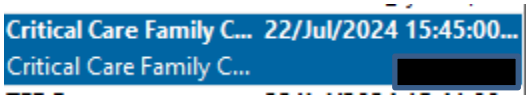
Critical Care Comments Family Communication : Updated [redacted] at the bedside that he had deteriorated after his procedure likely because his already diseased liver couldn't cope with losing the right side but also possibly because of a PV thrombus for which he has gone for a scan today. Explained that the management is primarily supportive and that he is currently stable/marginally better but given he is critically ill, could go either way.
This all came as a shock for her and she feels the communication from the teams prior to his ITU admission was suboptimal. Apologised and explained that sometimes the teams are busy and that in focussing on looking after the patient, we forget to update the family.
She understood and was happy with the plan.

Hepatology Progress ... 18/Jul/2024 11:31:43...
Liver SpR Note [redacted]

Discussion with Dr [redacted]
R PV occluded which would be expected post PVE
Small extension into Main PV but may have been overcalled on initial scan
No contraindication to giving treatment dose LMWH. Noted on prophylactic dose at present
I will feed back to [redacted] and she will advise further



Daughters [redacted] on bedside
Explained in detail what had happened, why pt is in ITU and current main issue, which is liver failure likely secondary to PVE on a background of HCV cirrhosis, which the patient did not tolerate well. Complicating is the current sepsis issue, where the gallbladder seems to be the likely source
Current management is to try and support patient as best as possible so the liver can recover, however, possible outcomes including lethality explained to them
Overall [redacted] were quite upset as the felt the did not receive enough information, and I apologised for this.
We will stay in touch and call them should any meaningful changes occur.



Family Members present : [redacted]

Critical Care Comments Family Communication : [redacted] expressed significant challenges in communication with medical team on ward and ICU so far. Harriet and I both apologised on behalf of the wider team. Offered psychological support which Katie was keen t take up

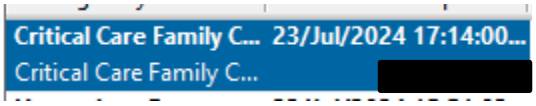
[redacted] stated that her mum [redacted] was struggling to retain the info provided by the medical team and so it was probably better for the medi tteam to communicate directly with [redacted]

She was aware that her father was in liver failure. I expressed that we have seen ongoing deterioration in liver function. Ideally would hav wanted to see trajectory of improvement but this has not been the case and the longer we see persistent organ failure, the more likely it that John will not suvive critical ilness.

[redacted] expressed that she would not want her father to suffer; he looked like he was crying when she saw him today. I said we will absolut prioritse his comfort and pain. Will start him on regular analgesia. If it becomes clea that we are delivering futile therapy then we will not p him through prolonged suffering.

I said that today we were concerned that there might be an element of infection and that we are trying to get on top of it. I think we should take next 48-72 hours to understnad this and hen aim to sit down with family towards the middle/later in this week.

We have also put in place a DNAR order (see TEP for further details of this discussion)



Family Members present : [redacted]

Critical Care Comments Family Communication : Explained that Mr Tompkins remains in persistent organ failure. CT shows clot extension. Family very clear that Mr Tompkins would not want to be put through futile treatments if it was clear that outcome was inevitable. They are very clear that they do not want him to suffer and be in pain. They said that at the moment he is able to communicate with difficuty while intubated and he was expressing that he had severe back pain.

have explained thatthe current trajectory indicates that John is unlikely to survive. And unfortunately there does not appear to be reversibility here and we do not have any additional treatment options available. I discussed this with Prof Agarwal (who is taking over care tomorrow) who is also in agreement. We have asked the hepatology team to also review John and they will do so tomorrow.

asked [redacted] tomorrow so they can sit down with the medical team to talk through the next steps.

[redacted] specifically asked what withdrawal of treatment could look like. I said that if this was felt to be the right course of action, we would prioritise John's comfort and dignity and then actively withdraw current supportive measures.

Discussion between ICU Cons [redacted] and Hepatology [redacted]

In agreement that patient is very unwell, remains in multi organ failure.
There are no further treatment options other than supportive care.
Given pt has showed any signs of improvement over last two weeks, and continues to deteriorate, further treatment is futile.
Emphasis of care should be to prioritise comfort.

Will discuss with the family.

Consultant Review 24/Jul/2024 15:55:00...
Mr Iype Progress Note [redacted]

I discussed the case with [redacted] by reviewing the course so far. We had a meeting with the family (wife and two daughters) - I checked their understanding of the the patient's current condition. They had discussions with ITU team in the preceding few days - good understanding of the course - worsening liver failure and no meaningful treatment options other than supportive care. They were agreeable with ITU suggestion withdrawing of support. They expressed the view that they are 'prepared and want him not to suffer.'

Plan and requested actions
I note the consultation with hepatology.
I am deeply sad to see the poor outcome following the IR procedure and I would agree with the family's wishes for end of life care.

Intensive Care Progr... 24/Jul/2024 17:47:52...
[redacted]

Plan
Withdraw active care (stop norad, CVVH, extubate on RA, ABx)
Palliative care referral sent
[redacted]- daughter
07469 353055

Please call [redacted]ather than wife Jan who is listed as NOK if John passes away overnight.
This is the request of [redacted]

Intensive Care Progr... 25/Jul/2024 01:28:40...
ITU Night Review [redacted]

Addendum by [redacted] on 25 July 2024 02:38:13 BST (Verified)
John has passed away
Daughter has already been informed by n/s

Appendix 2: Summary of Guidance and policies

a. NatSSIPs2 national guideline

The National Safety Standards for Invasive Procedures (NatSSIPs) have been established to standardise safety protocols across healthcare settings for invasive procedures. These guidelines

aim to minimise errors, enhance teamwork, and prevent 'Never Events,' which are serious incidents that are entirely preventable.

NatSSIPs: The original guidelines were first introduced in 2015 by NHS England. These guidelines were formulated based on extensive research and collaboration among healthcare professionals. The primary goal was to create a set of safety standards that could be applied across all specialised areas where invasive procedures are performed, including operating rooms, radiology suites, and outpatient clinics. Key Objectives:

- To reduce the occurrence of errors during invasive procedures.
- To enhance communication and teamwork among healthcare teams.
- To Create a safer environment for patients undergoing invasive procedures.

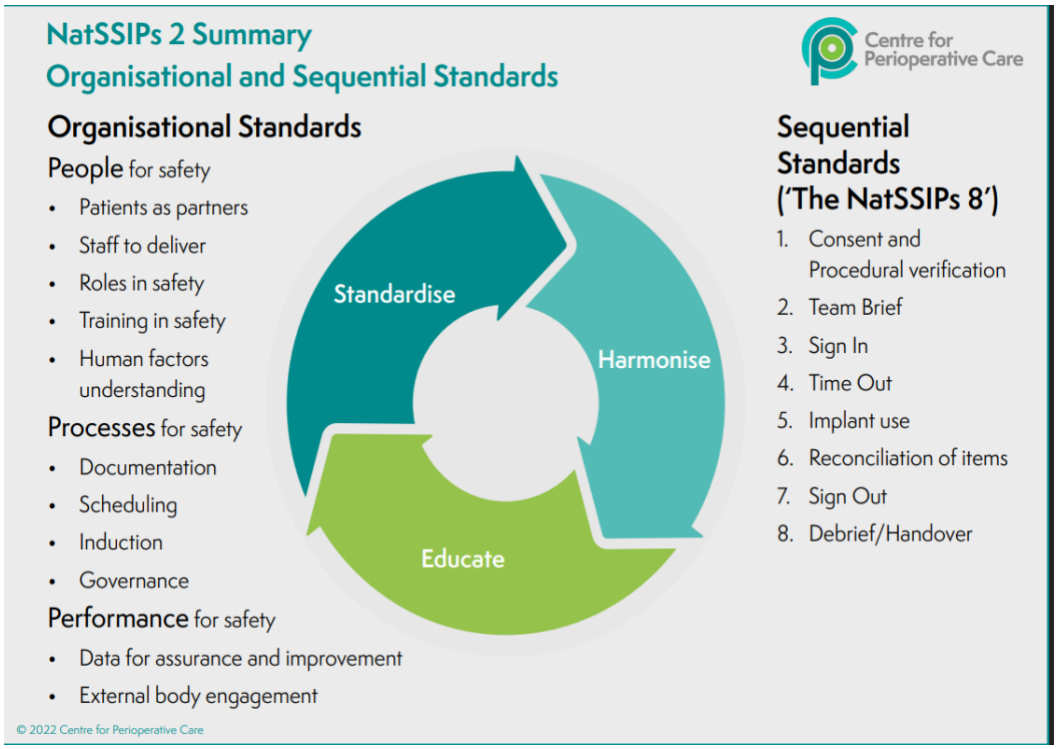


Figure 3 NatSSIPs organisational and sequential standards

b. Royal Free Consent Policy

(Date issued: 15/11/2021, Review date: November 2022)

To ensure valid consent, the patient's decision must be voluntary, informed, and made with full capacity.

Material Risk: (Montgomery v Lanarkshire Health Board)
The material risk for each option should be discussed with the patient. The test of materiality is twofold:
- Whether a reasonable person in the patient's position would likely attach significance to the risk.
- Whether the doctor is or should reasonably be aware that the particular patient would likely attach significance to it.

At RFL, doctors who are deemed competent either to perform the procedure or to obtain consent for it are responsible for obtaining consent. If the operating surgeon is not the doctor who obtained the consent, they must countersign the consent form to indicate they are satisfied that the consent process has been properly conducted. This must occur before induction of anaesthesia.

The health professional with overall responsibility for the patient's care is ultimately responsible for ensuring that the patient is genuinely consenting to the procedure.
The consent process involves two stages:
1. Informative
2. Confirmatory

When the patient should sign the consent form:

It is preferable that signatures are obtained before the patient has begun preparation for treatment (e.g., before changing into a hospital gown). However, the confirmatory stage of consent and verification of site/side marking may be done simultaneously, but this must occur before the patient reaches the anaesthetic room or theatre.

Who is responsible for seeking consent?

At the Royal Free London NHS Foundation Trust, taking of consent is undertaken by doctors who have been deemed competent either to carry out the procedure or to obtain consent for it. If the operating surgeon is not the doctor who obtained the consent, it is their duty to countersign the consent form to show that they are satisfied that the consent process has occurred. This must occur prior to induction of anaesthesia.

The health professional with overall responsibility for the patient care is ultimately responsible for ensuring that the patient is genuinely consenting to what is being done: it is they who will be held responsible in law if this is challenged later. Where this is not possible for the healthcare professional with overall responsibility for the patient's care it may be devolved to another member of the team, but that person should have full knowledge of the proposed treatment, the material risks and any side effects. For these reasons and due to the variable experience of foundation

doctors it is not acceptable for foundation doctors to be taking consent via the signing of consent forms.

c. Royal Free New Interventional Procedures (NIPs) policy

Definition:
An interventional procedure should be considered new if:
• A doctor no longer in a training post is using it for the first time in his or her NHS clinical practice.
• It has not previously been performed in the NHS.
• It has not previously been performed at the trust.

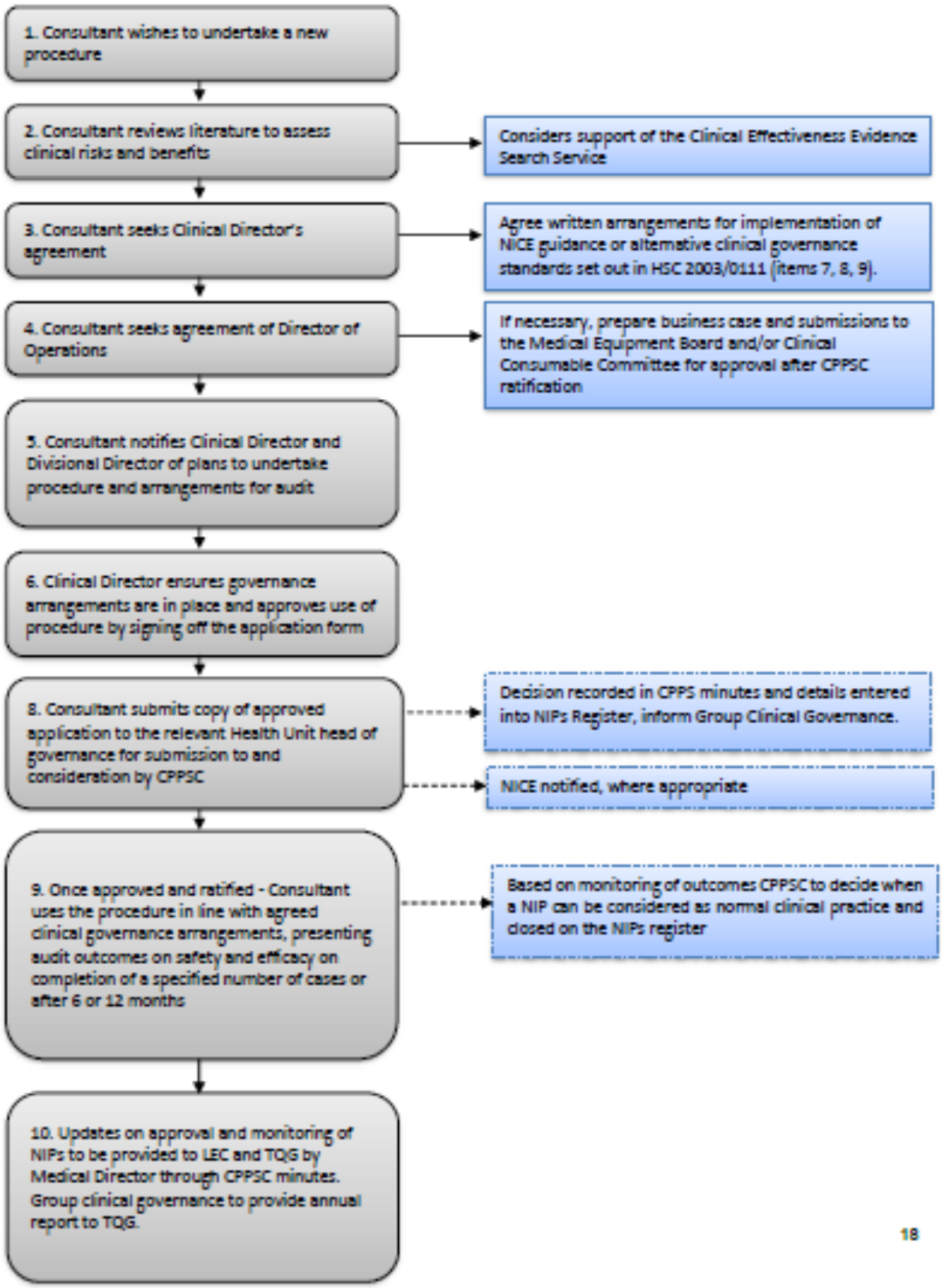
Department of health, Health Service Circular (HSC 2003/011) specifies that:
Medical practitioners planning to undertake new interventional procedures should seek approval from their NHS Trust's Clinical Governance Committee before doing so.

The Chair of the Clinical Governance Committee should notify the procedure to the Interventional Procedures Programme at NICE unless it is already listed there. In a case where the procedure must be used in an emergency the procedure should be notified to the Clinical Governance Committee within 72 hours.

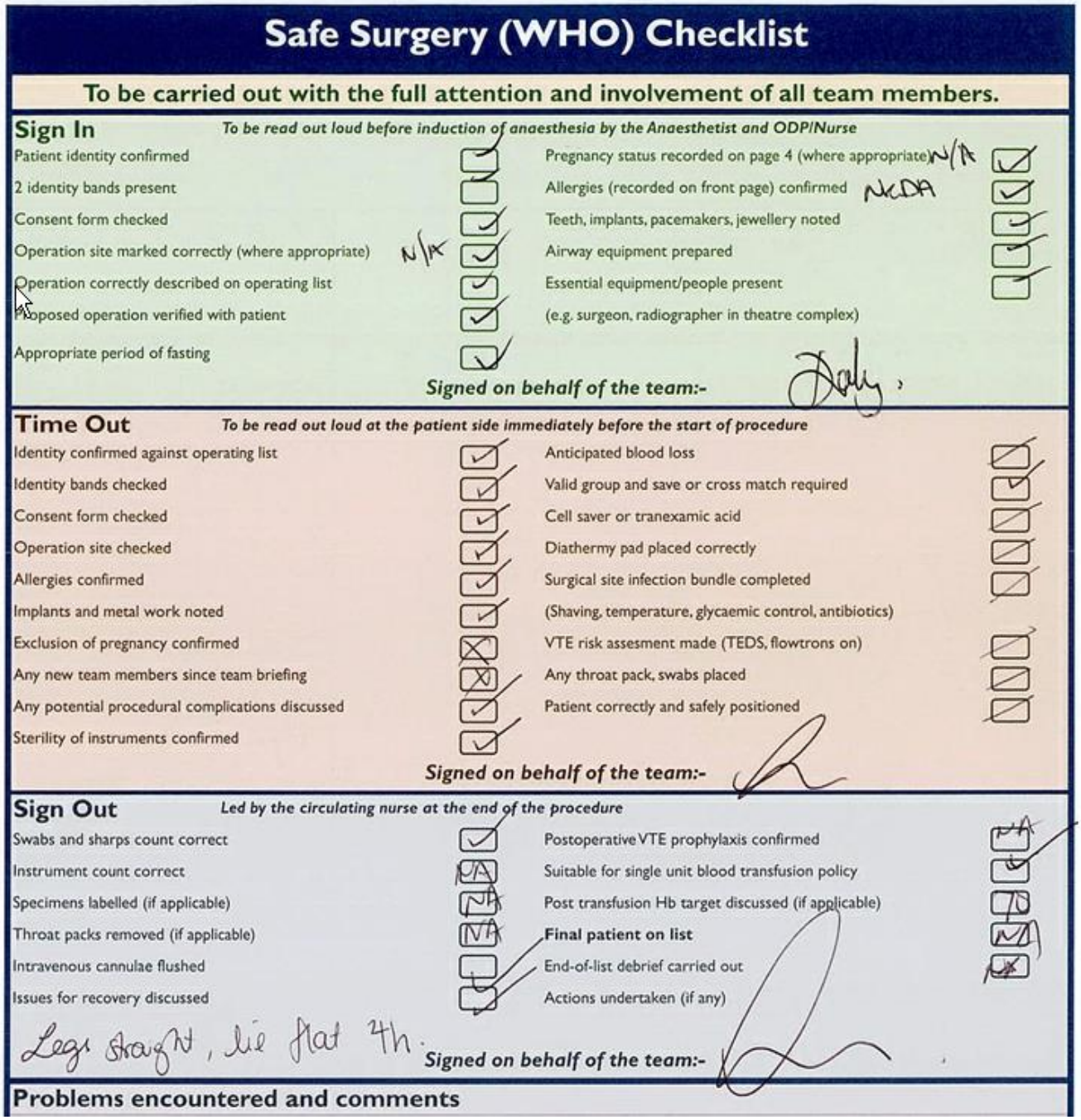
Any doctor considering use in the NHS of a new interventional procedure which he/she has not used before, or only used outside the NHS, should seek the prior approval of their NHS Trust's Clinical Governance Committee. If the procedure is the subject of NICE guidance, the Committee should consider whether the proposed use of the procedure complies with the guidance before approving it. It is recognised that in rare circumstances, where no other treatment options exist, there may be a need to use a new procedure in a clinical emergency so as not to place a patient at serious risk.

If a doctor has performed a new interventional procedure in such circumstances, he/she must inform the Associate Medical Director and their Clinical Director within 72 hours. The procedure will then go through the standard process for approval and ratification as described in this policy.

Appendix 2: New Interventional Procedure Process at Royal Free London NHS Foundation Trust



Appendix 3: LocSSIPs



Safe Surgery (WHO) Checklist

To be carried out with the full attention and involvement of all team members.

Sign In

To be read out loud before induction of anaesthesia by the Anaesthetist and ODP/Nurse

- Patient identity confirmed ✓
- 2 identity bands present ☐
- Consent form checked ✓
- Operation site marked correctly (where appropriate) N/A ✓
- Operation correctly described on operating list ✓
- Proposed operation verified with patient ✓
- Appropriate period of fasting ✓
- Pregnancy status recorded on page 4 (where appropriate) N/A ✓
- Allergies (recorded on front page) confirmed NKDA ✓
- Teeth, implants, pacemakers, jewellery noted ✓
- Airway equipment prepared ✓
- Essential equipment/people present ✓ (e.g. surgeon, radiographer in theatre complex)

Signed on behalf of the team:- Daly

Time Out

To be read out loud at the patient side immediately before the start of procedure

- Identity confirmed against operating list ✓
- Identity bands checked ✓
- Consent form checked ✓
- Operation site checked ✓
- Allergies confirmed ✓
- Implants and metal work noted ✓
- Exclusion of pregnancy confirmed ☒
- Any new team members since team briefing ☒
- Any potential procedural complications discussed ✓
- Sterility of instruments confirmed ✓
- Anticipated blood loss ☐
- Valid group and save or cross match required ✓
- Cell saver or tranexamic acid ☐
- Diathermy pad placed correctly ☐
- Surgical site infection bundle completed ☐ (Shaving, temperature, glycaemic control, antibiotics)
- VTE risk assesment made (TEDS, flowtrons on) ☐
- Any throat pack, swabs placed ☐
- Patient correctly and safely positioned ☐

Signed on behalf of the team:-

Sign Out

Led by the circulating nurse at the end of the procedure

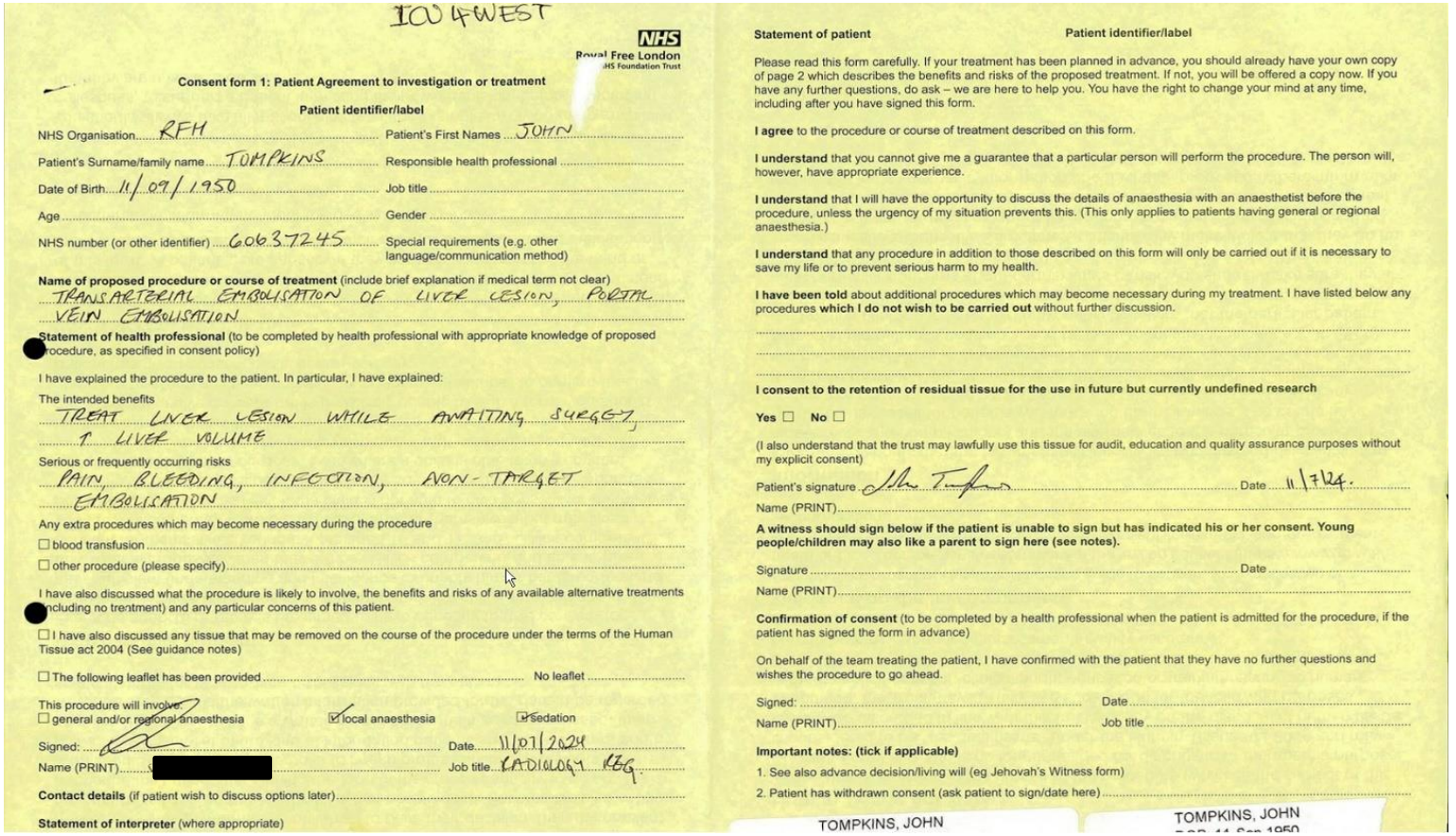
- Swabs and sharps count correct ✓
- Instrument count correct N/A
- Specimens labelled (if applicable) N/A
- Throat packs removed (if applicable) N/A
- Intravenous cannulae flushed ☐
- Issues for recovery discussed ✓
- Postoperative VTE prophylaxis confirmed N/A ✓
- Suitable for single unit blood transfusion policy ✓
- Post transfusion Hb target discussed (if applicable) 70
- **Final patient on list** ✓
- End-of-list debrief carried out N/A
- Actions undertaken (if any)

Legs straight, lie flat 4h.

Signed on behalf of the team:-

Problems encountered and comments

Appendix 4 Consent form Signed



ICU 4WEST

NHS
Royal Free London
NHS Foundation Trust

Consent form 1: Patient Agreement to investigation or treatment

Patient identifier/label

NHS Organisation RFH — Patient's First Names JOHN

Patient's Surname/family name TOMPKINS — Responsible health professional

Date of Birth 11/09/1950 — Job title

Age — Gender

NHS number (or other identifier) 6063 7245 — Special requirements (e.g. other language/communication method)

Name of proposed procedure or course of treatment (include brief explanation if medical term not clear)
TRANSARTERIAL EMBOLISATION OF LIVER LESION, PORTAL VEIN EMBOLISATION

Statement of health professional (to be completed by health professional with appropriate knowledge of proposed procedure, as specified in consent policy)

I have explained the procedure to the patient. In particular, I have explained:

The intended benefits
TREAT LIVER LESION WHILE AWAITING SURGERY, ↑ LIVER VOLUME

Serious or frequently occurring risks
PAIN, BLEEDING, INFECTION, NON-TARGET EMBOLISATION

Any extra procedures which may become necessary during the procedure

☐ blood transfusion

☐ other procedure (please specify)

I have also discussed what the procedure is likely to involve, the benefits and risks of any available alternative treatments (including no treatment) and any particular concerns of this patient.

☐ I have also discussed any tissue that may be removed on the course of the procedure under the terms of the Human Tissue act 2004 (See guidance notes)

☐ The following leaflet has been provided — No leaflet

This procedure will involve:
☐ general and/or regional anaesthesia ☑ local anaesthesia ☐ sedation

Signed: — Date 11/07/2024

Name (PRINT) [redacted] — Job title RADIOLOGY REG

Contact details (if patient wish to discuss options later)

Statement of interpreter (where appropriate)

Statement of patient — **Patient identifier/label**

Please read this form carefully. If your treatment has been planned in advance, you should already have your own copy of page 2 which describes the benefits and risks of the proposed treatment. If not, you will be offered a copy now. If you have any further questions, do ask – we are here to help you. You have the right to change your mind at any time, including after you have signed this form.

I agree to the procedure or course of treatment described on this form.

I understand that you cannot give me a guarantee that a particular person will perform the procedure. The person will, however, have appropriate experience.

I understand that I will have the opportunity to discuss the details of anaesthesia with an anaesthetist before the procedure, unless the urgency of my situation prevents this. (This only applies to patients having general or regional anaesthesia.)

I understand that any procedure in addition to those described on this form will only be carried out if it is necessary to save my life or to prevent serious harm to my health.

I have been told about additional procedures which may become necessary during my treatment. I have listed below any procedures **which I do not wish to be carried out** without further discussion.

I consent to the retention of residual tissue for the use in future but currently undefined research

Yes ☐ **No** ☐

(I also understand that the trust may lawfully use this tissue for audit, education and quality assurance purposes without my explicit consent)

Patient's signature — Date 11/7/24.

Name (PRINT)

A witness should sign below if the patient is unable to sign but has indicated his or her consent. Young people/children may also like a parent to sign here (see notes).

Signature — Date

Name (PRINT)

Confirmation of consent (to be completed by a health professional when the patient is admitted for the procedure, if the patient has signed the form in advance)

On behalf of the team treating the patient, I have confirmed with the patient that they have no further questions and wishes the procedure to go ahead.

Signed: — Date

Name (PRINT) — Job title

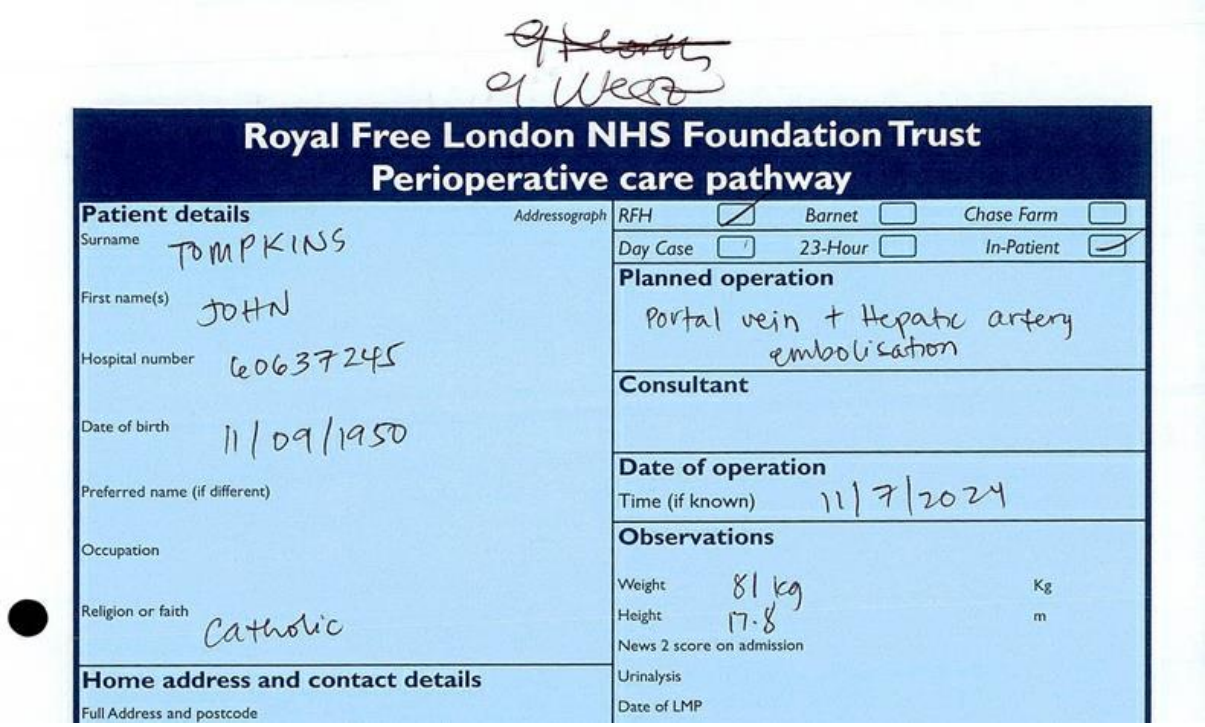
Important notes: (tick if applicable)

1. See also advance decision/living will (eg Jehovah's Witness form)
2. Patient has withdrawn consent (ask patient to sign/date here)

TOMPKINS, JOHN

TOMPKINS, JOHN

Appendix 5: Peri-operative care pathway



~~4 Weeks~~
4 Weeks

Royal Free London NHS Foundation Trust
Perioperative care pathway

Patient details Addressograph

Surname: TOMPKINS
First name(s): JOHN
Hospital number: 60637245
Date of birth: 11/09/1950
Preferred name (if different):
Occupation:
Religion or faith: Catholic

Home address and contact details
Full Address and postcode

RFH ☒ Barnet ☐ Chase Farm ☐
Day Case ☐ 23-Hour ☐ In-Patient ☑

Planned operation
Portal vein + Hepatic artery embolisation

Consultant

Date of operation
Time (if known) 11/7/2024

Observations
Weight 81 kg Kg
Height 17.8 m
News 2 score on admission
Urinalysis
Date of LMP