Patient’s death as a result of anaesthesia administered during magnetic resonance imaging in January 2025

T2025-01

FOREWORD

Pursuant to section 2, subsection 2 of the Safety Investigation Act of Finland (525/2011), the Safety Investigation Authority decided to investigate the death of a patient as a result of anaesthesia administered during magnetic resonance imaging on 2 January 2025.

The purpose of safety investigations is to promote general safety and to prevent accidents and incidents as well as losses resulting from accidents. A safety investigation is not conducted in order to allocate legal liability.

Senior Safety Investigator Marleena Komulainen served as Head of the Investigation team until 21 May 2025. After this date, Senior Safety Investigator Heikki Harri took over this role. Expert Leo Evijärvi, Expert Päivi Porkka and Expert Mikko Virtanen were appointed as members of the investigation team. The Investigator in Charge was Chief Investigator Hanna Tiirinki.

Professor and Chief Physicist Jani Saunavaara and Docent Kimmo Mattila, D.Med.Sc. and Specialist in Radiology, served as senior specialists to the supplementary investigation of the patient's MRI images using reference data. Klaus Olkkola, Professor of Anaesthesiology and Intensive Care, Chief Physician, D.Med.Sc., was appointed as a senior specialist to the supplementary investigation of medications administered to the patient during anaesthesia and on the prerequisites for ensuring safety.

A safety investigation examines the sequence, causes and consequences of events as well as the rescue operations undertaken and the actions of the authorities. In particular, the investigation seeks to establish if safety was adequately addressed in the activities that led to the accident and in the design, manufacture, construction and use of the equipment and structures that caused the accident or incident or that were affected by it. The investigation also determines if direction, supervision and inspection activities were organised and taken care of appropriately. If necessary, any shortcomings in provisions and regulations applicable to safety and the authorities must also be investigated.

The investigation report describes the sequence of events, the factors leading to the accident and its consequences as well as safety recommendations addressed to the appropriate authorities and other instances regarding measures that are necessary in order to promote general safety, prevent further accidents and incidents, prevent losses and improve the effectiveness of the operations of search and rescue and other authorities.

The parties involved in the accident and the authorities responsible for supervision in the sector of the accident under investigation are given an opportunity to comment on the draft investigation report. Their comments were taken into account when finalising the investigation report. A summary of the comments is provided at the end of the investigation report. Pursuant to the Safety Investigation Act of Finland, comments given by private individuals are not published.

The investigation report summary was translated into English by Lingsoft.

The investigation report together with its summary and appendices were published on 11.02.2026 on the Safety Investigation Authority's website at *www.turvallisuustutkinta.fi*.

Investigation ID: T2025-01
Publication series: 2/2026
ISBN: 978–951–836-692-1 (PDF)
ISSN: 2341–5991

Cover image: SIAF

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1 EVENTS

1.1 Sequence of events

A patient underwent magnetic resonance imaging (MRI) under anaesthesia at a private medical centre on 2 January 2025. As a result of the event, the patient died despite intensive care on 7 January 2025.

The patient visited a private medical centre for examinations due to shoulder pain caused by an accident in December 2024. After experiencing continued intense pain, the patient visited the same unit three times for appointments with different orthopaedic and traumatology specialists. An MRI of the shoulder had been attempted twice at the private medical centre in December 2024, but the scan was unsuccessful due to the patient's claustrophobia. The examination was also unsuccessful with sedative medication administered orally. An orthopaedist referred the patient to Kuopio University Hospital (KUH) for an MRI under general anaesthesia. The referral was approved on 30 December 2024, but the patient had not been informed of the examination date.

On the morning of 2 January 2025, the patient arrived at the private medical centre for an ultrasound examination of their shoulder. After this, the patient asked to talk to a physician about pain treatment. An anaesthesiologist talked to the patient in the corridor. The patient expressed frustration about the waiting period of several weeks for an MRI at Kuopio University Hospital.

The anaesthesiologist suggested performing the MRI at the unit in question, with the anaesthesiologist handling the patient's anaesthesia themselves. The patient was interested in this plan and the anaesthesiologist made a decision to perform an MRI under sedation during an imaging slot that was available at 15:30 on the same day. The anaesthesiologist asked the patient for information on their medical history and looked at previous patient records in the private health care unit's information system. After being instructed to fast, the patient went home to wait for imaging on the same day.

Accompanied by a family member, the patient returned to the private medical centre at the agreed time. The patient was directed to the imaging ward and asked to fill in the preliminary information form for an MRI. The preliminary information form did not reveal any contraindications[1] for MRI. In the imaging ward, radiographer A established intravenous access via the back of the patient's left hand. Imaging under sedation was an unplanned procedure for the MRI unit staff.

The anaesthesiologist arrived with medications taken from the operating room's recovery room, an oxygen mask, oxygen tube, oropharyngeal tube and an oxygen bottle that could be taken into the MRI room. The patient was instructed to lie on their back on the imaging table with their head towards the scanner. The anaesthesiologist opened the valve on an oxygen bottle containing 100% medical oxygen for a 4 l/min flow and placed an oxygen mask on the patient. The oxygen bottle was placed on the floor next to the scanner. The anaesthesiologist administered benzodiazepine and an anaesthetic agent intravenously. After the patient fell asleep, an oropharyngeal tube was inserted into the pharynx.

The patient was moved into the MRI scanner. The patient's lower limbs were visible from the knees down outside the scanner tube. The scan consisted of a localizer sequence and five

[1] In medical science, a contraindication refers to a situation or factor that makes a treatment, medicine, procedure or examination inadvisable or potentially dangerous for the patient.

separate imaging sequences lasting approximately three minutes each. The first localizer sequence began at 15:30. During the localizer sequence, the patient moved and the anaesthesiologist administered an additional dose of intravenous anaesthetic. The patient stopped moving after this. At the end of the localizer sequence, radiographer A entered the imaging room to check the patient's position. The second imaging sequence began at 15:32 and ended at 15:36. The third imaging sequence started at 15:36 and ended at 15:39. The fourth imaging sequence began at 15:41 and ended at 15:43. The fifth imaging sequence started at 15:43 and ended at 15:46. The sixth and last imaging sequence began at 15:46 and ended at 15:49.

During the imaging, the anaesthesiologist administered several additional doses of intravenous anaesthetic. When the imaging ended, the anaesthesiologist administered one dose of antidote to the patient. The aim of this was to reverse the effect of the medication. Only the total quantities of the medicines administered were entered in the patient record.

During the scan, the anaesthesiologist sat in a chair in the imaging room next to the patient's lower limbs and monitored the patient's condition visually. The anaesthesiologist stated that they had left the open end of the MRI scanner to go behind the MRI scanner between imaging sequences to check for misting of the patient's oxygen mask and chest respiration movements. There was no other monitoring of vital signs. Radiographers A and B were in the control room during the imaging. A third radiographer C was in the adjacent corridor.

After the imaging ended, radiographers B and C left to get a bed from the recovery room in order to move the patient to the recovery room. At the same time, radiographer A went into the imaging room and pulled the patient out of the scanner. Radiographer A immediately noticed that the skin colour of the patient's upper limbs had become pale and the patient did not react to movement or speech. The anaesthesiologist tried to wake the patient up. The radiographer checked the arterial pulse in the wrist and stated that they could not feel any pulse. Radiographer A asked the anaesthesiologist about starting life support, lowered the imaging table and began cardiopulmonary resuscitation (CPR). The radiographers who had left to get the bed returned with it. Radiographer B went to the recovery room to get a bag valve mask.

After radiographer B returned, radiographers A, B and C and the anaesthesiologist lifted the large patient from the imaging table onto the floor and used a transfer sheet to pull the patient from the imaging room into the control room. Radiographer A left to get a defibrillator from the entrance lobby. Advanced cardiac life support (ACLS)[2] continued with CPR and ventilation of the patient with a bag valve mask. The bag valve mask was connected to the oxygen bottle in the MRI room. Radiographer B went to the recovery room to get a resuscitation cart and more supplies. A call button in the imaging room was used to request additional staff to help with the situation. Several people arrived on the scene to provide help.

After connection, the semi-automatic defibrillator reported that there was no shockable rhythm. Radiographer B brought a resuscitation cart. The patient was given two doses of intravenous resuscitation medication, and a pulse was detected after this. The patient was connected to a monitor that showed a normal cardiac rhythm. An attempt was made to insert a breathing tube for the patient using a video laryngoscope[3]. The resuscitation cart did not

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[2] ACLS is a type of resuscitation performed by health care professionals using resuscitation medicines and treatment devices.

[3] A laryngeal endoscope used when securing a patient's airway.

contain the correct size of videolaryngoscope blade, and the first attempt to insert the breathing tube was unsuccessful. The anaesthesiologist then inserted a breathing tube with an ordinary laryngoscope and continued to assist breathing with the bag valve mask. The patient's oxygenation was initially poor and their blood pressure was slightly low, but the situation improved to a satisfactory level during monitoring. The patient began to breathe on their own.

Radiographer C called the emergency number at 16:02. The Emergency Response Centre assigned the task to an EMS unit and an EMS unit with a physician as an urgent category A[4] event. When the EMS unit arrived at the scene at 16:11, the patient had already been intubated and blood circulation restored. The patient was connected to the EMS unit's ventilator and the events were reported orally to the paramedics and physician. Responsibility for treating the patient was transferred to pre-hospital emergency medical services.

The patient's next of kin had arrived to pick up the patient and saw them being transferred to an ambulance. The anaesthesiologist talked with the next of kin and assessed the patient's prognosis as good. The patient's transfer to the intensive care unit at KUH for further treatment began at 16:45 p.m. In the intensive care unit, the situation was handled according to the treatment protocol. Examinations performed at the hospital determined that the patient could not recover and intensive care was terminated. The patient died in the intensive care unit on 7 January 2025.

After the accident, the medical centre personnel continued their daily tasks normally. A group discussion led by an occupational psychologist was held on 16 January 2025. The imaging unit's service manager also organised a discussion session for the department staff on 17 January 2025.

Occupational health care provided psychosocial support for the patient's close relatives. KUH also provided instructions for making contact if a need for support arose.

[4] Category A = A high-risk emergency medical assignment, Category B = An emergency medical assignment with a probable high risk, Category C = An emergency medical assignment in which basic vital functions are slightly disrupted, Category D = An emergency medical assignment with no disruption of basic vital functions.

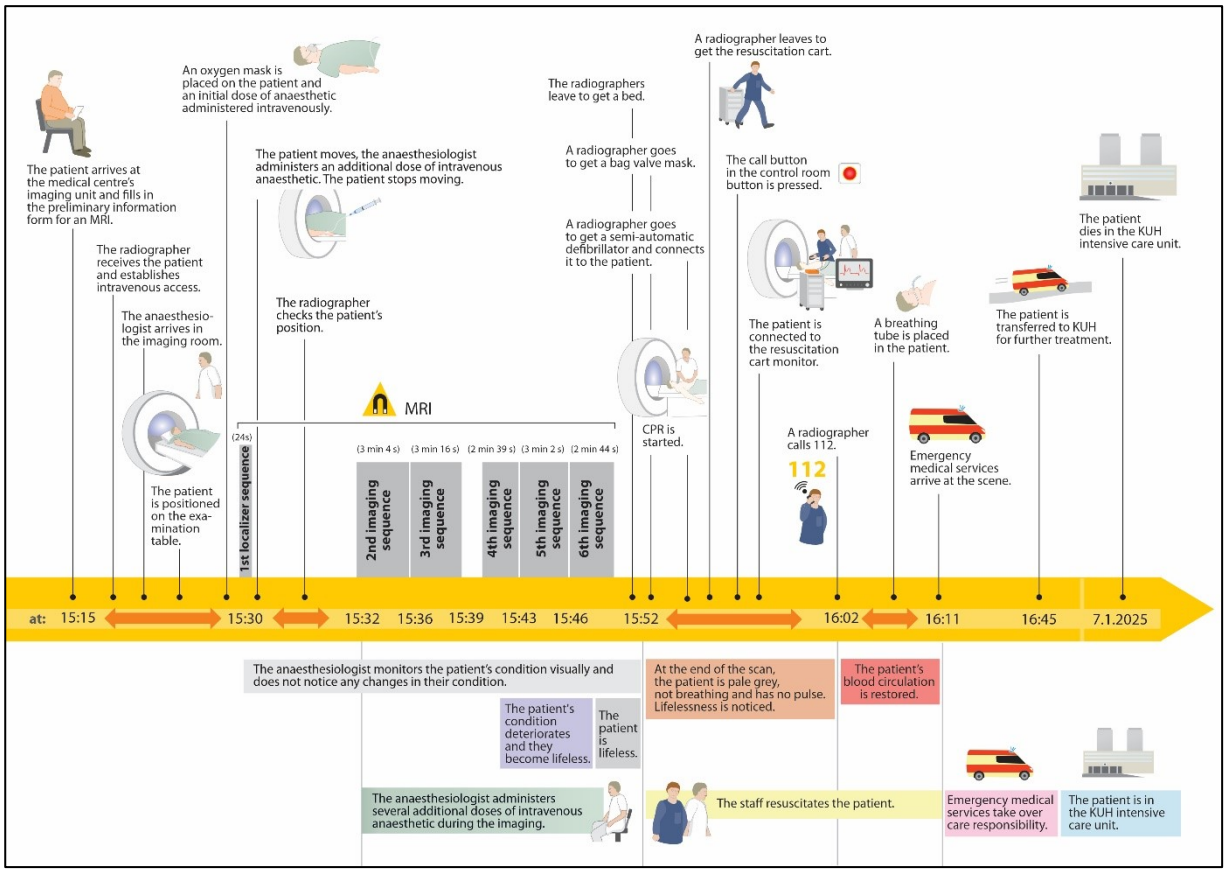

Image 1. Sequence of events. (Image: SIAF)

1.2 Alerts and rescue operations

A radiographer from the **private medical centre** called the Emergency Response Centre at 16:02:58 on 2 January 2025. Based on the initial information provided by the radiographer, the Emergency Response Centre operator assigned the task to prehospital emergency medical services as a code 700 (lifeless), urgency level A.

The Emergency Response Centre dispatched pre-hospital emergency medical services to the location at 16:03:52 p.m. Prehospital emergency care unit units EPS222, EPS271, EFH60 were assigned to the task as well as RPS101 as the first response unit. The first unit arrived at the private medical centre that performed the MRI at 16:08:34.

Table 1. Rescue units dispatched by the Emergency Response Centre

Rescue Unit	Alerted	At the scene	Location	Type
EFH60	16:03:35	16:17:25	Kuopio	EMS unit with physician
EPS222	16:03:35	16:09:24	Kuopio	Advanced life support (ALS) ambulance
EPS271	16:03:35	16:13:52	Kuopio	Community paramedicine unit
RPS101	16:03:35	16:08:34	Kuopio	Rescue unit

1.3 Consequences

A person undergoing an MRI scan was found to be lifeless at the end of the examination. The person died on 7 January 2025 as a result of irreversible damage caused by lifelessness that occurred during an MRI scan.

The health care unit responsible for the patient's further treatment reported the incident in writing and by telephone to the Regional State Administrative Agency for Eastern Finland on 3 January 2025, because it suspected the possibility of a medical error.

The Regional State Administrative Agency for Eastern Finland issued an oral decision to suspend imaging procedures performed under anaesthesia to Pihlajalinna Kuopio's Leväsentie location on 3 January 2025. The Pihlajalinna Group then voluntarily suspended similar activities at all of its other locations. The professional practice of the anaesthesiologist who acted as the service provider continued normally.

The Finnish Supervisory Agency for Health and Welfare has prepared its own report on the event.

The police have started a pre-trial investigation of the case.

2 BACKGROUND INFORMATION

2.1 Environment, equipment and systems

2.1.1 Magnetic resonance imaging (MRI)

MRI is an imaging method that uses a strong magnetic field and radio waves to produce accurate internal images of body tissues. It is based on the magnetic properties of the body's hydrogen atoms and produces images without X-ray radiation.[5] MRI is suitable for diagnosing a wide range of diseases and injuries, especially in the joints, spine, head, and blood vessels. The examination can be performed without a contrast agent or by using an intravenous or local contrast agent (e.g., intra-articular).

Current MRI equipment typically has a strong static magnetic field[6] produced by a superconducting magnet with a typical strength of 1.5 or 3 Tesla[7]. The aim is to contain the magnetic field inside the device, but in practice this is not entirely possible.

The strong magnetic field attracts ferromagnetic objects with[8] such force that even large objects in the magnetic field will hit the MRI scanner or fly into it at high speed. Foreign bodies, implants, and medical devices within the patient may shift or be damaged during magnetic resonance imaging. This is why only equipment that has been specifically identified as suitable for use in the MRI room may be taken into the room. A monitoring device unsuitable for use in an MRI room may provide inaccurate information about the patient's condition and thereby create a hazardous situation.

Prior to an MRI procedure, it is essential to always determine whether the person has any factors, such as metal objects or implants, that could prevent or compromise the scan. A preliminary information form is generally used to assess contraindications.

2.1.2 Anaesthesia and its safe administration

Anaesthesia refers to a condition in which a patient's pain and sensations are temporarily reduced or eliminated through medication, usually during a medical procedure or examination. Anaesthesia is a general term that covers various forms of anaesthesia, including sedation, general anaesthesia and various regional and local anaesthesia techniques.

The need for anaesthesia may be due to the patient or a planned operation, procedure or examination. Severe claustrophobia in an adult may prevent successful MRI imaging without anaesthesia. An intellectual disability, fear or anxiety may also cause a need for anaesthesia in connection with dental care, for example.

Situations in which non-operating room anaesthesia (NORA) is used include imaging examinations, cardiac examinations, endoscopy of the bowel, and electrotherapy of the brain. The use of NORA is increasing. The range of procedures is developing and less invasive procedures are favoured when this is a viable alternative to a high-risk surgical procedure.

When using NORA, the anaesthesia staff usually have to bring all the equipment, medications and devices they need to the site. The environment is different from operating rooms, where

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5 The magnetic properties of the body's hydrogen atoms enable magnetic resonance imaging (MRI), which uses a strong magnetic field and radio waves to manipulate the nuclei of hydrogen atoms and then measures their response to identify various types of tissue.

6 The MRI scanner contains a magnet consisting of a superconductor that does not resist electrical current.

7 In an MRI scanner, "Tesla" (T) is the unit used to measure the strength of the magnetic field in the scanner.

8 Ferromagnetic objects are items or substances made of ferromagnetic materials – i.e. substances that can be strongly magnetised and remain magnetic even after removal of the external magnetic field.

anaesthesia equipment and supplies are usually already in place. Backup power may not be available outside the operating room in sudden exceptional situations, such as power outages. Handling various medical emergencies, such as an allergic reaction or a difficult airway,[9] may also be challenging.

Anaesthesia is performed by staff who have special training for this task. An anaesthesiologist is usually responsible for administering anaesthesia unless it only involves mild sedation. A nurse anaesthetist implements the anaesthesia and monitors the patient's condition.

Sedation refers to using medication to induce a state of calmness and relaxation in a patient. The patient breathes on their own. Sedation can be divided into mild and deep sedation depending on how sleepy the patient is.

General anaesthesia refers to anaesthesia in which the patient becomes unconscious and has no pain sensations. During general anaesthesia, the airway is secured with a breathing tube placed in the trachea or a laryngeal mask airway, and the patient is on a ventilator.

In cases of deep sedation and general anaesthesia, the human resources required for anaesthesia do not differ from those needed in the operating room, and the anaesthesia environment and equipment requirements are similar. The requirements are less strict in cases of light sedation.

Light sedation refers to sedation in which the level of consciousness does not significantly decrease, breathing is independent, protective reflexes function, and the patient reacts to speech and touch in the way that could be expected from a person who is either completely awake or slightly drowsy. This type of sedation is most commonly implemented with benzodiazepine medication administered orally.

Deep sedation involves reducing the patient's level of consciousness, typically by administering anaesthetic substances and/or opioid group analgesics intravenously. It is not easy to wake a patient who is under deep sedation. Partial loss of protective reflexes is a typical feature of deep sedation. For example, a patient's airway cannot be considered fully secure unless it is monitored at all times.

The Finnish Society of Anaesthesiologists has issued a recommendation on monitoring anaesthesia and the organisation of anaesthesia activities.[10] According to the recommendation, deep sedation should be treated in the same way as general anaesthesia in terms of staffing and the equipment in the procedure room. The same equipment and staff requirements must be complied with as in operating rooms.

According to the recommendations, the oxygenation of a patient under general anaesthesia is monitored with a pulse oximeter and by measuring adequate oxygen concentration in inhaled air. Current recommendations also include the use of a high-speed oxygen sensor to measure the percentage of oxygen in exhaled air. Adequate patient ventilation (breathing volume) is monitored by measuring the amount of carbon dioxide in exhaled air. This ensures that carbon dioxide elimination is sufficient both while the patient is connected to a ventilator and during any spontaneous breathing. When the patient receives supplementary oxygen via an oxygen mask, the instructions concerning the speed of oxygen flow must be followed to

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9 For example, situations in which respiration management and inserting a breathing tube are more difficult than usual for anatomical reasons or due to swelling.

10 Finnish Society of Anaesthesiologists. Finanest 4/2019. https://say.fi/finnanest/finnanest-1-2019 and Finanest 1/2017. (Only available in Finnish) https://say.fi/finnanest/finnanest-1-2017

achieve both the target oxygen concentration in inhaled air and adequate elimination of carbon dioxide in exhaled air.

The sufficiency of blood circulation is ensured by ECG monitoring and repeated blood pressure measurements. Blood pressure may also be measured directly from the artery in high-risk procedures or if the patient is unstable. Cuff pressure measurement is usually sufficient for low-risk procedures. The patient's core body temperature is also measured during longer periods of anaesthesia. If it is important for the patient to be immobile during a procedure under general anaesthesia, a neuromuscular blocking agent can be administered for this purpose. An adequate medication response should be confirmed with a quantitative peripheral nerve stimulator[11]. The same device is also needed to assess the recovery of neuromuscular transmission.

According to the recommendations of the Finnish Society of Anaesthesiologists, measuring the adequacy of anaesthesia is necessary to prevent accidental awareness and avoid unnecessarily deep anaesthesia. The adequacy of anaesthesia is traditionally monitored by observing the clinical status. The adequacy of anaesthesia is currently assessed using key values calculated from the electroencephalogram (EEG), such as entropy[12] or bispectral index[13]. Monitoring of a patient's vital signs involves continuous observation of the above factors and the use of audible alarms in the monitoring equipment. It is particularly important to set an audible alarm to indicate if a patient's spontaneous breathing is depressed or if the respiratory rate of a patient on a ventilator falls below the set limit. Observation of a decrease in oxygen concentration in inhaled air must also be confirmed with an audible alarm. Prior to administering anaesthesia, an anaesthesiologist assesses the patient's fitness for anaesthesia. A preliminary information form is used to map risk information and familiarise the anaesthesiologist with previous patient record information. The risks associated with anaesthesia should always be compared to the medical indication for the planned procedure or examination.

Deep sedations and general anaesthesia can be safely implemented outside operating rooms, but this requires adequate readiness as described above of both staff and equipment.

2.1.3 MRI and anaesthesia services at the private medical centre

The private medical centre offered both MRI and anaesthesia services to its clients. It has provided MRI services since 2022. The MRI room was equipped for MRI imaging. There were no medical devices intended for monitoring a patient's vital signs in the MRI room. The control room had general instructions for actions in an emergency situation. Some of the radiographers working at the medical centre had training related to resuscitation situations, but the radiographers involved in treating the person during this incident had not received refresher training.

The private medical centre provided anaesthesia services so that one anaesthesiologist was working at the medical centre under their own company name (see 2.4). That person also served as the head of anaesthesia at the medical centre.

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[11] A quantitative peripheral nerve stimulator is a device that produces a controlled, measurable and adjustable electrical stimulus in the peripheral nervous system with the aim of assessing the functional status of the nerve.

[12] Entropy is an indicator used in data processing and signal analysis to assess the complexity of electrical activity in the brain.

[13] Bispectral index is an EEG-based multimodal measurement that analyses the bispectral interactions in an electroencephalogram. It is commonly used to assess the depth of anaesthesia.

The medical centre had a surgical unit with three operating rooms and a recovery room. As a general rule, anaesthesia activities were only performed in the operating rooms. Procedures involving anaesthesia were only performed occasionally in the recovery room.

The medical centre was responsible for all medical devices and medicines related to administering anaesthesia. The nurse anaesthetists were medical centre employees.

Oxygen was stored on the lower floor of the facility. In the medical centre, oxygen was available from a wall tap in the operating rooms and in the recovery room. In other facilities, a separate oxygen bottle that was stored in the recovery room had to be brought in. The selection included 3-litre oxygen bottles suitable for use in the MRI room.

2.1.4 Facilities and equipment at the private medical centre

The private medical centre had a surgical ward with patient waiting rooms and facilities for overnight observation. The ward had three operating rooms for day surgery. Recovery rooms for adult and paediatric patients were located in the immediate vicinity.

Procedures requiring anaesthesia were usually performed in the surgical ward facilities, which were equipped for this purpose. The anaesthesia related to the imaging procedure currently under investigation was performed in an imaging room that was not equipped for anaesthesia. The space did not have MRI-compatible monitoring equipment, a resuscitation cart, defibrillator, medicines suitable for resuscitation or oxygen delivery devices located on the wall. During the procedure, a portable oxygen bottle compatible with magnetic resonance imaging was brought into the imaging room.

When viewed from the main entrance, the MRI room was located opposite the surgical ward. The resuscitation cart and bag valve mask needed to resuscitate the patient were retrieved from the recovery room, which was approximately 51 metres away and located behind three closed doors. The defibrillator was retrieved from the lobby near the main entrance, which was approximately 24 metres away from the imaging rooms and behind one closed door.

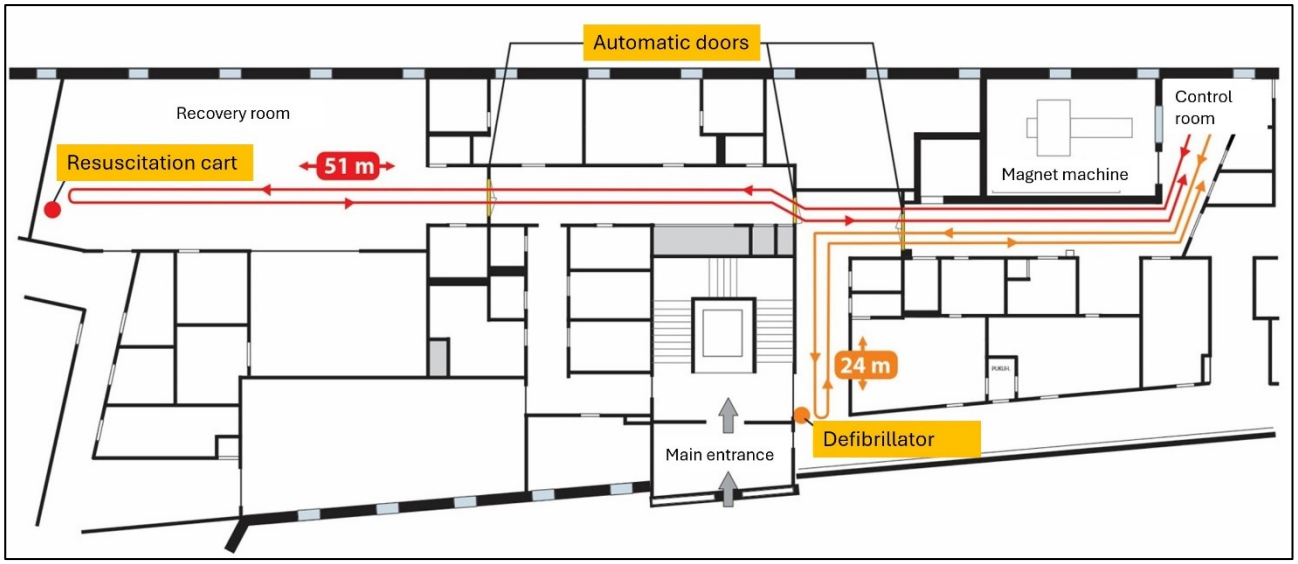

Image 2. Location of the MRI room and its control room in the medical centre building. Resuscitation was performed on the floor of the control room, and the arrow lines show the distances and locations from which the equipment was taken for resuscitation purposes. (Image: SIAF)

The imaging facilities had spaces for MRI, mammography, ultrasound examinations, and X-ray imaging. The areas reserved for MRI included separate facilities for receiving patients, waiting for the procedure and changing rooms, as well as the imaging control room and MRI scanner room related to the actual imaging.

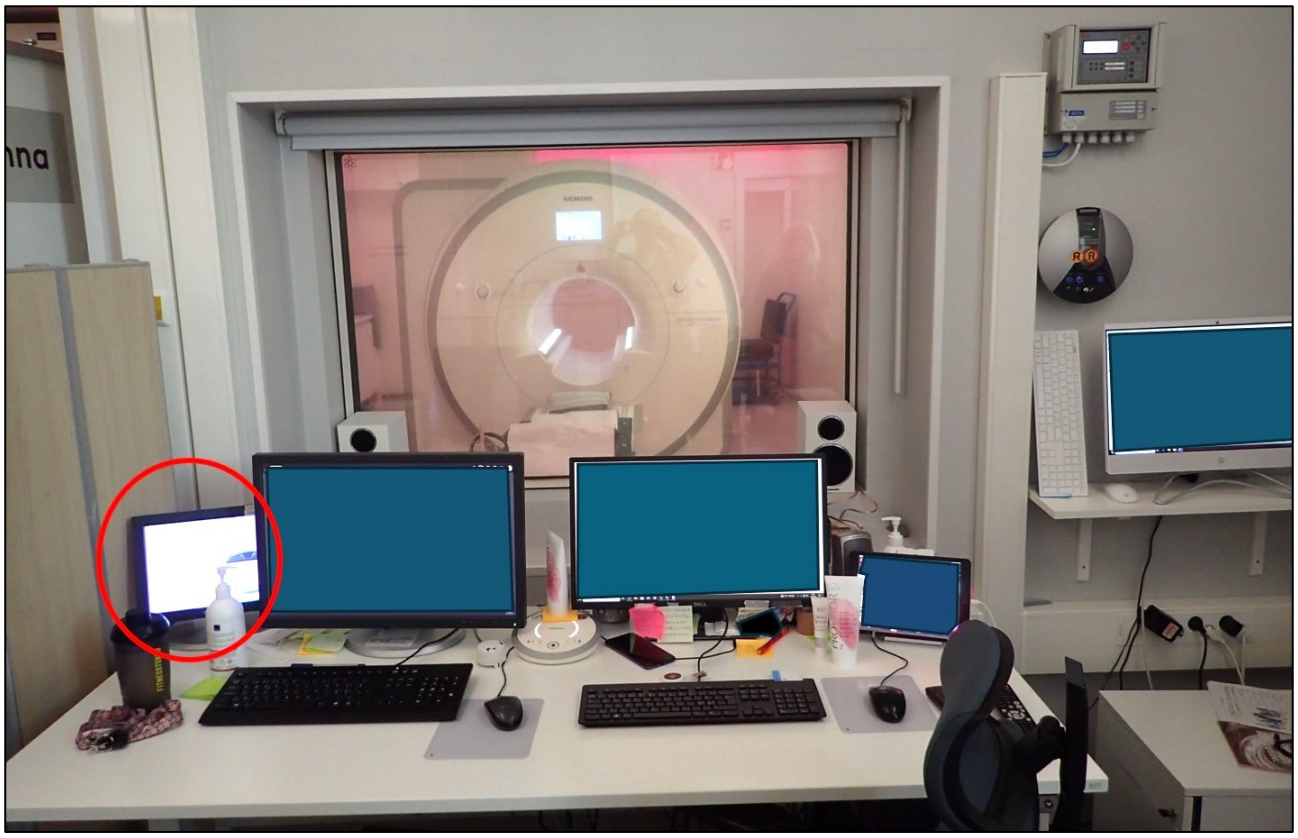

Image 3. The photo shows the control and monitoring point for the MRI scanner. The red circle on the left marks the monitoring camera screen at one end of the MRI scanner. The screens shown in the photo have been blurred. (Photo: SIAF)

A monitoring camera mounted on the back wall of the MRI room was focused on the patient's head area. The camera did not have a recording function. There was an MRI-compatible[14] wheelchair available for patient transfer.

2.2 Conditions

The event occurred in the afternoon of a normal weekday. The radiographers' shift had just changed. Two radiographers were present during the MRI, which was normal procedure. An anaesthesiologist was handling the patient's anaesthesia. The anaesthesiologist brought an oxygen bottle, medications and other equipment from the operating room to the imaging unit. Anaesthesia was administered in the imaging facilities of the medical centre less than once a year, so this was not a normal situation. The anaesthesiologist did not normally work in the imaging unit.

[14] The MRI scanner uses strong magnets that can cause a hazardous situation with metal objects. Metal objects must not be brought into the examination room. The magnets can also interfere with metal implants or devices, such as pacemakers. Some implants may be MRI-compatible.

The health care unit had ordinary medical devices intended for monitoring basic vital signs that could not be taken into the MRI room because of the strong magnetic field.

The equipment for performing resuscitation was brought from another room on the same floor after the patient's lifelessness was detected. Two separate trips were made to get the bag valve mask and resuscitation cart from the operating room's recovery room. The defibrillator was taken from the entrance lobby of the medical centre.

2.3 Recorded data

The investigation utilised the Emergency Response Centre's emergency call recordings and the recordings of radio communications in the public authority network (Virve). The information in these recordings was used to assess the content of emergency calls, alerts issued by the Emergency Response Centre and the progress of rescue operations.

The investigation also had access to magnetic image recordings from the patient's imaging data. For comparison purposes, the investigation used the MRI images of six anonymous patients obtained using the same MRI scanner and the same scanning protocol. The exact times and durations of the MRI sequences were examined in the patient's MRI images. The patient's MRI images were compared to the reference data with the aim of detecting when the patient became lifeless based on the end of motion artefact[15] and vascular imaging findings.

2.4 Persons and organisations associated with the accident and safety management

2.4.1 Persons involved

The person who died in the incident was middle-aged and had not been diagnosed with any long-term illnesses requiring regular medication. They had previously been anaesthetised at KUH, for example, in connection with several procedures in the pharynx area. The person suffered from claustrophobia, which had caused the failure of two previous imaging attempts. By the date of the incident, the person had been experiencing pain for about one month. The pain had a negative impact on their quality of life. The person was taking long-acting anti-inflammatory painkillers and a muscle relaxant medication and using cold therapy for the pain.

Physician A was an anaesthesiologist. The anaesthesiologist was responsible for sedation of the person being scanned. They had worked as a specialist for more than 20 years in the public and private sector. The anaesthesiologist had been a private service provider offering anaesthesia services under their own company name for more than 10 years. The anaesthesiologist had worked at Pihlajalinna[16] for just under 10 years.

The anaesthesiologist who treated the person also served as the head of anaesthesia at the medical centre.

Physician B was an orthopaedic and traumatology specialist, who also served as the head physician at the medical centre.

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15 Motion artefact in radiology refers to an error or disturbance in an imaging examination caused by the patient's movement during imaging. This is not a real finding in the patient's body, but a distortion in the image caused, for example, by unintended movement such as breathing, heart cycles, and blood circulation in the body.

16 The Pihlajalinna Group acquired Pohjola Hospital in 2022. As a result of the merger, all Pohjola Hospital employees were transferred to Pihlajalinna.

Radiographer A was the service manager for imaging at the service unit. They had graduated as a radiographer nearly 20 years earlier. They began working for Pihlajalinna in 2021 and moved to the Leväsentie unit a few years later. They were responsible for patient care, instructed the patient before imaging and established intravenous access.

Radiographer B had a wide range of specialised work experience related to imaging. They had graduated as a radiographer nearly 30 years earlier and worked as a radiographer in the public and private sector. They had been working at Pihlajalinna for just under 10 years. Radiographer B handled the imaging and did not see the patient before the procedure.

Radiographer C had graduated as a radiographer nearly 40 years earlier. This person did not participate in the imaging and was about to go home after their shift.

2.4.2 Health care service providers involved

The **Wellbeing Services County of North Savo** is responsible for organising health care, social welfare and rescue services in its region. Its task is to ensure high-quality, equal and cost-effective services for residents at all stages of life. The wellbeing services county is responsible for basic healthcare, specialised healthcare, social services, services for older persons and persons with disabilities, mental health and substance abuse services and child welfare. The task of **pre-hospital emergency medical services** (pre-hospital emergency medical care and rescue services) is to provide urgent care when a person suddenly falls ill or suffers an injury and, if necessary, transport the patient to an emergency healthcare unit. An important part of pre-hospital emergency medical care involves assessing the patient's need for treatment and directing the patient to the correct place of care. Pre-hospital emergency medical care plans the organisation of care with a unit that provides urgent and emergency care services, ensuring that the patient's needs are met and treatment is carried out in a timely manner.

Pihlajalinna Oyj provides healthcare services to private customers, occupational healthcare customers, insurance companies and as an outsourced service to wellbeing services counties. The healthcare services include reception services, diagnostics, hospital and surgical activities and occupational healthcare services. Services are provided at in-person appointments and, where applicable, remotely. Pihlajalinna has been operating since 2001 and provides services in all wellbeing services counties and Helsinki.

In addition to its own staff, Pihlajalinna utilises external service providers, which includes purchasing services from an anaesthesia service provider. The anaesthesiologist involved in the case operated as a service provider of anaesthesia services at Pihlajalinna. The company providing anaesthesia services and Pihlajalinna Oy have a written agreement that specifies the content, schedules, compensation and responsibilities related to the service.

Pihlajalinna Kuopio Leväsentie is a full-service medical centre and hospital. The medical centre's imaging unit has equipment for X-ray and ultrasound examinations, as well as a 3T MRI scanner[17] for magnetic resonance imaging.

The company that provided the anaesthesia services was established in 2014. It provides anaesthesia services to medical centres and private hospitals as well as for procedures performed outside the hospital, such as anaesthesia for dental care. The company employed two people in 2025.

[17] The MRI scanner was a 3 Tesla machine supplied by Siemens. (Siemens Magnetom Skyra 3T).

Kuopio University Hospital (KUH) provides comprehensive specialised health care services for the residents of the Wellbeing Services County of North Savo. It also ensures the availability of university hospital-level services throughout the co-operation area of Eastern Finland, covering not only the Wellbeing Services County of North Savo but also those of South Savo, Central Finland and North Karelia. According to normal practice, the person was brought to KUH for treatment and follow-up after prehospital emergency medical care.

2.4.3 Safety management at the private medical centre

Safety management at the private medical centre can be roughly divided into the organisation's operating principles, roles and responsibilities, device safety and technical prerequisites, as well as staff competence and training.

Operating principles of the organisation

The private medical centre uses a **preliminary information form for an MRI**. The purpose of the form is to ensure that the patient does not have any MRI-related risk factors, such as metal objects in their body. The preliminary information form only applies to the safety of MRI scanning and does not address the risks associated with anaesthesia.

The private medical centre also has a **preliminary information form for the operating room**. This differs from the preliminary information form for an MRI in terms of its content. It assesses the patient's general condition, possible anaesthesia risks and special needs related to the surgery. The preliminary information form for the operating room was not used in the case under investigation. The person booking the treatment usually sends the patient a preliminary information form to be completed in advance.

All Pihlajalinna Group units use a patient information register. It can only be accessed by employees of Pihlajalinna or its partners who have the right to process the information in question based on their duties. The information needed to organise the care, such as the patient's personal data, medical history, examination and treatment results, patient records and other care-related documents, are entered in the patient information register. The patient's risk factors related to performing a planned procedure can be checked in the patient information register. A physician may also review patient information recorded by other organisations in the Kanta register maintained by Kela if the patient has provided their consent for this in the Kanta service. Kanta contains patient information produced by different service providers.

The patient had received fasting instructions prior to the preparation and sedation activities, which they had to follow between the doctor's appointment in the morning and the MRI procedure starting at 15:30. When asked, the patient said that they had followed the fasting instructions before the examination started. Fasting before anaesthesia is important because of the risk of vomiting associated with anaesthesia.

The **service provider agreement** between Pihlajalinna Terveys Oy and the company providing anaesthesia services was signed in 2022. The service provider agreement defined the roles, tasks and responsibilities of the parties and their commitment to comply with legislation and the unit's internal practices to ensure patient safety. The agreement defined the service company's liability for damage caused to the patient by the service company and that of the physician employed by the service company. The agreement also assigned responsibility to the service provider for complying with generally accepted medical principles and the ethical and other guidelines issued by the Finnish Medical Association or other parties. According to the agreement, Pihlajalinna provided the service company with a conventionally equipped reception space/surgical facility with ordinary assisting staff.

The Group-level **self-supervision programme and self-supervision plan** of Pihlajalinna Terveys Oy and its subsidiaries were updated in summer 2024. Self-supervision means that the service provider systematically monitors, assesses and develops its own activities to ensure that they meet the requirements of legislation, official regulations and quality and safety requirements. Each health care unit prepares a self-supervision plan for this purpose. At the time of the event, the Pihlajalinna location did not have a unit-specific self-supervision plan. Instead, it was using the general Group-level plan. A self-supervision programme refers to an entity consisting of a self-supervision plan and its practical implementation.

Pharmacotherapy plans were in use at the Pihlajalinna location and in its imaging unit. They are used to ensure the safe implementation, development and supervision of pharmacotherapy and to provide orientation for the professionals implementing pharmacotherapy. The plans define the objectives, responsibilities and roles in pharmacotherapy as well as practices for the procurement, storage, distribution, administration, recording and monitoring of medicines. The plan also describes the staff's competence requirements, training and procedures for handling deviations. The pharmacotherapy plan for imaging states that the physician is responsible for the patient's pharmacotherapy as a whole. It also states that the physician is responsible for prescribing medicines and implementing pharmacotherapy as allowed by their education, competence and orientation. According to the pharmacotherapy plan for imaging, the radiographer can administer intravenous medication and fluid therapy. The pharmacotherapy plan for imaging also states that administration of the medicine should be recorded in the radiological information system (RIS) together with the examination performed on the patient.[18]. The pharmacotherapy plan for the medical centre provides a detailed description of the measures to be taken in the event of a patient safety incident involving pharmacotherapy.

The pharmacotherapy plan for the imaging unit at the Pihlajalinna location does not contain any instructions related to procedures performed under anaesthesia. Unlike the imaging units in Oulu and Tampere, this medical centre did not have any instructions related to MRI scans performed under anaesthesia.

HaiPro[19] is used at Pihlajalinna locations. It is an electronic reporting system used to report and process incidents that put patient and client safety at risk. HaiPro has become established as a key tool in Finnish health care, and it allows personnel to report adverse events and near misses inside the organisation. The notifications are not usually transferred directly to the supervisory authority, and they are mainly used for learning and developing activities inside the unit and the organisation.

Device safety and technical prerequisites

Pihlajalinna is responsible for ensuring that the devices and equipment in use comply with the requirements for the procedures performed by private service providers working in their facilities. Pihlajalinna is responsible for device procurement, device maintenance and inspections.

Supplementary oxygen was available from wall taps in the recovery room and operating room at the Pihlajalinna location. Portable oxygen bottles are used for other procedures and imaging examinations that require oxygen in the unit. An MRI-compatible 3-litre aluminium oxygen bottle was used during the magnetic resonance imaging.

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[18] Radu RIS is an ERP system for ordering, scheduling, recording and reporting imaging examinations intended for use by healthcare professionals.

[19] Awanic, 2022. Products and services, HaiPro. Available at: www.awanic.fi. Cited on 15 September 2025.

The Pihlajalinna location is prepared for various first aid and resuscitation situations. The facilities have a semi-automatic defibrillator, a monitor/defibrillator intended for professional use, a patient transfer sheet, and a separate resuscitation cart. The semi-automatic defibrillator is located near the main entrance approximately 23 metres from the MRI unit and the resuscitation cart is beside the rear wall of the recovery room, approximately 51 metres from the MRI unit (Figure 2). The resuscitation cart contains an ECG monitor/defibrillator, resuscitation medications, a videolaryngoscope, a bag valve mask, laryngoscope blades in different sizes, and an oxygen bottle. The supplies in the imaging unit include an adrenaline injection, antihistamine, blood pressure monitor and equipment for cannulation. The MRI control room also has a call button, which can be used to call more staff from other parts of the medical centre if necessary.

After changes to the facilities made in connection with the merger, a municipal inspector performed a statutory[20] inspection of the Pihlajalinna premises[21] in 2022.

Roles and responsibilities

During an MRI performed under anaesthesia, each employee has a clear role, and each one handles their own tasks. There were three radiographers in the control room during the imaging, two of whom participated in imaging the patient. The anaesthesiologist was beside the patient in the imaging room, and they monitored the patient's vital signs and administered the anaesthetic agents.

The chief administrative physician and medical management are responsible for implementation of self-supervision at Pihlajalinna, and this is handled locally by the chief physician and the physicians working under them. The responsible radiologist at the Pihlajalinna Kuopio imaging unit was a specialist in radiology. They were also responsible for other imaging units in the same Pihlajalinna region. They were not aware of previous MRI scans performed under sedation at the Kuopio unit. The responsible radiologist was not contacted before the imaging, and only heard about the event afterwards.

The anaesthesiologist monitored the patient’s breathing based on chest movements during the imaging procedure. Between the imaging sequences, the anaesthesiologist assessed the patient’s breathing by moving to the patient’s head to check misting on the oxygen mask.

Staff competence and training

All of the persons involved in the imaging were experienced professionals in their own fields. The radiographers did not have a lot of experience with magnetic resonance imaging under anaesthesia in this unit, as these were rarely performed.

Pihlajalinna organises annual **resuscitation training**, and exercises were also organised in a targeted manner inside different procedure units. The most recent resuscitation exercise had been organised in the previous spring. Approximately 50% of the employees at the medical centre’s imaging unit had completed resuscitation and/or emergency first aid training.

2.4.4 Safety management at the company that provided the anaesthesia services

The anaesthesiologists from the private company providing anaesthesia services operate as service providers. When providing services to Pihlajalinna, they comply with the operating practices of Pihlajalinna and the valid legislation, especially with regard to client and patient

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20 152/1990. (Only available in Finnish)

21 After the 2023 wellbeing services county reform, this responsibility was transferred from the municipality to the wellbeing services county.

safety, data protection and patient documents. Although the anaesthesia service is provided through an external actor, Pihlajalinna is responsible for ensuring that the care is of high quality, safe and part of a smooth care chain. The company's pharmacotherapy plan prepared in 2017 and the agreement between the companies on health care services signed in 2022 state that when the company operates in the premises of another service provider, they will comply with the instructions valid at that location.

The self-supervision plan of the private company providing anaesthesia services was updated at the end of 2024. The company providing anaesthesia services also has a patient safety risk management plan that was prepared at the same time. That plan defines the strategies and measures for identifying, assessing and managing potential patient safety risks.

The patient safety risk management plan prepared by the company providing anaesthesia services at the end of 2024 describes how the company's employees must monitor their own activities in order to ensure that these are safe. The self-supervision plan of the company providing anaesthesia services states that careful preparation and clear operating practices ensure the safety of anaesthesia. The patient's preliminary information is reviewed, medications and allergies are confirmed, and the most suitable form of anaesthesia is discussed with the patient. Measures prior to the procedure include arranging for the availability of emergency medicines, making preparations to secure the airway and ensuring appropriate monitoring. Regular inspections of the resuscitation equipment at the facility are performed in cooperation with the responsible nurses. Generally accepted anaesthesia methods must be in use. Checklists are also used in the operating room, and the potential risk phases of the care path are discussed with the staff.

When medication is given to the patient, administration of the medicine must be double-checked by saying what is being administered out loud. The nurse confirms the medication and amount with the anaesthesiologist before administering it to the patient. The plan also states that all deviations must be recorded and communicated about openly so that the activities can be developed and patient safety assured on a continuous basis. Implementation of the pharmacotherapy plans is monitored as part of self-supervision.

The company providing anaesthesia services also employs a nurse anaesthetist who has often participated in NORA procedures performed by the anaesthesiologist. When working at locations other than Pihlajalinna medical centres, the anaesthesiologist has brought supplementary oxygen and the equipment needed to monitor vital signs.

2.4.5 The role and actions of supervisory authorities in the event

The Regional State Administrative Agency for Eastern Finland (ISAVI) received a notification of a suspected medical error from KUH on 3 January 2025. ISAVI immediately began investigating the incident and issued an oral site-specific order to suspend MRI scans performed under sedation on 3 January 2025. ISAVI contacted Valvira on the same day, and a decision made at that time stated that ISAVI would begin an assessment of the event. On the same day, ISAVI sent a request for clarification concerning the event to Pihlajalinna.

Pihlajalinna's response to the request for clarification arrived at ISAVI on 9 January 2025. On the same day, ISAVI received information about the patient's death from KUH and promptly relayed it to Valvira. In a written decision dated 15 January 2025, ISAVI ordered the suspension of sedation activities during MRI imaging at Pihlajalinna Kuopio's Leväsentie location.

ISAVI discussed the division of work related to supervision with Valvira on 15 January 2025. As a result, Valvira took responsibility for the national supervision of Pihlajalinna with regard

to MRI examinations performed under sedation. Valvira also began supervising the company providing private anaesthesia services.

ISAVI continued to monitor Pihlajalinna. As a result of the patient's death, assessment of the appropriateness of care was transferred to Valvira on 3 March 2025. On 14 April 2025, Valvira decided to deal with the supervision of MRI examinations performed under anaesthesia at Pihlajalinna Kuopio Leväsentie as a separate supervisory measure.

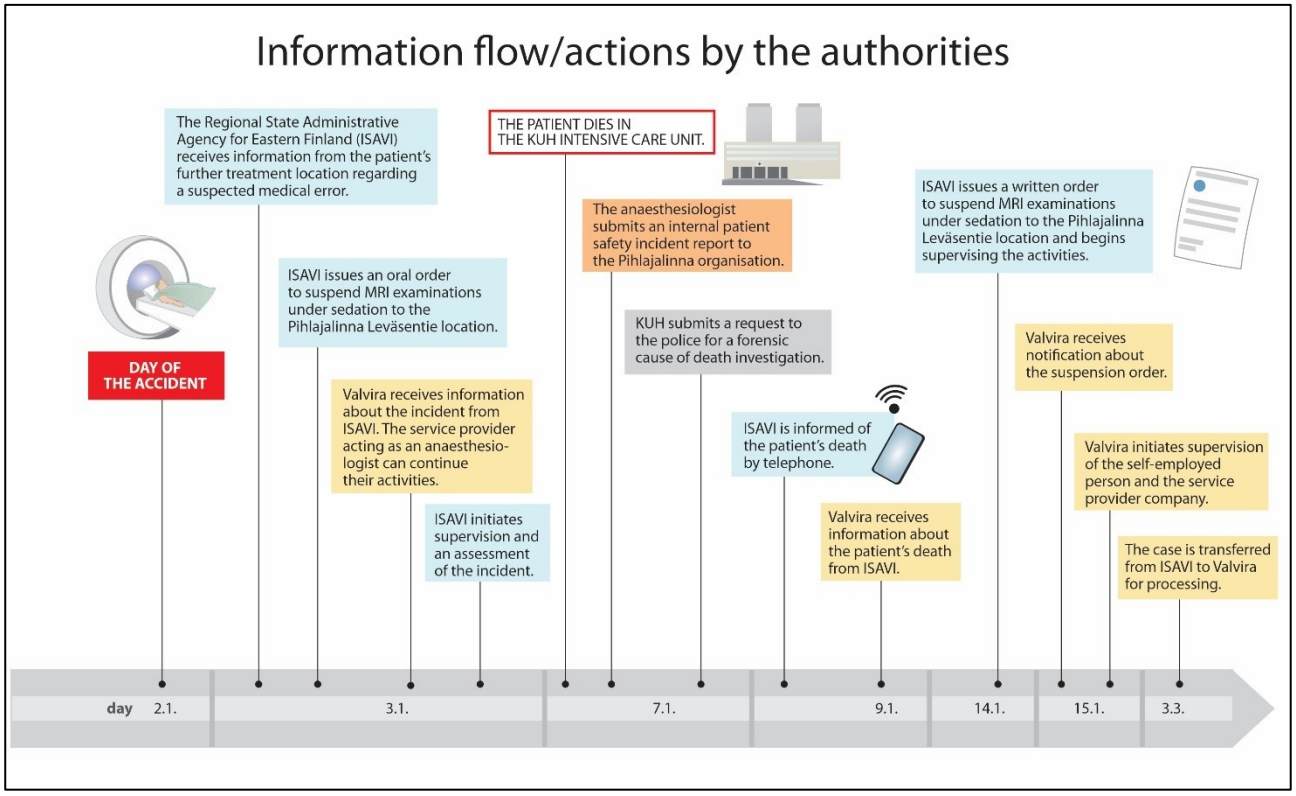

Image 4. Information flow between authorities. (Image: SIAF)

2.5 Preventive actions of authorities

The **Ministry of Social Affairs and Health (MSAH)** is responsible for preparing social and health care legislation and national policies, which also guide the activities of private medical clinics. The Ministry defines the boundary conditions for service provision, such as quality requirements and the principles of client and patient safety. The statutes and guidelines drawn up by the Ministry of Social Affairs and Health provide a framework for the activities of private service providers. Valvira and the Regional State Administrative Agencies (Finnish Supervisory Agency from 1 January 2026) are responsible for supervision, but the Ministry of Social Affairs and Health steers the activities of these authorities and develops supervision structures at the national level.

The **Finnish Institute for Health and Welfare (THL)** is a national expert and research institute that provides information to support decision-making and activities in the wellbeing services counties.

THL maintains the national Care Register (Hilmo), which collects data on social and health care services. The system is divided into three parts: specialised care, inpatient care and day surgery (Health-Hilmo), primary care and oral health care outpatient visits (Avohilmo), and

social care services (Sosiaali-Hilmo). The data is used to compile statistics and forms an extensive data repository for monitoring and developing services and their use.

The investigation examined Hilmo statistics on non-operating room anaesthesia in private health care. The statistical data was retrieved by combining selected examination and procedure codes and anaesthesia codes. It became evident that although information on private health care procedures is currently collected in the Care Register, private health care units do not record anaesthesia-related procedure codes in their notifications to the register. This meant that it was not possible to obtain statistical data on non-operating room anaesthesia procedures from Hilmo. THL issued an administrative decision in 2024 according to which health care service providers must enter all procedures that are part of HILMO data collection in the care register in a manner consistent with the public sector. This also applies to anaesthesia procedures.[22]

The National Supervisory Authority for Welfare and Health (VALVIRA) is the central agency in the administrative branch of the Ministry of Social Affairs and Health. Its duties include the nationwide supervision of the appropriateness of social and health care, early childhood education and care, the alcohol industry and environmental health care, granting permits in the administrative branch of social and health care and steering the Regional State Administrative Agencies.

In order to provide social and health care services in Finland, the service provider must be registered in the national Soteri register[23] maintained by Valvira. Registration is a prerequisite for starting service activities and involves both administrative and operational obligations.

Under the Act on the Supervision of Healthcare and Social Welfare Services[24], a service provider must apply for registration in the Soteri register before starting operations. Among other things, the service provider's registration application must include basic information on their activities, the services being provided, the responsible persons, patient insurance, and the service points of the service unit. In conjunction with registration, the service provider must indicate the date their self-supervision plan was compiled, but they do not need to actually submit the self-supervision plan to the supervisory authorities.

Prior to the introduction of the Soteri register, data on private health care service providers was maintained in the Valveri register. Valveri used a different method of classifying service sectors, which is why the service sectors in earlier data do not necessarily correspond to those used in Soteri. The data was automatically transferred from Valveri to the Soteri register and, during this register conversion, what was previously called the anaesthesia services sector became non-psychiatric specialised health care in Soteri. Other service sectors, such as specialist appointments, issuing statements in specialised health care and surgical activities, also became part of this same service sector.

The Soteri register did not collect data on the registrations of operators in the anaesthesia services sector from the beginning of 2024 until July 2025 unless the service provider separately reported this in the additional information section of the application.

In the future, the Aura classification of the Soteri register will include a sub-classification, which will make it possible to find more detailed information in the register. Development

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22 THL/5166/5.03.00/2023, updated on 22 May 2024.

23 The Soteri register (formerly Valveri) is a national register of Valvira that was introduced in 2024. It brings together data on private service providers and service units in social and health care and early childhood education and care.

24 741/2023.

work on the Soteri register was still in progress when it was introduced. Users have described the register as difficult and slow and failing to provide users with guidance.

According to the Act on the Supervision of Healthcare and Social Welfare Services, an advance inspection of large social welfare units and units that have hospital activities or activities that require the presence of an anaesthesiologist is always performed in conjunction with registration. The people performing a hospital inspection may ask to see the self-supervision plan. If two separate service providers work together to provide services, they will be assessed as separate actors in connection with the registration.

More detailed instructions are being prepared for the registration of anaesthesia activities. The facilities and equipment in a service unit that is planning to start anaesthesia activities are inspected before the activities begin. The self-supervision plan and the pharmacotherapy plan of a company providing anaesthesia services must take into account the devices and equipment available for use in the activities.

Valvira's supervisory duties include for example cases in which a medical error is suspected to have caused a patient's death or severe permanent injury[25], as well as matters that officials responsible for handling supervisory cases at the Regional State Administrative Agencies are precluded from handling[26]. Valvira is responsible for supervision measures targeting the activities of physicians and registered nurses.[27] Valvira provides nationwide guidance and supervision of healthcare professionals, while the Regional State Administrative Agencies guide and supervise the activities of healthcare professionals within their respective regions. Valvira is also responsible for handling matters of principle that are wide-ranging in terms of their scope.

Guidelines for application concerning the Act on the Supervision of Healthcare and Social Welfare Services were published in November 2023.[28] Valvira provides administrative guidance related to the supervision of social and health care in order to improve the safety of activities. The new Act on the Supervision of Healthcare and Social Welfare Services requires that a matter be transferred to supervisory authorities if the service provider is unable to handle the matter using self-supervision methods. The wellbeing services counties are also responsible for the organisation of services outsourced by a wellbeing services county and for self-supervision of those services.

Valvira strives to form a situational picture for supervisory work by obtaining information from various sources, such as the Regional State Administrative Agencies, self-supervision data, THL's information on access to treatment and dimensioning, and social welfare data. The previous supervision history of a supervision target is also reviewed in conjunction with a supervision matter. Valvira is developing a risk tool with the aim of obtaining a better situational picture from wellbeing services counties. Obtaining an adequate situational picture has been perceived as difficult in Valvira.

A social and health care monitoring programme for the government term is being prepared for Valvira's plan-based supervisory work. This will include a separate supervision programme for each year. In recent years, plan-based supervision has usually targeted large entities and focused on public service providers rather than private service providers.

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25 559/1994. 24§
26 741/2023. 32§
27 559/1994.
28 STM (VN/33652/2023) Guidelines for application concerning the Act on the Supervision of Healthcare and Social Welfare Services (Only available in Finnish)

Valvira's ex ante supervision includes the rights to practice a social and health care profession and the registration of large national companies operating in several Regional State Administrative Agency areas. Valvira is also responsible for the registration of service providers providing remote services.

Valvira carries out ex post supervision based, among other things, on notifications received, and the cases taken up for supervision typically come to its attention with a delay. The supervision involves reviewing the supervision history related to the situation and requesting access to the service providers' self-supervision plans related to the case if necessary.

Written reports are requested from the professionals involved in the case. Valvira also requests an ex post report on the self-supervision measures taken. Supervision is the same for public and private service providers. Valvira may perform inspections at social and health care units in connection with its supervision work. Valvira may also conduct an inspection without prior notification on, for example, a unit about which concerning information has been received regarding the safety of its activities.

The Regional State Administrative Agency for Eastern Finland (ISAVI) is one of six Regional State Administrative Agencies in Finland, and it is responsible for the supervision, steering and permit administration related to social and health care services in its area. ISAVI's supervisory tasks in social and health care include monitoring the quality and availability of care and services, processing complaints and notifications of a deficiency, and risk-based targeting of official supervision. A Regional State Administrative Agency may also perform inspections, provide guidance and, if necessary, intervene in the organisation or provision of services.

Self-supervision is the service provider's own, proactive and continuous supervision, which is intended to safeguard the safety, quality and equality of health care services. The purpose of self-supervision is to ensure that services meet the statutory requirements and are safe for clients and patients, and to detect and correct any deviations without delay.

Self-supervision is based on the Act on the Supervision of Healthcare and Social Welfare Services[29], section 27 of which requires the service provider to ensure that, starting on 1 January 2024, its own activities and those of subcontractors and actors providing outsourced services on its behalf meet the requirements of the Act, are appropriate in terms of client and patient safety, and are within the scope of the service provider's self-supervision. The service provider has overall responsibility for the quality and safety of the services, regardless of whether the services are provided by itself or through external actors.

The service provider must monitor the quality and appropriateness of its own activities and those of the subcontractor, as well as client and patient safety. The service provider must prepare a self-supervision plan for each service unit to ensure the quality, appropriateness and safety of daily activities and to monitor the adequacy of the personnel participating in client and patient work. The self-supervision plan covers the service provider and the services provided on its behalf in the service unit. The self-supervision plan is the key and primary tool for self-supervision. It must include a description of the reporting and learning procedure related to patient safety incidents.

The self-supervision plan must be compiled electronically and published openly in the information network or in some other way that promotes its publicity. It must be displayed in the service unit. Implementation of the plan must be monitored continuously and a report on

[29] 741/2023.

observations must be prepared every four months. Any changes made on the basis of the observations must be updated and posted publicly.

The Social Insurance Institution of Finland (KELA) is the organisation that implements social security. It is also responsible for reimbursements of medical costs for private health care services. Kela collects information on the activities of private medical centres mainly through the reimbursement system. When a patient receives treatment at a private clinic and applies for Kela reimbursement, the care information is forwarded to Kela either through the direct reimbursement procedure or as an application submitted by the patient. Based on this information, Kela compiles statistics on the use of services, costs and care practices. This information is utilised in such areas as monitoring of the service system, research and decision-making.

The investigation examined statistical data in Kela's register on non-operating room anaesthesia in private health care by combining selected examination and procedure codes and anaesthesia codes. It became apparent that medical care reimbursement for anaesthesia has not been granted since 1 January 2023, so it was not possible to obtain statistical data from Kela's register for the time of the event.

2.6 Organisations that participated in the rescue operation and their standby readiness

As outlined in the cooperation agreement, the rescue department provides emergency medical services to the Wellbeing Services County of North Savo from the rescue stations in Kuopio, Varkaus and Suonenjoki. The prehospital emergency medical care units handle an average of 30,000 emergency medical assignments each year.

A first response unit (RPS101), advanced life support ambulance (EPS222), community paramedicine unit (EPS271) and an EMS unit with a physician (EFH60) were dispatched to the Pihlajalinna Kuopio imaging unit.

The first unit arrived on the scene five minutes after the alert at 16:08:34.

2.7 Statutes, regulations and instructions

The **Act on Wellbeing Services Counties**[30] lays the foundation for a new administrative structure for social and health care and rescue services in Finland. According to the Act, wellbeing services counties are self-governing bodies governed by public law that are responsible for organising services in their region. The Act defines the duties of the wellbeing services counties, administrative structures, financial management, rights for residents to participate and relations with the state and municipalities. It also steers the activities of regional councils and cooperation with other authorities. The objective of the Act is to ensure the equality, quality and cost-effectiveness of services throughout the country.

The **Act on the Supervision of Healthcare and Social Welfare Services**[31] entered into force on 1 January 2024, and its purpose is, among other things, to ensure client and patient safety in social and health care and high-quality social and health care services.

The Ministry of Social Affairs and Health published guidelines for application of the new Act on the Supervision of Healthcare and Social Welfare Services at the end of November 2023. These entered into force on 1 January 2024. The guidelines for application provide more

30 611/2021.
31 741/2023.

specific instructions on applying the Act in practice and steer both public and private service providers to operate as required by the Act. Among other things, the Act on the Supervision of Healthcare and Social Welfare Services defines the operational prerequisites for service organisers and providers, registration obligations, implementation of self-supervision and principles of supervision by the authorities. The guidelines also address the introduction of the new Soteri service provider register and its role as a monitoring tool. The guidelines for application support the implementation of the Act and harmonise supervisory practices at the national level.

On 14 May 2025, the National Supervisory Authority for Welfare and Health Valvira published a regulation on the content, preparation and monitoring of a self-supervision plan[32], which also provides instructions on the content of the plan. The regulation entered into force on 15 May 2024. Valvira's instructions state that the plan must describe how the service provider and staff monitor and ensure the quality, appropriateness, safety of services and the adequacy of staff participating in client and patient work.

The purpose of the **Act on Organising Health Care and Social Welfare Services**[33] is to promote and maintain the well-being and health of the population and to ensure equal, interoperable and cost-effective social and health care services throughout the country.

The **Act on Health Care Professionals**[34] regulates the activities of all health care professionals in Finland, including those working in the private sector. Its purpose is to ensure the safety of patients and quality of care.

The **Act on Private Health Care**[35] stipulates how private operators can offer health care services in Finland. It also specifies what the services cover and what types of facilities, equipment and staff the service providers must have. The Act states that operations require a permit issued by the Regional State Administrative Agencies or Valvira. The aim is to ensure that private services are safe, high quality and compatible with other health care services. The Act on Private Health Care was repealed on 1 January 2024 and replaced by the Act on the Supervision of Social and Health Care[36].

The **Act on the Status and Rights of Patients**[37] safeguards the patient's status in health care. Its purpose is to ensure that every person receives quality care in an equal manner and with respect to their human dignity and right to self-determination The Act requires that the patient be provided with clear information about the care and its alternatives and that the care be implemented in mutual understanding with them.

The Ministry of Social Affairs and Health Decree on Emergency Medical Services[38] includes more specific content relating to emergency medical care and provides more details on the organisation, content and operating structures of emergency medical services in Finland.

According to the **National Client and Patient Safety Strategy and Implementation Plan (2021–2026)**[39], social and health care services must be of high quality, safe and

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32 Valvira 1/2024: Regulation on the content, preparation and monitoring of a unit-specific self-supervision plan for a social and health care provider. (Only available in Finnish)
33 612/2021.
34 559/1994.
35 152/1990.
36 741/2023
37 785/1992.
38 585/2017.
39 Publications of the Ministry of Social Affairs and Health 2022:2.

appropriately delivered. The activities must be based on evidence and good clinical

and policy practices. The strategy also emphasises the safe use of diagnostic and care devices and adequate training. Service providers must also aim for real-time reporting with regard to monitoring the most serious adverse events and safety incidents and critical quality data.

According to the strategy, everyone involved in social and health care services should subscribe to the promotion of client and patient safety as one of their values. The organisational and management structures of the service providers should be built to strengthen safety work. The strategy states that the principles of risk management must be understood at all organisational levels. Every working unit must be aware of how the processes of processing, reporting and learning from serious safety incidents work and who is responsible for them.

According to the **ethical guidelines of the Finnish Medical Association**, decisions concerning patient care and examinations must be ethically acceptable and medically justified. Physicians are obliged to apply generally accepted and experience-based, justified procedures in their professional activities in accordance with their education. Physicians must also strive to continuously supplement their training.[40]

The **Finnish Society of Anaesthesiologists**[41] has issued a recommendation on the organisation of anaesthesia activities[42] and on the monitoring of anaesthesia[43]. In practice, these two recommendations describe the safety standard that is the goal in Finnish anaesthesia activities.

According to the recommendation of the Finnish Society of Anaesthesiologists, deep sedation or general anaesthesia performed outside the operating room requires the presence of an anaesthesia team. An anaesthesia team refers to an anaesthesiologist and a nurse anaesthetist. The requirements for the anaesthesia team, the anaesthesia environment and the equipment do not differ in any way from the resources in operating rooms. The information on an anaesthesia procedure must be recorded in the anaesthesia record in the same way as it is in operating rooms. The purpose of the anaesthesia report section compiled during the procedure is to support anaesthesiology care and serve as a document for self-supervision and official supervision.

According to the recommendation, the patient's oxygenation during general anaesthesia must be monitored by measuring adequate oxygen concentration in inhaled air and the amount of carbon dioxide in exhaled air. Current recommendations also include the use of a high-speed oxygen sensor to measure the percentage of oxygen in exhaled air. Adequate oxygenation at the tissue level is also monitored by continuously measuring peripheral oxygen saturation with a pulse oximeter. The parameters being monitored always include at least blood pressure and heart rhythm.

Second Victim protocol[44] refers to an operating model that supports social and health care professionals who have become the second victims after a safety incident – such as a

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40 Ethics manual for physicians 2021. (Only available in Finnish.)

41 The Finnish Society of Anaesthesiologists (SAY) is an organisation for anaesthesiology and intensive care specialist physicians. https://say.fi/

42 Finnish Society of Anaesthesiologists. Finanest 4/2019. (Only available in Finnish) https://say.fi/finnanest/finnanest-1-2019

43 Finnish Society of Anaesthesiologists. Finanest 1/2017. (Only available in Finnish) https://say.fi/finnanest/finnanest-1-2017

44 Ikonen et al. (2023) How to act when you suspect patient safety is threatened. (Only available in Finnish) Lääketieteellinen Aikakauskirja Duodecim 2023;139(19):1554–62.

medication error, complication or other adverse event – and experience psychological or emotional strain as a result of the incident. The aim of the protocol is to provide support to the professionals involved in the event so that they can process it and continue their work.

2.8 Other information

2.8.1 Current state of practices involving NORA

The Safety Investigation Authority conducted an anonymous Webropol survey, which assessed NORA practices in private health care. The survey targeted professionals working with procedures and imaging examinations that require anaesthesia in Finland. A total of 111 responses were received to the Webropol survey: 37% from anaesthetists, 24% from dentists, 34% from radiographers and 5% from other health care employees.

A total of 75% of the respondents reported that they perform examinations or procedures requiring anaesthesia outside the operating room. The majority of the procedures requiring anaesthesia involved imaging examinations and/or procedures performed in the imaging unit, as well as dental procedures. Nearly a half of the respondents stated that the reason for using anaesthesia in a procedure may also be attributable to the patient. In practice, this means that patient groups who have difficulties remaining still during imaging (e.g. children, patients with fear) are strongly represented in terms of the need for anaesthesia during imaging.

The most common anaesthesia types were light and moderate sedation, which was utilised in approximately two thirds of the units. Deep sedation was clearly performed less often, in about one third of the units. It is significant that nearly one half of the respondents reported the use of general anaesthesia outside the operating room. The highest number of short-term anaesthesia procedures and the lowest number of general anaesthesia procedures were used in X-ray imaging.

When examining the differences between the professional groups, it became apparent that anaesthesiologists reported the use of more comprehensive and systematic practices in almost all cases in comparison to other respondent groups. In their responses, general anaesthesia is considerably more common, monitoring is systematic, and a preliminary information form for anaesthesia and the patient's suitability criteria are almost always in use. The responses were less clear for the other groups, which is probably due to the fact that the anaesthesiologist is usually responsible for completing the preliminary information form and checking the suitability criteria when deciding on the patient's suitability for anaesthesia.

The data indicates that units where anaesthesia is administered in connection with imaging examinations often report that they also administer anaesthesia for reasons attributable to the client or patient. This is understandable, as magnetic resonance imaging in particular often involves the need for anaesthesia: a successful examination requires complete patient immobility in a confined and noisy environment. A majority of the respondents did not know the medical status classification[45] of the space being used for anaesthesia, while one quarter reported that the classification was G1, which means that a power outage does not expose the patient to any risk.

[45] Medical location classifications (0, 1 and 2) describe the level of technical requirements for health care facilities according to how critical and dependent on electrical devices the procedures being performed on the patient are.

The responses were less clear for the other groups, which is probably due to the fact that the anaesthesiologist is usually responsible for completing the preliminary information form and checking the suitability criteria when deciding on the patient's suitability for anaesthesia.

Nearly all respondents report using pulse oximetry during light and moderate sedation and short-term anaesthesia procedures. Approximately one half of the respondents (75% of anaesthesiologists) reported that they also use ECG and blood pressure measurement. Monitoring was usually more extensive in general anaesthesia, and anaesthesiologists reported using a wide range of different devices. These included pulse oximetry, ECG, blood pressure, measurement of carbon dioxide in exhaled air and often also measurement of anaesthesia depth and muscle relaxation. The responses also showed a strong correlation between the monitoring devices, which indicates that if a unit reports using one monitoring method, it often uses others as well.

The responses showed that the use of respiratory support and management devices was clearly more common among anaesthesiologists than in other respondent groups. This is explained by the fact that anaesthesiologists are responsible for the patient's breathing while other employees focus on their own tasks. The most common devices were nasal cannula, an oxygen mask and bag valve mask, which were used in almost all of their units. Supraglottic[46] airway devices and intubation were also mentioned often and there was a strong link between them: if the unit had readiness for intubation, supraglottic devices were almost always available as well. It should be noted that this question did not distinguish between the depth of the anaesthesia being administered, which may affect the responses and explain some of the differences observed between the units.

Nearly all the anaesthesiologists reported that they record the amount of medication administered, the time of administration, oxygen saturation, heart rate, and blood pressure during the procedure.

Almost all the respondents had received training in CPR and the use of a defibrillator. Just over half of the respondents received regular training in airway management and treating an allergic reaction. On the other hand, training related to exceptional situations was considerably less common. For example, only some of the respondents had received training related to managing a difficult airway, treating an anaesthetic poisoning or dealing with power outages or fire during an anaesthesia procedure.

Based on the responses from all respondents, near misses related to anaesthesia activities during which a dangerous situation is noticed in time and the patient suffers no harm occur approximately twice a year. According to anaesthesiologists, this occurs approximately four times in three years. Adverse events and patient safety incidents resulting in harm to the patient were reported to occur approximately 0.5 times in three years in all responses and twice as often according to anaesthesiologists.

According to the respondents, common practices after a patient safety incident include reviewing the incidents with the staff and submitting a HaiPro notification. Some units reported performing a root cause analysis of the patient safety incident.

When respondents were asked about incidents encountered in connection with NORA, they described situations involving impairment of oxygenation in a patient who was breathing spontaneously due to respiratory paralysis or challenges related to keeping the airway open.

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[46] A supraglottic airway device is placed in the pharynx above the larynx and used to secure the airway during anaesthesia or in emergency situations.

Incidents had also been caused by uncertain vascular access, a decrease in blood pressure, a malfunction of a monitoring screen, a poor or disturbed signal when monitoring vital signs, and a malfunction in the delivery of supplementary oxygen. The fact that the patient had not followed the fasting instructions or the unit had incorrect information about the medication being taken by the patient had also caused incidents.

The measures taken to improve the safety of NORA included careful patient selection, the use of checklists, anticipation of incidents with the team in advance, appropriate monitoring and care equipment, and comprehensive equipment for handling emergency situations. Training and simulation exercises for dealing with resuscitation and emergency situations were also mentioned. The responses proposed that a patient in poor condition should be anaesthetised in the recovery room. The responses also mentioned national quality criteria and minimum standards for both monitoring of vital functions and for staff. The respondents hoped that post-anaesthesia monitoring would always be performed in a recovery-level unit.

2.8.2 Supplementary investigation of the patient's MRI images using reference data

Based on the MRI findings, the injury to the shoulder was minor in severity. The investigation included a supplementary investigation using the MRI data of the patient involved in the event and six reference procedures in which the same examination had been performed using the same MRI scanner and scan protocol. The images (6) from the reference examination were anonymised. The aim was to use the data to determine the motion artefact[47] during imaging caused by the blood circulation and respiratory movements of the patient who was the focus of the investigation and to determine when lifelessness began based on the loss of motion artefact. The scan protocol used for the patient's MRI is presented in Table 2.

Table 2. The MRI scan protocol for the patient involved in the event.

Sequence no.	Sequence name	Sequence duration
1	Localizer	24 s
2	PD TSE fs Sag	3 min 46 s
3	PD TSE fs Cor	3 min 16 s
4	PD TSE fs Tra	2 min 39 s
5	T1 TSE Cor	3 min 2 s
6	T2 TSE Sag	2 min 44 s

Sequence 1 is the localizer image sequence, which is a quick sequence that produces images from three different directions. The radiographer performing the imaging uses the localizer sequence as the basis for positioning the slices for other sequences. The localizer image sequence was not included in the submitted material, as localizer sequences are usually not sent to the image archive after their acquisition.

[47] Motion artefact is a visual distortion or disturbance in MRI imaging that is caused by physical movement during an examination. Motion artefact can manifest itself in MRI images as blurring, dual images, or repetition of structures.

Table 3. Time stamps for the patient's MRI image reconstruction.

Sequence no.	Sequence name	Time of image sequence completion	Time between completion of images
2	PD TSE fs Sag	15:36:23	
3	PD TSE fs Cor	15:39:32	(2–3) 3 min 9 s
4	PD TSE fs Tra	15:43:24	(3–4) 3 min 52 s
5	T1 TSE Cor	15:46:30	(4–5) 3 min 6 s
6	T2 TSE Sag	15:49:38	(5–6) 3 min 8 s

When comparing the data in Table 1 and Table 2, it becomes apparent that the breaks between the image sequences 2–6 were very short. The overall progress of the imaging was even quicker than the corresponding imaging sessions in the reference data. The scan protocol did not include any technology to assist in slice positioning. In normal conditions, the time between the image sequences primarily depends on the time used by the radiographer to position the slices and possible communication with the patient. In comparison to the reference data, the examination being investigated progressed even faster than average.

In general, minimal motion artefact was observed in the imaging sequences. This was expected since the imaging took place under anaesthesia. However, artefacts caused by respiratory movements and blood circulation were expected. Efforts were made to minimise their visibility in the images by using the "Flow Compensation" option to reduce flow artefacts in the imaging sequences (2, 3 and 4) and by placing a saturation band over the lung area. The purpose of the saturation band is to minimise the signal from outside the imaging area to reduce artefacts caused by respiratory movements. Despite the use of such methods, these artefacts cannot be completely eliminated and they are visible in both the patient's images and the reference data.

Table 4. Assessment of the patient's motion artefacts by image sequence for the case under investigation.

Sequence	Observations of motion artefacts
2. PD FS Sag	Motion artefacts (respiratory movement) observed in the sequence.
3. PD FS Cor	Some motion artefact visible in the images.
4. PD FS Ax	Some motion artefact visible in the images.
5. T1 Cor	Slight motion artefacts.
6. T2 Sag	No motion artefacts observed. It is likely that there was no blood circulation or respiratory movements during the sequence imaging, or they ended very soon after the start of the sequence.

The supplementary investigation demonstrated that the patient's imaging went well and there were no significant pauses between the image sequences. Motion artefacts from

respiratory movements and/or blood circulation were still visible in the axial imaging sequence (sequence no. 4, PD TSE FS Tra). However, motion artefacts were no longer observed in the last imaging sequence (sequence no. 6, T2 TSE Sag). The T1 TSE Cor sequence, which only lasted for just over 3 minutes, was performed between these two sequences, and assessment of motion artefacts in that sequence proved to be very difficult.

Based on the supplementary investigation, the patient's blood circulation and respiratory movement stopped during a time window between the end of sequence 4 and the beginning of sequence 6. According to the clock on the MRI scanner's image reconstruction unit[48], this was a period of approximately 6 minutes between 15:41 and 15:47.

2.8.3 Supplementary investigation of medications administered to the patient during anaesthesia

The investigation included a supplementary investigation that used the Tivatrainer program to simulate the concentrations of propofol in the patient's blood[49].

The patient initially received approximately 150 mg of propofol intravenously, and an additional dose of approximately 50 mg after the localizer sequence. The other additional doses were approximately 20-30 mg at a time. The total dose was 600 mg of propofol during approximately 20 minutes of anaesthesia. The patient also received 2-3 mg of midazolam intravenously at the start and additional later doses of 1 mg. The total dose was 5 mg of midazolam. At the end of the procedure, the patient received 0.5 mg of flumazenil intravenously to reverse the effect of the midazolam.

Tivatrainer was used to simulate the patient's blood propofol concentrations. Tivatrainer is a very good predictor of blood propofol concentrations when the patient's age, weight and gender are known, and there is sufficient information about the propofol dosing. The pharmacokinetic model for propofol developed by Eleveld was used in the simulation[50]. Based on the simulation, it is possible to reliably estimate that the patient's blood propofol concentrations were between 3.5 and 7 mg/l most of the time.

General anaesthesia requires a blood propofol concentration of 3.5-5 mg/l when the patient does not also receive opioids or drugs of the benzodiazepine group. However, the patient in the case under investigation also received midazolam in addition to the propofol. Midazolam is known to increase sensitivity to propofol by 15-30%[51]. Based on the simulation, it can be reliably estimated that the medications administered to the patient resulted in a situation equivalent to general anaesthesia rather than the lighter sedation.

2.8.4 International recommendations

The European Board of Anaesthesiology (EBA) published a recommendation in 2018 on the minimum standards for monitoring a patient during and after anaesthesia. Monitoring reduces risks because it gives early warning of a patient's deteriorating condition and makes it possible to intervene in the situation in time. According to the recommendation, certain parameters should be monitored whenever anaesthesia is administered to a patient, regardless of the form or duration of the anaesthesia. The standard is the same in general

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48 The time shown by the image reconstruction unit does not necessarily correspond to the general network time.

49 Tivatrainer is a drug analysis simulator used to assess the concentrations of intravenous drugs. www.tivatrainer.com

50 Eleveld DJ, Proost JH, Cortínez LI, Absalom AR & Struys MM (2014) A general purpose pharmacokinetic model for propofol. Anesthesia & analgesia, 118(6), 1221-1237. https://doi.org/10.1213/ane.0000000000000165

51 McClune S, McKay AC, Wright PM, Patterson CC, Clarke RS. Synergistic interaction between midazolam and propofol. Br J Anaesth 1992;69:240-245. https://doi.org/10.1093/bja/69.3.240

anaesthesia, regional and local anaesthesia, and sedation as well as in all different environments where anaesthesia is performed. According to the recommendation, patient monitoring should always use at least pulse oximetry, blood pressure measurement, cardiac rhythm monitoring (ECG) and, in cases of moderate or deep sedation, measurement of carbon dioxide in exhaled air. It is essential to continuously monitor the concentration of oxygen administered to the patient during anaesthesia, and this parameter should be equipped with an audible alarm. All alarms must have safe limits set for the patient in question and audible alarms must be enabled. After the anaesthesia, the same parameters must be monitored until the patient has fully recovered from the anaesthesia.

The European Society of Anaesthesiology and the European Board of Anaesthesiology (Hinkelbein et al. 2018) have published guidelines on sedation and pain management in adult patients in connection with examinations or procedures. In addition to the above-mentioned minimum monitoring standards, using electroencephalography (EEG) to monitor the depth of anaesthesia should be considered when propofol is used as an anaesthetic agent. Post-anaesthesia monitoring must continue for at least 30 minutes in a recovery-level unit.

The following requirements are set for the safe **implementation of sedation**: The patient's airway must be critically evaluated before anaesthesia. The patient must be informed of the risks of planned anaesthesia in advance. The best and safest medication and anaesthesia implementation method must be selected for each patient. The patient must fast for a sufficient period prior to the anaesthesia. The location where the anaesthesia is carried out must meet the requirements, and the person responsible for the anaesthesia must be able to concentrate only on the anaesthesia. The same person cannot be responsible for both anaesthesia and performing the procedure. The person administering the anaesthesia must have sufficient competence related to the medicines being used and their properties. The person monitoring the anaesthesia must be able to identify and manage any problems and complications that may arise during anaesthesia. They must have sufficient competence in monitoring vital signs and interpreting the information. If the anaesthesia is supervised by someone other than an anaesthesiologist (e.g. a nurse anaesthetist), the anaesthesiologist must be close by and immediately available if necessary. Equipment for difficult airways[52] and resuscitation equipment must be immediately accessible. Staff must have resuscitation and cannulation skills.

2.8.5 Patient safety during magnetic resonance imaging

The number of MRI examinations in Finland is increasing annually, and approximately 400,000 were performed in 2018[53]. Patient injuries during MRI examinations are very rare, and are only reported in conjunction with 0.35% of all MRI examinations. Fatal accidents are extremely rare, occurring approximately once in every 15 million imaging examinations[54].

The most common patient safety incidents in connection with MRI scans are related to the use of contrast medium or an inadequate MRI referral. The most common types of other patient safety incidents are burns and metal objects or implants unexpectedly being pulled into the magnetic field. Burns can occur in situations where the radio frequency field causes

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[52] Equipment for a difficult airway equipment are special airway management devices used in situations where a breathing tube cannot be inserted into the trachea with conventional equipment.

[53] Ruonala, V (2019) Number of radiological examinations in Finland in 2018. STUK-B 242, Helsinki 2019

[54] Tarkiainen T (2022) Adverse events in medical imaging in Finland. (Abstract in English)

University of Oulu Graduate School; University of Oulu, Faculty of Medicine Acta Univ. Oul. D 1688, 2022, https://urn.fi/URN:ISBN:9789526234199

overheating of tissues or materials that are touching the patient. Metal or an implant in the patient's body may also cause a serious MRI incident.

Another type of patient safety incident involves a situation in which the strong magnetic field pulls a metal object that is within the scope of the magnetic field towards the device with great force. Reported situations include items such as patient transport and mobility devices, gas cylinders, tools and coins or keys left in pockets being pulled into the magnetic field[5556].

A total of 162 notices of injury were filed in Finland between 1991 and 2017. Six of those concerned accidents or injuries, and 42 were related to infection or complications. Health care professionals reported a total of 776 MRI-related patient safety incidents between 2007 and 2017[57].

[55] Delfino, J. G., Krainak, D. M., Flesher, S. A., & Miller, D. L. (2019) MRI-related FDA adverse event reports: A 10-yr review. Medical Physics. https://doi.org/10.1002/mp.13768

[56] Hudson D, Jones AP, A 3-year review of MRI safety incidents within a UK independent sector provider of diagnostic services, *BJR|Open*, Volume 1, Issue 1, 1 November 2019, bjro.20180006, https://doi.org/10.1259/bjro.20180006

[57] Awanic (2022) Products and services, HaiPro. Available at: www.awanic.fi. Cited on 15 July 2025.

3 ANALYSIS

To analyse the event, the Accimap[58] method developed further by the Safety Investigation Authority was used. The analysis text is structured based on an Accimap diagram prepared in the course of the investigation. At the bottom of the diagram, the accident is described as a chain of events. Factors emerging in the background of the chain of events are analysed in the diagram at different levels.

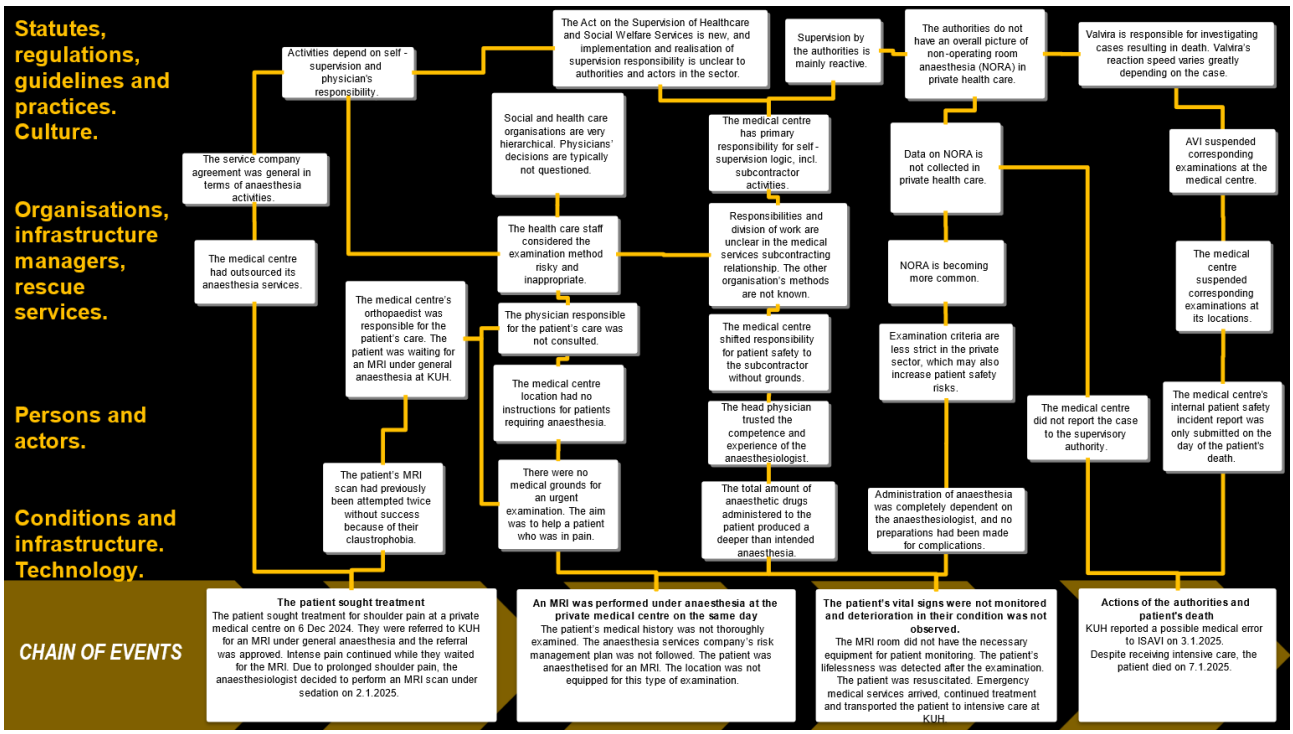

Image 5. ACCIMAP analysis diagram T2025-01. (Image: SIAF)

3.1 Analysis of the event

The patient sought treatment at a private health care unit due to shoulder pain caused by an accident in December 2024. The patient suffered from claustrophobia, which is why an MRI was performed on the patient under anaesthesia at a private medical centre on 2 January 2025. During the examination, the patient became lifeless but was resuscitated. Despite receiving intensive care, the patient died at KUH on 7 January 2025.

3.1.1 The patient sought treatment

After experiencing continued intense pain, the patient visited the same unit three times for appointments with different orthopaedic and traumatology specialists. An MRI had been attempted twice, but the scan was unsuccessful due to the patient's claustrophobia.

The patient was referred to KUH for an MRI under general anaesthesia and the referral had been approved. The severe pain continued while the patient was waiting for the examination. On the day of the event, the patient had an ultrasound examination of the shoulder. Due to the intense pain, the patient went to the medical centre reception after the examination. A receptionist then called an anaesthesiologist to assess the patient's pain situation.

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58 Rasmussen, J. & Svedung, I. (2000) *Proactive Risk Management in a Dynamic Society*. Karlstad, Sweden: Swedish Rescue Services Agency.

Based on a discussion with the patient and with consideration to the pain situation, the anaesthesiologist decided to perform an MRI scan under sedation on 2 January 2025 even though an orthopaedist at the medical centre was responsible for treating the patient. The medical centre's anaesthesiologist services had been outsourced to an external company.

3.1.2 An MRI was performed under anaesthesia at the private medical centre on the same day

Although the private medical centre had access to the Kanta service and patient records, this background information was not fully assessed. The wellbeing services county's previous patient records contained additional information indicating that the patient had an increased risk of their airway not remaining open during anaesthesia performed with spontaneous breathing[59] .

The preliminary information form for the operating room was not used at all in the patient's pre-anaesthesia assessment because the patient did not go through the normal process in which the person booking the procedure sends the preliminary information form to the patient in advance. The objective of the preliminary information form is to review the risk factors that require consideration in terms of anaesthesia in a checklist-type manner. Without the preliminary information form, questions are based only on memory and important risk factors may not be addressed at all.

The service provider's preliminary information form contained a question about health information, based on which the plan to implement anaesthesia in the unit in question might possibly have been cancelled. Each health care service provider that uses preliminary information forms in Finland typically has its own version of the form, and the content and style of the questions vary. In addition to diagnoses, a comprehensive way of asking questions in a preliminary information form is to find out whether the person has any symptoms that increase the risks of anaesthesia. This approach is more likely to reveal risk factors.

A decision was made to perform an MRI scan under anaesthesia without consulting the patient's attending physician, who had referred the patient for imaging at KUH. The anaesthesiologist who made the imaging decision was not responsible for the patient's care, and thus did not have the authority to change or bypass the care plan drawn up by the physician treating the patient. Social and health care organisations are very hierarchical, and decisions made by physicians are not usually questioned. The anaesthesiologist had not worked with the imaging employees very often, and the anaesthesiologist also operated through their own company. This meant that no open discussion culture or operating methods had developed between these parties in which decisions and operating methods could be questioned and commented on more openly.

A number of private medical practitioners were working under the chief physician of the medical centre, and their activities were based on their own assessment of safe operating methods. There was no systematic monitoring of their activities even though they were working under another organisation. The responsibility for any injury caused to a patient lies with the physician who provided the care, but also with the organisation where the care was administered. Although contractual documents between the medical centre and the company

[59] The patient breathes on their own without mechanical ventilation devices.

providing anaesthesia services clearly defined the responsibilities and operating principles, their interpretation and practical implementation were not unambiguous in day-to-day operations. Patients also often do not know which organisation employs the person caring for them and who is responsible for the care.

Under an agreement between the companies, the private medical centre had transferred the responsibility for patient safety to the company providing anaesthesia services. This was the case even though the Act on the Supervision of Healthcare and Social Welfare Services states that the service provider – the private medical centre – has primary responsibility for the activities of subcontractors.

The responsibilities and division of labour in the subcontracting relationship were unclear, and the medical centre had not supervised the safety of the subcontractor's activities. The operating methods of the other organisation were not known and they were not subject to any self-supervision monitoring.

The Act on the Supervision of Healthcare and Social Welfare Services is new, and its application in private health care service chains is still not established. Implementation of The Act on the Supervision of Healthcare and Social Welfare Services in practise is partly unclear for both the authorities and operators. Supervision by the authorities is mainly reactive in nature: shortcomings are usually only identified after a deviation or incident.

When performing medical examinations and procedures, a risk assessment must always be carried out concerning the benefits and possible adverse effects. Imaging is a diagnostic tool rather than a procedure that directly alleviates pain. There were no medical grounds for performing it urgently on a patient whose life was not at risk in a unit where it could not be performed safely.

No instructions for performing imaging under anaesthesia had been compiled for the medical centre imaging unit. The medical centre's anaesthesia services had been outsourced to a subcontractor who had a risk management plan in place to improve patient safety. However, the risk management plan was not observed.

The intent was to perform the imaging under moderate sedation, in which case the patient breathes on their own and is unresponsive to speech but reacts to a strong stimulus. The aim was to ensure that the patient was immobile. However, based on the total amount of medication administered to the patient, significantly more anaesthetic agent was administered than would have been required for sedation-level anaesthesia. This led to a situation equivalent to general anaesthesia, the safe implementation of which would have required airway and breathing management.

The patient's response to medicinal substances is always individual, and it is not possible to safely achieve a suitable sedation level for all patients, in which the patient would be completely immobile while simultaneously maintaining a trouble-free airway and breathing. Setting the oxygen flow in the oxygen mask at a lower level than recommended also contributed to deterioration of the patient's condition in this situation. Excessively low oxygen flow reduces the elimination of carbon dioxide in exhaled air and exposes the patient to harmful accumulation of carbon dioxide in the body. The oxygen concentration in inhaled air produced as a result of lower oxygen flow than recommended was also probably too low for the patient in relation to the situation and subjected the patient to hypoxia.

3.1.3 The patient's vital signs were not monitored and deterioration in their condition was not observed

The patient's MRI was performed in the medical centre's imaging unit in accordance with a plan made on the same day. The anaesthesiologist made a decision to perform the MRI at the medical centre because the date of the appointment for an MRI examination at KUH had not been confirmed. The patient was under the impression that they would have to wait a long time for the examination. The patient's pain was not under control.

The MRI room did not have any of the monitoring devices needed to measure the patient's basic vital signs (respiration, circulation, carbon dioxide concentration in exhaled air). According to the recommendations, the monitoring used when performing deep sedation should be the same as that used in general anaesthesia. The monitoring requirement is also the same regardless of where the anaesthesia is being administered.

There was no backup or emergency plan for possible anaesthesia-related complications. The times of administration or amounts of anaesthetic agents administered were not recorded in the patient information. There was no agreement concerning the performance of MRI examinations under anaesthesia at the private medical centre. Group-level guidelines concerning this existed for the Oulu and Tampere locations, both of which had the required monitoring equipment and instructions for imaging performed under anaesthesia. However, not all people working in the Kuopio imaging unit were aware of the Group-level guidelines.

The same anaesthesiologist had previously performed similar anaesthesia procedures at the private medical centre even though, according to the personnel, this involved a clear patient safety risk. Although imaging was rarely performed under anaesthesia, the imaging unit staff were concerned about doing it. In this case, deterioration in the patient's condition was not observed early enough and the patient became lifeless during the imaging procedure.

The implementation of anaesthesia was dependent solely on the anaesthesiologist, as the other employees participating in the examination were radiographers by education and did not have special expertise in the tasks of a nurse anaesthetist. Resuscitation training sessions had been organised in the imaging unit, but only 50% of the staff had participated in them, and the sessions were not organised on a regular basis. The training sessions had dealt with basic life support situations, and they did not provide instruction on how to manage exceptional situations.

The imaging unit was not prepared for a patient becoming lifeless during imaging. The anaesthesiologist did not bring any equipment to handle an emergency situation. The imaging unit was only prepared for an emergency caused by an allergic reaction. The bag valve mask used to assist the patient's breathing had to be retrieved from the operating room's recovery room, which was located more than 50 metres from the imaging unit. Similarly, the semi-automated defibrillator and the resuscitation cart had to be retrieved from outside the imaging unit and they were not compatible with the MRI room.

It was difficult to move the large and lifeless patient from the MRI scanner table because there was no transfer sheet under the patient. The control room also had no patient bed, and this had to be retrieved from the recovery room. The delay in starting ACLS, delay in transferring the patient, and the need to retrieve resuscitation equipment from other locations had a negative impact on the patient's chances of survival.

The criteria for access to an examination are less strict in private health care units than in public health care. This leads to increased patient safety risks. There was no urgent reason for imaging in the case under investigation.

NORA is becoming more common, but information on its use in private health care is not collected in any official register. No party or supervisory authority has an overall picture of non-operating room anaesthesia in private health care. The information is fragmented or not available at all, for example, in THL's HILMO register, Valvira's Soteri register, or the Social Insurance Institution of Finland registers.

3.1.4 Actions of the authorities and the patient's death

A suspicion of a medical error arose at KUH, and it notified ISAVI of a possible medical error already on 3 January 2025. ISAVI reacted to the situation by issuing an oral order (and later a written one) to suspend MRI scans performed under sedation at the private medical centre. ISAVI also contacted Valvira on the same day and, by joint decision, ISAVI continued to investigate the case. This included sending a request for clarification to the medical centre. Despite receiving intensive care, the patient died on 7 January 2025.

The medical centre did not immediately prepare an internal patient safety incident report. The medical centre did not submit a report to the authority, because ISAVI's contact made it clear that the matter was already progressing through official routes. The medical centre voluntarily suspended corresponding examinations at all of its locations in Finland. The medical centre believed that the MRI in question should not have been performed under sedation at the Kuopio location without the appropriate equipment.

After receiving the medical centre's response to its request for clarification, ISAVI issued a written decision on the suspension of sedation activities during MRI imaging at Pihlajalinna's Kuopio location.

ISAVI forwarded the suspension decision to Valvira. ISAVI discussed the division of work related to supervision with Valvira on 15 January 2025. According to legislation, Valvira is the organisation responsible for investigating cases that result in death. Valvira's reaction time may vary greatly depending on the case and the flow of information. As a result of these discussions, Valvira assumed responsibility for the national supervision of Pihlajalinna in connection with magnetic examinations performed under sedation. In addition, Valvira took responsibility for supervising the company that provided the private anaesthesia services and for assessing the appropriateness of patient care. The transfer of the entire case from ISAVI to Valvira for supervision was confirmed on 20 February 2025.

Valvira decided on 14 April 2025 to designate the supervision of MRI examinations performed under anaesthesia at Pihlajalinna Kuopio Leväsentie as a separate supervision case.

The scope of Valvira's supervision includes cases in which a medical error is suspected to have caused a patient's death or severe permanent injury. In the case under investigation, the supervisory authorities performed supervisory work and exercised authority, each based on the statutes applicable to them. They worked together to the extent needed to proceed with the case. The fact that the patient died while the processing of a possible medical error was still in progress at ISAVI posed a challenge to cooperation in the case. After the patient's death, the case should have been transferred directly to Valvira.

4 CONCLUSIONS

The conclusions deal with the causes of the accident or incident. The cause refers to the different background factors of the accident and the direct and indirect elements that had a bearing on it.

1. Pihlajalinna's self-supervision plan and risk management were inadequate. Self-supervision was only carried out at the top level in the Group, and the special features of the activities at different locations were not taken into account. The parties responsible for self-supervision did not have sufficient special expertise or tools for assessing the safety of anaesthesia activities.

   Conclusion: *Self-supervision requires competence that covers the entire range of activities and continuous risk assessment, documentation and monitoring. There are no national safety criteria for NORA activities that could be utilised in self-supervision.*

2. The agreement between Pihlajalinna and the company providing anaesthesia services was general in terms of its specification of responsibilities and roles. The Act on the Supervision of Healthcare and Social Welfare Services is new and its application was based on interpretation by each operator.

   Conclusion: *Trust in professional expertise and ethics is emphasised when providing health services. Systematic client and patient safety assurance and risk management will fail without a clear agreement on roles and responsibilities.*

3. The anaesthesiologist deviated from the national recommendations concerning the safe administration of NORA. They failed to comply with their own company's risk management plan. The anaesthesiologist did not thoroughly examine the patient's medical history or use the preliminary information form for the operating room to assess anaesthesia risks.

   Conclusion: *The national recommendations for monitoring a patient during anaesthesia are not binding. In addition, the national recommendations do not specify an unambiguous minimum standard for monitoring, which may lead to risky practices at different locations.*

4. The private medical centre provided anaesthesiologist services, the safe delivery of which would have required medical devices that complied with the recommendation, but this equipment had not been acquired.

   Conclusion: *In private health care, a medical device may not always be acquired if there is an expectation that it will only be used rarely.*

5. The goal during the sedation performed in connection with the MRI was patient immobility, but the amount of anaesthetic agent administered was high enough to bring about a situation equivalent to general anaesthesia. Oxygen flow in the oxygen mask was too low and this also had a negative impact on the patient's condition. This resulted in loss of the patient's airway, respiratory depression and lifelessness. The patient's deteriorating condition was not noticed in time due to the lack of a monitor.

   Conclusion: *When performing anaesthesia without appropriate monitoring, it may not be possible to notice deterioration of the patient's condition in time. A lack of appropriate monitoring increases the likelihood of serious client and patient safety risks.*

6. Preparations had not been made for deterioration of the patient's condition during the MRI procedure and for handling the emergency situation. After the patient's lifelessness had been detected, the required resuscitation equipment had to be retrieved from other facilities. The start of ACLS was also delayed because the patient had to be moved to another room without appropriate transfer equipment.

   Conclusion: *The medical centre had not prepared appropriately for emergencies. A delay in initiating the required emergency treatment procedures may be life-threatening for a patient.*

7. The supervisory authorities do not have information about NORA activities in private health care, as detailed information on the procedures is not reported to the authorities. Commensurate information is not available in any register.

   Conclusion: *No comprehensive and up-to-date national information is available on NORA procedures, which makes it difficult for supervisory authorities to form an overall picture of the quality, safety and compliance of services. This lack of information reduces the systematic nature, risk-based nature and impact of supervision.*

8. The physician's decision to perform an MRI scan under anaesthesia without appropriate monitoring was not questioned in a manner that would have prevented performance of the examination. The other staff did not have access to any instructions or criteria that they could have referred to in the situation.

   Conclusion**:** *There is a high threshold for health care employees to question the decision of an employee who is above them in the hierarchy or employed by a different organisation, especially if there are no clear written guidelines or criteria available in the situation.*

9. The authority supervising social and health care has not received sufficient guidance from the Ministry of Social Affairs and Health on interpreting the Act on the Supervision of Healthcare and Social Welfare Services in supervisory work. Valvira has carried out supervisory work without comprehensive instructions on how the Act on the Supervision of Healthcare and Social Welfare Services should be implemented in practice.

   Conclusion: *Interpretation of the Act on the Supervision of Healthcare and Social Welfare Services has been challenging for supervisory authorities, which is why service providers have not received sufficient guidance concerning how to apply the Act in self-supervision and practical activities.*

5 SAFETY RECOMMENDATIONS

5.1 Developing self-supervision

Sufficient competence and understanding of the importance of self-supervision are key prerequisites for ensuring client and patient safety. However, self-supervision practices in social and health care vary, which reduces the consistency of safety and risk management.

There is a contradiction between the legislative requirements related to self-supervision and practical implementation. The self-supervision plan does not always provide sufficient concrete guidance for implementing safety in practical activities. In connection with self-supervision, it is important to ensure that the operating units have adequate instructions for all activities. In particular, the self-supervision plan must provide a detailed description of safety-critical services, the risks associated with them and restrictions on the scope of activities.

An inadequate self-supervision plan reduces the effectiveness of self-supervision and may result in failure to identify safety risks or react to them in time. Insufficient self-supervision increases the likelihood of serious client and patient safety risks.

Clarifying the importance and implementation of self-supervision and strengthening the related competence can promote the objectives of self-supervision, its appropriate implementation and the development of safety management in social and health care.

The Safety Investigation Authority recommends that

> *The Ministry of Social Affairs and Health, in cooperation with the Finnish Supervisory Agency, ensure the development of self-supervision in a way that provides clear and uniform instructions for the practical implementation and evaluation of self-supervision. [2026-S4]*

The practical implementation of the recommendation should involve cooperation with, among others, the Finnish Centre for Client and Patient Safety.

5.2 Specifying safe implementation of NORA

There are no uniform national guidelines or unambiguous minimum requirements for the implementation of NORA activities, even though they have become more common in different environments. This leads to varying practices and client and patient safety risks.

Clear definitions and uniform guidelines support safe operation, consistency and the competence of different professional groups in units with different operating environments.

The Safety Investigation Authority recommends that

The Ministry of Social Affairs and Health ensure that national minimum requirements and safe implementation methods are specified for NORA activities. [2026-S5]

When implementing the recommendation, it is advisable to make extensive use of different expert bodies of social and health care, such as the Finnish Medical Society Duodecim's Current Care Guidelines, the Nursing Research Foundation's Clinical Practice Guidelines, the competence of the Finnish Centre for Client and Patient Safety, and the Finnish Society of Anaesthesiologists.

5.3 Strengthening data collection on procedures being performed in private social and health care

There is no summarised information available in Finland concerning NORA activities in private health care, as detailed information on the measures is not reported to the authorities. This makes it more difficult for supervisory authorities to form an overall picture of the quantity, quality, safety and consistency of services.

A lack of information weakens the systematic nature, risk-based approach and effectiveness of the authority's steering and supervision work. Targeting actions to promote the quality and safety of services is challenging if an overall picture is not available.

The Safety Investigation Authority recommends that

THL develop systematic data collection concerning private health care procedures in order to provide a comprehensive picture of them that meets the needs of different authorities. [2026-S6]

The HILMO register also produces data on private social and health care services, but the extent of the data and obligations concerning data collection currently vary. It is also important to develop clearer recording instructions for service providers.

5.4 Actions taken

After the event, the **private medical centre** began to update its self-supervision plan. It also initiated immediate actions to improve safety at the Group level, which resulted in the termination of NORA at all Group locations. After the event, the Group's MRI units also began using a transfer sheet placed under the patient in all MRI examinations in case of unexpected situations requiring the patient's transfer to another location.

The Finnish Institute for Health and Welfare updated its administrative decision on the notification obligation concerning care notifications in health care in September 2025. A new method for delivering data to wellbeing services counties has been added to the data disclosure practices. The transition period for new data delivery methods was simultaneously extended until 1 January 2028 for reporting parties that already submit Hilmo data.

The Finnish Society of Anaesthesiologists published a "Pre-operative assessment" recommendation in November 2025.[60] The aim of the recommendation is to harmonise and develop the pre-operative assessment of patients, maintain and increase patient safety at the population level, promote the rational and evidence-based use of health care resources, and increase cooperation between different actors in the evaluation process.

In September 2025, the **Finnish Institute for Health and Welfare** (THL) issued a new administrative decision concerning the obligation to disclose care register data, replacing the decision issued in 2024. The 2024 administrative decision had already required private healthcare providers to submit their care notification data in accordance with the HILMO reporting guidelines. The new decision issued in 2025 updated the earlier decision in certain respects but did not change the obligation of private healthcare providers to disclose their data. The purpose of these decisions is to ensure consistent and comprehensive reporting of care notification data across the entire healthcare sector.[61]

During the investigation, on 1 October 2025, the **Government Decree** (888/2025) on Certain Surgical Procedures and Medical Interventions entered into force. The Decree lays down more detailed provisions, among other things, on procedures performed under anaesthesia outside hospital settings. Under the Decree, certain matters must be agreed upon in procurement contracts concluded with private service providers.

The Decree applies to wellbeing services counties, the City of Helsinki, and the HUS Group. It also applies to procurements made by wellbeing services counties, the City of Helsinki, and the HUS Group from private service providers. MRI examinations performed under anaesthesia would fall within the scope of the Decree if they were organised as in-house services or procured by a wellbeing services county, the City of Helsinki, or the HUS Group.

In autumn 2025, the Ministry of Social Affairs and Health, together with the Finnish Institute for Health and Welfare (THL), launched an update of the national criteria for access to non-urgent care under section 7 of the Health Care Act as part of its information guidance activities. The update of the uniform criteria for care is being carried out in cooperation with the medical specialties and specialty associations of the wellbeing services counties. In this context, the Ministry of Social Affairs and Health will take into account, as appropriate, the findings of the Safety Investigation Authority.

60 Finnish Society of Anaesthesiologists (2025) Pre-operative assessment. (Only available in Finnish) Cited on 6 November 2025 SAY_Leikkausta_edeltavan_arvioinnin_suositus_10_2025.pdf

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Investigation material

1) On-site investigation photographs, measurements and other material
2) Hearings
3) Client and patient documents
4) Imaging recordings and reference data
5) Emergency Response Centre Agency recordings
6) Ministry of Social Affairs and Health data
7) THL data
8) Valvira data
9) Kela data
10) Finnish Society of Anaesthesiologists data
11) Regional State Administrative Agency for Eastern Finland data
12) Private service provider's documents

SUMMARY OF COMMENTS RECEIVED ON THE DRAFT INVESTIGATION REPORT

The draft investigation report was circulated for commenting to the Ministry of Social Affairs and Health, the Finnish Institute for Health and Welfare, the National Supervisory Authority for Welfare and Health Valvira, the Regional State Administrative Agency for Eastern Finland, Pihlajalinna, the private limited liability company providing anaesthesia services, and the family of the victim.

In accordance with the Safety Investigation Act of Finland, comments given by private individuals are not published.

Statements were received from the Ministry of Social Affairs and Health, the Finnish Institute for Health and Welfare, the National Supervisory Authority for Welfare and Health Valvira, the Regional State Administrative Agency for Eastern Finland, and Pihlajalinna.

According to the statement of the **Ministry of Social Affairs and Health**, the report provides a good description of the course of the event and the parties involved in it as well as the related conditions, analysis and conclusions. The report highlights several deficiencies identified in the activities, especially in connection with non-operating room anaesthesia and general deficiencies in steering and supervision related to activities in the private sector.

The Ministry of Social Affairs and Health points out that it can influence patient safety by means of steering related to norms, resources and information. As a general rule, the ministry does not issue individual operating instructions for different health care functions and the ministry states that it considers this to be impossible in practice. In its statement, the ministry points out that Finnish health care is also built on the expertise of professionals and, for example, the instructions and care recommendations in different specialities. The investigation report also highlighted this aspect.

The Ministry of Social Affairs and Health states that it considers that the legislation is quite up to date and focuses on ensuring patient safety, quality and competence in many ways. This is particularly the case in public health care, but also in private health care to a certain extent. However, the regulations governing private health care are less detailed than those that apply to public health care. The ministry emphasises that there are general regulations to ensure competence, quality and patient safety. Furthermore, the Act on the Supervision of Healthcare and Social Welfare Services contains provisions on, for example, appropriate premises and the appropriate competence and professional skills for the staff. The Act on the Supervision of Healthcare and Social Welfare Services applies to both private and public health care. The Health Care Act and the Act on Wellbeing Services Counties only apply to public health care.

Regarding the recommendations that apply to the Ministry of Social Affairs and Health, the ministry states that a reform of the Act on the Supervision of Healthcare and Social Welfare Services is currently in progress. A need for changes in the regulation of self-supervision arose in conjunction with this process. It will also be possible to supplement and renew Valvira's earlier self-supervision guidelines after the Finnish Supervisory Agency has begun operating.

With regard to the recommendation on non-operating room anaesthesia activities, the ministry states that in practice the care and action recommendations described in the recommendation are usually prepared independently by speciality associations in Finland. These recommendations can also be followed in private health care. The ministry does not issue any binding practical care recommendations or regulations that are specific to medical

specialities. In its statement, the ministry confirms that it will inform the Finnish Society of Anaesthesiologists about this recommendation.

According to the statement of the **Finnish Institute for Health and Welfare (THL)**, the recommendation to develop systematic data collection concerning private health care procedures presented in the draft investigation report is justified and corresponds to THL's own view. THL points out that the obligation to submit data to the Hilmo register has been in force since 2024 and that the new administrative decision issued in 2025 did not change this obligation.

In its statement, the **Finnish Supervisory Authority for Welfare and Health (Valvira)** states that Valvira is a national agency whose tasks cover the entire country. The statement emphasises that Valvira is responsible for the guidance and supervision of health care professionals as described in the Act on Health Care Professionals. Valvira further specifies that ex-post supervision may also be based on information other than the notifications that are received. When dealing with a supervision matter, Valvira always obtains sufficient information to resolve the matter.

In terms of official supervision, Valvira states that cooperation with the Regional State Administrative Agency was close and good and it was appropriate that organisational supervision was initially handled by the Regional State Administrative Agency. Valvira states that the Ministry of Social Affairs and Health has issued guidelines for application concerning the supervision of social and health care services and points out that the supervisory authority always has extensive discretion in supervisory work and when interpreting the law. Valvira's view concerning the ninth conclusion differs from that presented in the investigation report. Valvira considers it important to maintain a clear role for the supervisory authority.

According to the statement of the **Regional State Administrative Agency for Eastern Finland (ISAVI)**, the draft investigation report contains several inaccuracies related to legislation, the competence of authorities and terminology that require correction. ISAVI notes that part of the text incorrectly refers to the Act on the Supervision of Healthcare and Social Welfare Services which entered into force later, even though the Act on Private Health Care was applicable at the time of the incident and that the current legislation no longer contains the concept of a self-employed entrepreneur in health care. ISAVI also emphasises that the draft investigation report lacks a description of the information flow between the authorities after the patient's death and clarifications on the division of competence between Valvira and the Regional State Administrative Agencies. With regard to the conclusions, ISAVI considers that the statement on inadequate guidance concerning application of the Act on the Supervision of Healthcare and Social Welfare Services is not justified, as comprehensive guidance on self-supervision has been provided in the regulations and at training events.

According to the statement of **Pihlajalinna**, the services provided at Pihlajalinna's Oulu Hiironen and Tampere Koskiklinikka units include magnetic resonance imaging performed under sedation and the required equipment and instructions exist at those locations. According to Pihlajalinna, these units have experienced no deviations that endanger patient safety during MRI scans performed under sedation. Pihlajalinna made a decision to suspend imaging performed under sedation in both units on 15 January 2025, and they were completely discontinued on 6 November 2025. Pihlajalinna states that the range of services offered at the Kuopio unit did not include MRI imaging performed under sedation, which is why these examinations were not addressed in the pharmacotherapy plan and no instructions existed for them.

Pihlajalinna states that according to the Act on the Supervision of Healthcare and Social Welfare Services, the self-supervision plan is prepared by the service unit, and the private health services units at the medical centres use the same self-supervision procedures. Pihlajalinna states that its practices are the same as those utilised at other large private health service providers. The chief administrative physician and medical director are responsible for self-supervision procedures. Responsibility for implementing self-supervision at the unit lies with the physician responsible for the unit's health services and the unit's other management. Every professional working in private health care services is obliged to follow the self-supervision plan in their own activities. Pihlajalinna notes that if the instructions had been followed, an MRI scan under sedation would never have been performed on the patient in the Kuopio unit. Furthermore, Pihlajalinna points out that the imaging unit of the medical centre had no instructions for MRI scans performed under anaesthesia because these services were not offered at the Kuopio medical centre. Pihlajalinna states that since the patient's pain situation was not under control, discussion should have focused on improving the effectiveness of pain medication while waiting for an examination at Kuopio University Hospital.

In its statement, Pihlajalinna also presents some clarifications regarding the professional titles used in the investigation report and comments on the conclusions of the investigation. With reference to the first conclusion, Pihlajalinna states that the private health services at its medical centres comply with the common procedures for self-supervision, quality management and risk management described in the self-supervision plan for private health services. Pihlajalinna mentions that it has been developing the process for investigating serious patient safety incidents during 2025. Regarding the second conclusion, Pihlajalinna feels that the agreement between Pihlajalinna and the company providing anaesthesia services was clear in terms of how it specified responsibilities and roles. In the agreement, the service provider commits to comply with generally accepted medical principles, ethical guidelines issued by the Finnish Medical Association or another party, other instructions and the operating practices agreed upon at the service point, to ensure that the business fulfils its statutory obligations, to take responsibility for patient injuries caused by the company, and to maintain and develop the professional skills required for the activities in question. With reference to the third conclusion, Pihlajalinna states that the service provider committed to comply with generally accepted medical principles in the agreement. However, in this case the service provider deviated from the national recommendations concerning the safe implementation of non-operating room anaesthesia and failed to comply with the risk management plan of their own company.

With reference to the fourth and fifth conclusions, Pihlajalinna states that MRI examinations performed under sedation were not part of the range of services offered at the Kuopio unit. This is the reason why a monitoring device and other equipment suitable for the MRI examination had not been purchased. Regarding the sixth conclusion, Pihlajalinna mentions that anaesthesia activities at the Kuopio unit are performed in operating rooms and recovery rooms. The equipment needed to provide advanced cardiac life support (ACLS) is stored in the surgical unit. With reference to the eighth conclusion, Pihlajalinna states that the attending physician was not aware of the intention to deviate from the care plan they had prepared for the patient. This plan involved referring the patient for an imaging examination at Kuopio University Hospital. The range of services at the Kuopio unit did not include MRI examinations performed under sedation, so the radiographers did not have experience performing examinations under sedation. This may be why they did not have the readiness to sufficiently question the anaesthesiologist's decision. Pihlajalinna emphasises that the

organisation always encourages employees to report any deficiencies to supervisors and responsible persons and to submit a HaiPro notification concerning anything that jeopardises patient safety.

Finally, with reference to the ninth conclusion, Pihlajalinna states that clear and consistent guidance for service providers concerning application of the Act on the Supervision of Healthcare and Social Welfare Services would enhance and harmonise health care activities. Pihlajalinna also requests that the diagram showing the location of the resuscitation cart be removed from the investigation report.