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HEALTHCARE SAFETY INVESTIGATION BRANCH

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Undiagnosed cardiomyopathy in a young person with autism

Independent report by the
Healthcare Safety Investigation Branch I2018/026

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HEALTHCARE SAFETY
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About HSIB

The Healthcare Safety Investigation Branch (HSIB) conducts independent investigations of patient safety concerns in NHS-funded care across England. Most harm in healthcare results from problems within the systems and processes that determine how care is delivered. Our investigations identify the contributory factors that have led to harm or the potential for harm to patients.

The recommendations we make aim to improve healthcare systems and processes, to reduce risk and improve safety. Our organisation values independence, transparency, objectivity, expertise and learning for improvement. We work closely with patients, families and healthcare staff affected by patient safety incidents, and we never attribute blame or liability to individuals.

A note of acknowledgement

We are extremely grateful to the family whose experience is documented in this report. Their courage and openness has assisted the investigation greatly. The family expressed their wish that we use the name of their daughter, Alice, throughout relevant parts of this report.

Our investigations

Our team of investigators and analysts have diverse experience working in healthcare and other safety critical industries and are trained in human factors and safety science. We consult widely in England and internationally to ensure that our work is informed by appropriate clinical and other relevant expertise.

We undertake patient safety investigations through two programmes:

National investigations

Our national investigations can encompass any patient safety concern that occurred within NHS-funded care in England after 1 April 2017. We consider potential incidents or issues for investigation based on wide sources of information including that provided by healthcare organisations and our own research and analysis of NHS patient safety systems.

We decide what to investigate based on the scale of risk and harm, the impact on individuals involved and on public confidence in the healthcare system, and the learning potential to prevent future harm. We welcome information about patient safety concerns from the public, but we do not replace local investigations and cannot investigate on behalf of families, staff, organisations or regulators.

Our investigation reports identify opportunities for relevant organisations with power to make appropriate improvements though:

- 'Safety recommendations' made with the specific intention of preventing future, similar events; and
- 'Safety observations' with suggested actions for wider learning and improvement.

Our reports also identify 'safety actions' taken during an investigation to immediately improve patient safety.

We ask organisations subject to our recommendations to respond to us within 90 days. These responses are published on our website.

More information about our national investigations including in-depth explanations of our criteria, how we investigate, and how to refer a patient safety concern is available on our **website**.

Maternity investigations

From 1 April 2018, we have been responsible for all NHS patient safety investigations of maternity incidents which meet criteria for the **Each Baby Counts programme** (Royal College of Obstetricians and Gynaecologists, 2015) and also maternal deaths (excluding suicide). The purpose of this programme is to achieve learning and improvement in maternity services, and to identify common themes that offer opportunity for system-wide change. For these incidents HSIB's investigation replaces the local investigation, although the trust remains responsible for meeting the Duty of Candour and for referring the incident to us. We work closely with parents and families, healthcare staff and organisations during an investigation. Our reports are provided directly back to the families and to the trust. Our safety recommendations are based on the information derived from the investigations and other sources such as audit and safety studies, made with the intention of preventing future, similar events. These are for actions to be taken directly by the trust, local maternity network and national bodies.

Our reports also identify good practice and actions taken by the Trust to immediately improve patient safety.

Since 1 April 2019 we have been operating in all NHS Trusts in England.

We aim to make safety recommendations to local and national organisations for system-level improvements in maternity services. These are based on common themes arising from our trust-level investigations and where appropriate these themes will be put forward for investigation in the National Programme. More information about our maternity investigations is available on our **website**.

Executive Summary

Introduction

The objective of this investigation was to understand the context of magnetic resonance imaging (MRI) scanning under general anaesthetic and how care may be reasonably adjusted for patients with autism or learning disabilities. As an example, which we refer to as the 'reference event', we considered the experience of Alice, a teenage girl who had autism. Sadly, Alice died following her MRI scan under general anaesthetic.

The findings and conclusions of this investigation may be applicable to other non-invasive procedures carried out on patients who are under general anaesthetic.

The reference event

Alice, who was 14 years old, was being treated for growth hormone deficiency under the care of a consultant paediatrician, a community paediatrician and a regional specialist endocrinologist (an expert in conditions related to the glands and organs that produce hormones). Alice had a diagnosis of autism spectrum disorder which led to increased anxiety, and she also had learning difficulties.

Alice had begun having headaches and was referred for an MRI scan under general anaesthetic to rule out any serious illnesses. She attended a pre-anaesthetic assessment clinic a few weeks before attending for her scan.

On four occasions during the MRI scan, Alice required intervention to correct an abnormal heart rate. At the end of the scan she was found to be critically unwell. Alice was transferred to a specialist children's hospital, but sadly died a few days later.

At post-mortem, it was found that Alice had advanced hypertrophic cardiomyopathy (thickening of the heart walls) which had not previously been suspected, detected or diagnosed. Further tests conducted following Alice's post-mortem examination showed that she had a mitochondrial disorder which caused cardiac and skeletal muscle myopathy (muscle disease).

The national investigation

The reference event was referred to the Healthcare Safety Investigation Branch (HSIB) for potential investigation, and HSIB contacted the hospital where it had occurred. Following initial information gathering and evaluation against the HSIB patient safety risk criteria, HSIB's Chief Investigator authorised a national safety investigation.

The national investigation focused on: consent; pre-anaesthetic assessment services (assessments carried out by an appropriately trained clinician before a patient receives an anaesthetic); reasonable adjustments for autistic people and people with learning disabilities and learning difficulties; and preparing for unexpected adverse events relating to anaesthesia. This highlighted issues with the operationalisation of published practice guidance and opportunities to improve the experience of care and enhance safety. This has led to system-level safety recommendations being made to relevant bodies. The investigation identified:

- There is an opportunity to clarify the consent requirements for diagnostic imaging facilitated by a general anaesthetic.
- There is variation in the information given to patients regarding anaesthesia at the point of referral for an MRI scan under general anaesthetic.
- The observations and examinations to be routinely performed in pre-anaesthetic assessment are not defined nationally. The investigation found variation in the hospitals it visited.
- Children coming into hospital for an MRI scan who had been assessed as fit for anaesthetic were perceived as "well" by ward staff.
- Children with autism, learning disabilities and/or learning difficulties often find clinical environments distressing, which may be reflected in their physiological observations. This may result in diagnostic overshadowing, where problems such as autism (or a medical condition) are attributed as the cause of other new problems, rather than considering other underlying causes, thereby leaving other co-existing conditions potentially undiagnosed.
- Children with autism, learning disabilities or learning difficulties may benefit from reasonable adjustments being made when attending hospital.
- Electronic flagging systems can help staff identify patients who may benefit from reasonable adjustments. Hospital passports provide valuable information to assist with implementation of these adjustments.
- The model of care for learning disability nursing teams is not standardised nationally.

- There is an opportunity to enhance the existing published guidance available to assist clinicians involved in general anaesthetics to prepare for adverse events in the MRI scanning environment.
- Professional networks for anaesthetists provide the opportunity for shared learning and consensus regarding best practice.
- It is challenging to comply fully with the existing published standards for anaesthetic equipment used in MRI environments.

HSIB makes the following safety recommendations

Safety recommendation R/2020/079:
It is recommended that the Royal College of Anaesthetists convenes a working group to provide additional guidance regarding the responsibilities for obtaining consent for MRI and other non-invasive diagnostic and/or therapeutic procedures under general anaesthetic in children.

Safety recommendation R/2020/080:
It is recommended that the Royal College of Anaesthetists reviews standards for pre-assessment services, including their purpose, the required observations and examinations, and competencies of staff undertaking this work.

Safety recommendation R/2020/081:
It is recommended that NHS England and NHS Improvement strengthens its 'Learning disability improvement standards for NHS trusts' by including metrics which enable organisations to assess their progress against the outcomes for specialist learning disability teams.

Safety recommendation R/2020/082:
It is recommended that as part of the work to support the NHS Long Term Plan, NHS England and NHS Improvement should develop a role and competency framework for learning disability liaison nurses, to ensure that people with learning disabilities and autistic people receive optimal care which respects and protects their rights.

Safety recommendation R/2020/083:
It is recommended that NHSX develops a system for sharing care plans for patients with autism, learning disabilities or learning difficulties to enable reasonable adjustments to be made.

Safety recommendation R/2020/084:
It is recommended that NHSX develops a standardised care passport, which should include sections to support patients with autism, learning disabilities or learning difficulties.

Safety recommendation R/2020/085:
It is recommended that the Centre for Perioperative Care considers the remit of the National Safety Standards for Invasive Procedures (NatSSIPs) to cover the administration of general or regional anaesthesia for non-invasive diagnostic procedures.

Safety recommendation R/2020/086:
It is recommended that the Association of Anaesthetists reviews the dissemination and implementation of its 'Quick reference handbook' on managing adverse events during anaesthesia.

HSIB makes the following safety observation

Safety observation O/2020/065:
There are likely to be benefits for all organisations delivering anaesthesia to gain Anaesthesia Clinical Services Accreditation (ACSA) as this is likely to reduce unwarranted variation in practice.

HSIB notes the following safety actions

Safety action A/2020/030:
The recommendation for standardised anaesthetic equipment in the Royal College of Anaesthetists' 'Guidelines for the provision of anaesthetic services' is challenging within the MRI environment given the need for MR-safe/MR-conditional equipment. The Royal College of Anaesthetists has clarified this recommendation accordingly.

Safety action A/2020/031:
The Trust where the reference event took place has undertaken to resolve the errors with the clocks on the MRI scanner and anaesthetic monitoring equipment.

Contents

1 Background

1.1 Autism spectrum disorder

1.1.1 Autism spectrum disorder (ASD) is a lifelong developmental disorder, the signs of which usually emerge in the first two years of life. Formal diagnosis may take many years to reach and the developmental disorder may be accompanied by a learning disability or learning difficulty. The disorder affects approximately 1% of the population and affects males more commonly than females.

1.1.2 ASD describes the symptoms which affect the way people with the condition respond in day-to-day life. ASD historically covers a range of conditions similar to, and including, autism.

1.1.3 'All autistic people share certain difficulties, but being autistic will affect them in different ways. Some autistic people also have learning disabilities, mental health issues or other conditions, meaning people need different levels of support. All people on the autism spectrum learn and develop. With the right sort of support, all can be helped to live a more fulfilling life of their own choosing.' (National Autistic Society, 2020)

1.1.4 Autistic people may experience anxiety due to the way they perceive the world around them, and they can find it harder to take part in everyday life.

'Autistic people often do not 'look' disabled. Some parents of autistic children say that other people simply think their child is naughty.' (National Autistic Society, 2020)

1.1.5 The characteristics of autism vary from one person to another. Autism is diagnosed following input from a range of experts such as psychologists, psychiatrists, speech and language therapists and other healthcare professionals within a multidisciplinary team. For a diagnosis to be made the person's difficulties need to be assessed as being persistent. Diagnostic factors include 'social communication and social interaction and restricted and repetitive patterns of behaviours, activities or interests since early childhood, to the extent that these "limit and impair everyday functioning"' (National Autistic Society, 2020).

1.1.6 Some autistic people have sensory sensitivity which makes them either more or less sensitive to sounds, smells, lighting and other stimuli. This sensitivity may in turn cause anxiety and distress.

1.1.7 ASD varies in its severity in terms of its different characteristics. Many adults with ASD function independently with minimal social care and support, whereas others need intensive support which may require residential care.

1.2 Learning disability

1.2.1 Learning disability (LD) is defined by the Department of Health and Social Care as: 'A significantly reduced ability to understand new or complex information, to learn new skills (impaired intelligence), with a reduced ability to cope independently (impaired social functioning), which started before adulthood.' (Department of Health, 2001)

1.2.2 Learning disability may be caused by a chromosomal disorder, such as Down's or Turner's syndrome, may be caused by premature birth or a birth injury, or may occur with no identified cause.

1.2.3 In England, around 1.2 million people have a learning disability, of which around 300,000 are under 18 years of age. It is estimated that around a quarter of these 1.2 million people are known to health or social care services (Foundation for People with Learning Disabilities, 2019).

1.2.4 People with learning disabilities often lead shorter lives and die prematurely as they are less able to articulate their health problems and, therefore, disease detection can be delayed. In the report 'Confidential inquiry into premature deaths of people with learning disabilities (CIPOLD)' (Heslop et al., 2013), '[a] death was considered as premature if, 'without a specific event that formed part of the "pathway" that led to death, it was probable that the person would have continued to live for at least one more year' (Heslop et al., 2013).

1.3 Specific learning difficulties

1.3.1 Specific learning difficulties, also called learning difficulties, are very different from learning disabilities, although they are commonly confused, and the terms are sometimes – incorrectly – used interchangeably. Learning difficulties relate to the challenges in learning from an educational perspective rather than due to a cognitive impairment (as is the case with a learning disability).

1.3.2 There are many types of learning difficulties, including dyslexia, dyscalculia (difficulties learning about or understanding maths) and dyspraxia (a condition affecting physical co-ordination).

1.4 Magnetic resonance imaging

1.4.1 Magnetic resonance imaging (MRI) is a cross-sectional imaging technique which uses powerful magnetic and radio frequencies to create a detailed image of the tissues and structures in the body to aid in the diagnosis of diseases. Cross-sectional imaging provides images in 'slices' of the patient's anatomical structures which cannot be seen using other imaging techniques such as plain X-ray.

1.4.2 MRI is often reported as being an unpleasant and claustrophobic environment, and the scanning process creates loud noises. This, along with the usually long duration of scans, makes the experience daunting for many patients.

1.4.3 For some patients, the experience of being in an MRI scanner is so unpleasant that to tolerate it they require sedation (see 1.5.1) using oral (taken by mouth) medicines. In some cases, patients need to be fully anaesthetised. The use of sedation and/or general anaesthesia reduces anxiety and provides comfort to the patient. Sedation also ensures that the capture of the images is optimised as MRI requires the patient to be very still during the scanning process.

1.4.4 Due to the strong magnetic field and the radio frequencies emitted by MRI scanners, specialised equipment must be used, such as monitoring, anaesthetic machines and trolleys. The dedicated MRI equipment prevents damage to the MRI scanner, erroneous clinical readings, and injury to patients and operators.

1.5 Sedation and general anaesthesia

1.5.1 Sedation involves the use of medicines to achieve a targeted level of reduced consciousness. This varies from very light sedation, such as with an anaesthetic pre-medication, through to a deeper sedation used for invasive procedures such as endoscopy (where a long, thin tube with a camera at the end is put into the body). When sedated, patients are able to communicate but will be drowsy and have little memory of the procedure.

1.5.2 Every hospital (or other healthcare provider) carrying out sedation should have a sedation policy. This should be based on prevailing national healthcare guidance and other guidance from bodies such as medical royal colleges (such as the Royal College of Anaesthetists) and specialist organisations (such as the National Institute for Health and Care Excellence, Association of Anaesthetists, Association of Paediatric Anaesthetists, Safe Anaesthesia Liaison Group and Difficult Airway Society).

1.5.3 Sedation policies state who is authorised to prescribe sedative medicines and/or undertake sedation and provides information on the required standards of care when using sedation. These include standards for environmental considerations, staff competency, monitoring, medicines governance, access to emergency equipment and resuscitation training.

1.5.4 General anaesthetic is 'a state of controlled unconsciousness. During a general anaesthetic, medications are used to send you to sleep, so you're unaware of surgery and don't move or feel pain while it's carried out' (NHS, 2018).

1.5.5 Anaesthesia has inherent risk, and around 1 patient dies for every 100,000 anaesthetic procedures each year in the UK (see

Appendix A). For this reason, anaesthesia has very strict safety standards in place, developed by a range of stakeholder groups, including the Royal College of Anaesthetists, NHS England and Improvement and the Association of Anaesthetists. These organisations work together as the Safe Anaesthetic Liaison Group and publish extensive guidance on safe anaesthetic and sedation practice.

1.5.6 The Royal College of Anaesthetists and the Association of Anaesthetists publish guidance on all aspects of anaesthesia and sedation which covers its use in practice in all settings. This includes anaesthesia undertaken outside of the usual theatre environment, such as in endoscopy suites, pre-hospital care, and imaging settings.

1.5.7 It is not fully understood precisely how anaesthesia works, but the combination of analgesia (pain relief), sedation and, in some cases, neuromuscular blockade (paralysis) combine to create a state where the patient is unconscious, not breathing, unable to move, and unable to recall any events during the period of anaesthesia.

1.6 Consent

1.6.1 Consent is a fundamental aspect of healthcare delivery.

'Consent to treatment means a person must give permission before they receive any type of medical treatment, test or examination.' (NHS, 2019b)

1.6.2 The process of obtaining consent differs depending on the patient's age and their ability to give informed consent. Children may give consent for treatment if they are assessed as competent to do so under the 'Gillick competence' principles, which are used to decide whether a child under 16 years of age is able to consent to his or her own medical treatment (NHS, 2019c).

1.6.3 Consent may be given explicitly or tacitly, and, in the case of emergencies during which the patient cannot communicate, consent may be presumed.

1.7 Mitochondrial disease

1.7.1 Mitochondria are components found within almost every cell in the body and are responsible for producing energy. Cellular energy created by mitochondria is called adenosine triphosphate (ATP). The energy produced is used to power the cell and ensure that it functions correctly. In turn, these individual cells make up the body's structures (skeleton, muscles, connective tissues) and organs. Organs work together to form the body's systems such as the cardiovascular system (heart and blood vessels) and gastrointestinal system (stomach and intestines).

1.7.2 Therefore, it is essential that the function of the mitochondria is intact to produce ATP. If insufficient energy is produced, the cell will not function correctly, and therefore the organ or body system which contains that cell will not function properly, leading to disease or dysfunction.

1.7.3 The signs and symptoms experienced by people with mitochondrial diseases vary. The severity of the condition depends on how many cells are affected by the disease and the types of cells affected.

1.7.4 The progression of mitochondrial disease varies from person to person depending on which mitochondria are affected in each type of cell. It is a very complex disease process, and the progression of some of the diseases it causes, such as hypertrophic cardiomyopathy (see 1.8.1), can be highly protracted, developing over many years before outward signs appear.

1.7.5 The most commonly affected tissues, organs and systems are those which need the most ATP (energy). These include the heart, brain, skeletal muscle, liver and kidneys. Where these organs/structures are involved, the progression of the disease is usually slow.

1.7.6 Mitochondrial disease cannot be cured, but if identified, patients can be treated to reduce the symptoms of the diseases resulting from the condition.

1.8 Cardiomyopathy

1.8.1 Cardiomyopathy is a disease of the heart muscle ('cardio' means relating to the heart, and 'myopathy' means disease of muscle tissue). There are four main types of cardiomyopathy:

- **Dilated:** the heart muscle becomes thin, and the heart enlarges as a result. This leads to reduced ability to pump blood around the body.
- **Restrictive:** the heart muscle becomes stiff and inflexible. This leads to ineffective pumping of blood; while the heart muscle can contract, its recoil as it fills with blood after each heartbeat is reduced.
- **Hypertrophic:** the heart muscle enlarges due to an increase in the size of the cells (known as hypertrophy), and this results in a reduction in the size of the main chambers of the heart and a reduction in blood flow. The heart muscle cells become arranged in a disorganised way, and this affects electrical conduction in the heart, causing arrythmias – abnormalities in the electrical system in the heart that can cause it to beat too fast, too slow, or irregularly, which in some cases can lead to collapse and sudden death.
- **Left ventricular non-compaction cardiomyopathy (LVNC):** during normal development, the left ventricle (one of the chambers of the heart) contains bundles or pieces of muscle that extend into the heart chambers. While continuing to develop, the heart muscle is a sponge-like network of muscle fibres, and as normal development progresses, the bundles should become compacted leaving the heart muscle smooth and solid. LVNC occurs when compaction does not occur (non-compaction). People with LVNC may also have another type of cardiomyopathy. Diagnosis may be made at any age although in many patients it is not diagnosed until later in life.

1.8.2 Hypertrophic cardiomyopathy affects around 1 in 500 people in the UK. For most people with the condition, the genetic origin of the disease (such as mitochondrial disorder) is inherited from their parent(s), either through autosomal dominant inheritance or autosomal recessive inheritance (see 1.8.3 and 1.8.4). For a few patients, the cardiomyopathy originates as an intrinsic genetic problem rather than being passed on from their parent(s) (that is, it is neither dominant nor recessive).

1.8.3 In patients with dominant inheritance, one parent will have the defective gene which may be passed to one or more of their children based on a 50/50 chance of the defective gene forming a pair in their child. The parent may be asymptomatic (have no symptoms) and therefore not know that the gene has been passed on to their child.

1.8.4 In patients with recessive inheritance, one or both parents may be a carrier of the defective gene but not have cardiomyopathy themselves. If both parents are carriers, any of their children have a 25% chance of inheriting the defective gene.

1.8.5 Cardiomyopathy is a difficult disease to detect and diagnose and requires outward clinical signs and/or symptoms to raise suspicion in parents, carers and healthcare professionals. This difficulty means that 'hypertrophic cardiomyopathy is the most common cause of sudden unexpected death in childhood and in young athletes' (NHS, 2019a).

2 The reference event

Children who share the same challenges as Alice may have a variety of developmental, educational and/or cognitive impairments and may not receive a formal diagnosis until later in their childhood, or even into early adulthood. For this reason, the report uses the term **'developing differently'** in relation to people who may not have their final diagnoses in place, but who are not 'developing typically'. This is intended to prevent the report containing comparative words/language, such as 'normal', as this does not convey the most appropriate picture when describing people with autism, learning disabilities or learning difficulties.

The Healthcare Safety Investigation Branch (HSIB) is aware that many people with a diagnosis of autism prefer to be referred to as autistic (**'identity-first language'**) rather than as a person with autism (**'person-first language'**) (Kenny et al., 2016). The investigation therefore uses the term **'autistic people'** rather than **'people with autism'**.

2.1 Alice was a 14-year-old girl who was being treated for small stature (height), thought to be caused by a growth hormone deficiency (GHD). She was under the care of a consultant paediatrician at her local hospital, a community paediatrician, and a consultant paediatric endocrinologist (an expert in conditions related to the glands and organs that produce hormones) from a regional children's hospital. Alice was also diagnosed as being on the autistic spectrum and had a learning difficulty. She also had a history of hypermobility, mobility issues, developmental delay, visual impairment, poor co-ordination and intoeing (walking with toes pointing in). She had been experiencing increasing levels of fatigue and used a wheelchair after undertaking activity. She did not attend a mainstream school but despite the challenges she faced she was described as well, happy and enjoying life.

2.2 From birth, and up until the day of the magnetic resonance imaging (MRI) scan, Alice had many healthcare encounters. The events in this section are set out within three time periods:

- Period 1: from Alice's birth up until the day of the magnetic resonance imaging (MRI) scan. During this time Alice had many encounters with healthcare services.
- Period 2: the period of hours when the reference event took place, on the day Alice attended hospital for her MRI scan.
- Period 3: the hours and days following the scan until Alice's death.

2.3 Period 1: April 2004 until October 2018

2.3.1 Alice was born in April 2004. In her early years her parents noticed that she was small and, as she approached school age, they also noted some behavioural, co-ordination and developmental problems. At around four years of age, she was seen by her GP who referred her to a specialist team to investigate her short stature, as well as the increasing number of falls she was having, which were found to be due to her intoeing gait.

2.3.2 Over the coming years, Alice underwent assessment for her slow growth. Her height and weight were on average on the 4th centile [1], and her paediatrician organised a range of tests to establish why her stature was short. She underwent blood tests to check for the levels of growth hormone produced in her pituitary gland. She also underwent X-rays to test her bone age (as compared to her chronological age).

2.3.3 In 2010, Alice started having assessments for autism, dyslexia and dyspraxia. She was formally diagnosed with autism spectrum disorder (ASD) a few years later.

2.3.4 In February 2011, Alice was diagnosed with GHD and treatment options were discussed. It was agreed with Alice's parents to prescribe growth hormone therapy. A low dose was commenced and by February 2012 Alice was receiving 1.1mg of growth hormone each day by injection.

2.3.5 Alice was tested for Turner's syndrome, a condition which can affect females and may cause short stature and/or heart defects. The test was negative and she was not diagnosed with this syndrome.

2.3.6 Over the next four to five years, Alice progressed well, and her **'growth velocity'** was noted as being **'good'**. The dose of growth hormone was increased regularly in line with her six-monthly outpatient clinic attendances; these alternated between her local hospital and the regional children's hospital.

2.3.7 Alice's development and educational progress continued to be monitored and she was subject to a statement of educational need by her local authority.

2.3.8 In March 2018, Alice began complaining of headaches. Her paediatrician at the local hospital stopped her growth hormone therapy because, while headaches are a common side-effect (British National Formulary, 2019b), a rare but more serious complication is raised intracranial pressure (an increase in pressure inside the skull [2]). He arranged for Alice to have an MRI scan of her head to investigate the cause of the headaches.

2.3.9 Alice had become distressed during previous medical procedures. She had undergone general anaesthesia for a previous MRI scan and had been sedated for dental extractions.

2.3.10 The paediatrician gained written consent from Alice's parents for an MRI scan under general anaesthetic (MRI GA) and made the referral accordingly. The hospital arranged a date for her scan, and for Alice to attend a pre-anaesthetic assessment clinic, as per the local hospital's policy. Alice attended the pre-anaesthetic assessment clinic on 25 September in preparation for her MRI scan two weeks later.

2.3.11 While not all hospitals carry out a pre-anaesthetic assessment of patients having an MRI GA, the hospital where the reference event occurred had done so for the past six to eight years. Guidance issued by the Royal College of Anaesthetists recommends pre-anaesthetic assessment but does not stipulate that this needs to be in a dedicated clinic:

> 'All patients should be assessed before anaesthesia or sedation … by an appropriately trained doctor, nurse or PA [physician associate]'. (Royal College of Anaesthetists, 2019a)

2.3.12 In the pre-anaesthetic assessment clinic, patients are asked about their general health and any concerns they have about the procedure. The purpose of pre-anaesthetic assessment is to check the patient's suitability for anaesthetic, but also 'to optimise the patient prior to their admission' (Royal College of Anaesthetists, 2019a).

2.3.13 Physiological measurements (pulse/heart rate, blood pressure, oxygen saturation, electrocardiogram (ECG) [3]) are only undertaken on adult patients attending for pre-anaesthetic assessment. For children, these tests are only performed if the patient has a relevant history (such as existing heart disease) or is noted to have signs and/or symptoms (such as chest pain, shortness of breath). Therefore, as Alice was a child, she only had her height and weight recorded and the rest of the assessment was completed fully, but this excluded physiological observations. Alice's parents pointed out that she arrived in a wheelchair. This was not commented on during interviews with staff and it is unclear to what extent, if any, this was considered by them in their assessment. No concerns were identified or raised during the assessment, and Alice was not referred to the consultant anaesthetist in attendance in the clinic.

2.3.14 Following this assessment, Alice's MRI scan date was confirmed for a few weeks' time.

2.4 Period 2: 07:30 hours until 19:20 hours (day of event)

2.4.1 Alice arrived at the local hospital at around 07:30 hours for her MRI GA, accompanied by her mother. Alice arrived on the ward in her wheelchair, which she sometimes needed to use when she became tired. They went to the paediatric assessment unit and were greeted by the ward staff.

2.4.2 The assessment unit is primarily used to receive patients who have been referred from the community by GPs or from the hospital's emergency department. However, every fortnight the ward also provided care for children undergoing MRI scans under sedation or general anaesthetic.

2.4.3 After Alice's arrival, an associate practitioner [4] conducted a set of baseline observations, including heart rate and blood pressure. Alice's heart rate was fast and her blood pressure was raised. This was reported to the anaesthetists when they arrived on the ward at around 08:20 hours.

2.4.4 On the ward, the consultant anaesthetist assessed two younger children (a three-year-old and a six-year-old) who had also arrived

for an MRI scan that day. The anaesthetic registrar (a qualified doctor who is training to specialise as an anaesthetist) was asked to assess Alice who, as a 14-year-old, was considered to have a lower anaesthetic risk. The anaesthetic registrar said that Alice was "almost beside herself with anxiety". Otherwise Alice appeared physically well and there was nothing in the pre-anaesthetic assessment documentation that caused them to consider that her anaesthetic would be high risk. The registrar told the investigation that "nothing in the notes made me think [that this anaesthetic was] going to be risky".

2.4.5 The assessment included an examination of Alice's airway, because, as part of the anaesthetic, she was to have a tracheal tube inserted into her trachea (windpipe) through which she would be ventilated mechanically. The anaesthetic registrar spoke to Alice and her mother in order to take a history. No respiratory problems were noted. He concluded that the elevated heart rate and blood pressure were attributable to Alice's anxiety. The anaesthetic registrar was not made aware that Alice was calm at the time that the heart rate was recorded.

2.4.6 Verbal consent for the anaesthetic was given by Alice's mother. During the gaining of the verbal consent, the risk of death while under anaesthetic was not discussed.

2.4.7 Due to Alice's distress, the anaesthetist prescribed her an oral medicine called midazolam as a 'pre-med' [5] to help calm her prior to attempting the general anaesthetic. It was agreed between the anaesthetic registrar and the ward sister that the midazolam should be given 20 minutes before Alice was due to go to the MRI unit.

2.4.8 Just before 11:00 hours, the consultant anaesthetist phoned the ward to request that Alice be given her pre-med. At approximately 11:00 hours, 20mg of midazolam was given orally mixed with blackcurrant juice.

2.4.9 At around 11:20 hours (nearly four hours after being admitted), Alice was taken to the MRI suite, escorted by an associate practitioner and a qualified nurse (as was common practice when a patient was given midazolam).

2.4.10 Alice was taken to the MRI unit on her hospital bed. To help reduce her anxiety, it was agreed that her mother should lay on the bed and cuddle her while being taken to the MRI unit, and during the induction of anaesthesia.

2.4.11 On arrival at the MRI unit, Alice, still in her mother's arms, was taken into the 'prep room'. This is a multi-purpose room which was used as an anaesthetic room on days when MRI scans under general anaesthetic were carried out. The room contained an anaesthetic machine and specialised monitoring equipment which were suitable for use in the MRI environment (see 5.4).

2.4.12 The anaesthetic was carried out by a team of three healthcare professionals: a consultant anaesthetist, an experienced anaesthetic registrar and an operating department practitioner (ODP) [6].

2.4.13 Despite receiving midazolam, Alice was described by the anaesthetic team as unable to co-operate due to her distress, a situation that they reported as not unusual in children. Because of this, it was not possible to insert an intravenous cannula (a tube through which drugs or fluids are delivered into the vein) and so induction of anaesthesia using intravenous drugs was not possible. Therefore a 'gas induction' [7] was used, which involves the patient breathing in anaesthetic agents (nitrous oxide and sevoflurane [8] mixed with oxygen) via a facemask. Alice and her mother arrived at the MRI unit at 11:30 hours and the induction of the anaesthetic commenced at 11:40 hours.

2.4.14 The induction was successful, and Alice went to sleep. Following this, the other activities required to complete the anaesthetic were undertaken. These included: the insertion of an intravenous cannula, being given a muscle relaxant (atracurium), securing the airway with a tracheal tube (which delivers oxygen directly to the lungs), and checking all the monitoring equipment was functioning properly.

2.4.15 Alice was reported as being "stable" at this stage. Unlike in the hospital's main theatre, the MRI suite's monitor was not connected to the hospital network. As a result, a paper anaesthetic chart was started, and all subsequent medicines and observations were recorded manually on this chart at regular intervals.

2.4.16 Alice was taken to the area between the prep room and the MRI scanning room. Here, she was transferred to a special trolley which was suitable to be taken into the MRI scanner room. She was then taken into the MRI scanner room and transferred onto the MRI table, which can be controlled by the radiographer to move the patient in an out of the MRI scanner to obtain the images.

2.4.17 Once Alice was settled on the MRI scanning table, the anaesthetic team withdrew from the room. The anaesthetic team remained outside the MRI scanning room and the anaesthetic and monitoring occurred remotely. Anaesthetic guidance allows for anaesthetists to remain in the MRI scanning room if the patient clinically requires it, but this is rarely necessary.

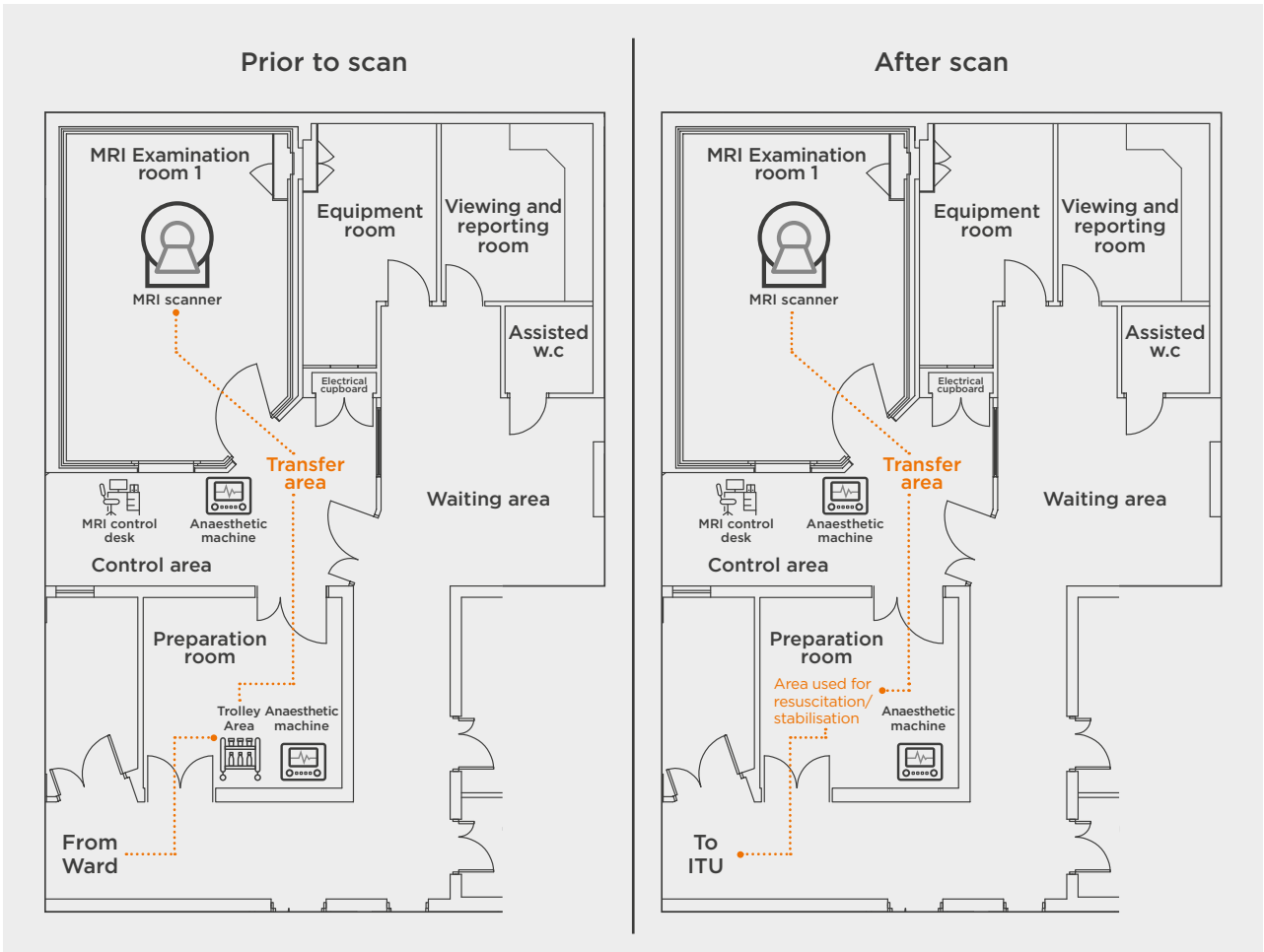
2.4.18 The ventilator circuit (breathing tubes) used were very long and passed through a hole in the wall of the scanning room. This allowed the anaesthetic to be controlled by the anaesthetists outside the room. The physiological monitoring device (for ECG, blood pressure, and so on) was wireless and transmitted data from a unit attached to the patient.

2.4.19 Due to the layout of the MRI unit (see Figure 1) and the location of the anaesthetic equipment, the anaesthetist could not see Alice unless he moved to where the radiographer was sitting to look through the window into the scanning room. When inside the MRI scanner, most of the patient is not visible.

2.4.20 The MRI scan was expected to take around 25 minutes. The scan began at 11:42 hours and ended at 12:43 hours, taking an hour and one minute – over double the predicted time. The extended time was caused by Alice's scan being interrupted four times due to the clinical complications which occurred during the scan (see 2.4.24 to 2.4.30).

2.4.21 The investigation found that the clock built into the MRI scanner was incorrect by 8 minutes, and the clock on the anaesthetic

Fig 1 Floor plan of the MRI suite showing key features and flow through the department



machine monitor was incorrect by 1 hour and 20 minutes. The inaccuracy on the anaesthetic monitor meant that the anaesthetic registrar had to calculate the correct time for each manual entry on the anaesthetic chart. (Note: the MRI scanning and anaesthetic chart timings stated in this report have not been corrected. For example, the induction of anaesthesia was logged at 11:40 hours, but the scan commenced at 11:42 hours, which is not possible within that time interval.)

2.4.22 During the early part of the scan, monitoring showed that Alice's heartbeat had slowed to an abnormally low rate, a condition known as bradycardia [9].

2.4.23 At this point in the scan, the consultant anaesthetist had left the MRI suite to return some equipment to the intensive therapy unit. He estimated that he was absent from the MRI suite for approximately five minutes; the family reported to the investigation that he returned at approximately 12:00 hours. The bradycardia was detected by the anaesthetic registrar and ODP.

2.4.24 Initially, the anaesthetic registrar had elected to use a drug called glycopyrrolate to treat the bradycardia and was about to administer this when the consultant anaesthetist returned. The consultant anaesthetist decided that atropine would be a better choice of drug as it was faster acting. At this point Alice's heart rate had fallen from 70 beats per minute to 30 beats per minute. (Note: these values were extracted from data plotted on a chart, rather than numerical data. Therefore, the actual values given may be slightly higher or lower).

2.4.25 The scan was paused approximately 10 minutes after it had commenced to allow the anaesthetic team to enter the scan room to administer the Atropine. The Atropine corrected Alice's bradycardia and the scan was recommenced.

2.4.26 A short time later, it was noted that Alice's heart was now beating too fast, a condition known as tachycardia [10].

2.4.27 Alice had a total of three periods of tachycardia and each time this occurred the scan was paused. Manual techniques [11] were performed and achieved a reduction in Alice's heart rate.

2.4.28 Figure 2 shows Alice's heart rate measurements recorded from the commencement of the general anaesthetic and throughout the scan, and until she was admitted to the intensive therapy unit.

2.4.29 Following the third period of tachycardia, the anaesthetic team considered whether to terminate the scan and wake Alice up from the anaesthetic. The investigation was told that the decision was taken to complete the scan based on the following factors:

- Alice's heart rate was considered to be stable
- the scan only had 10 more minutes left to completion

Fig 2 Heart rate measurements during MRI scan

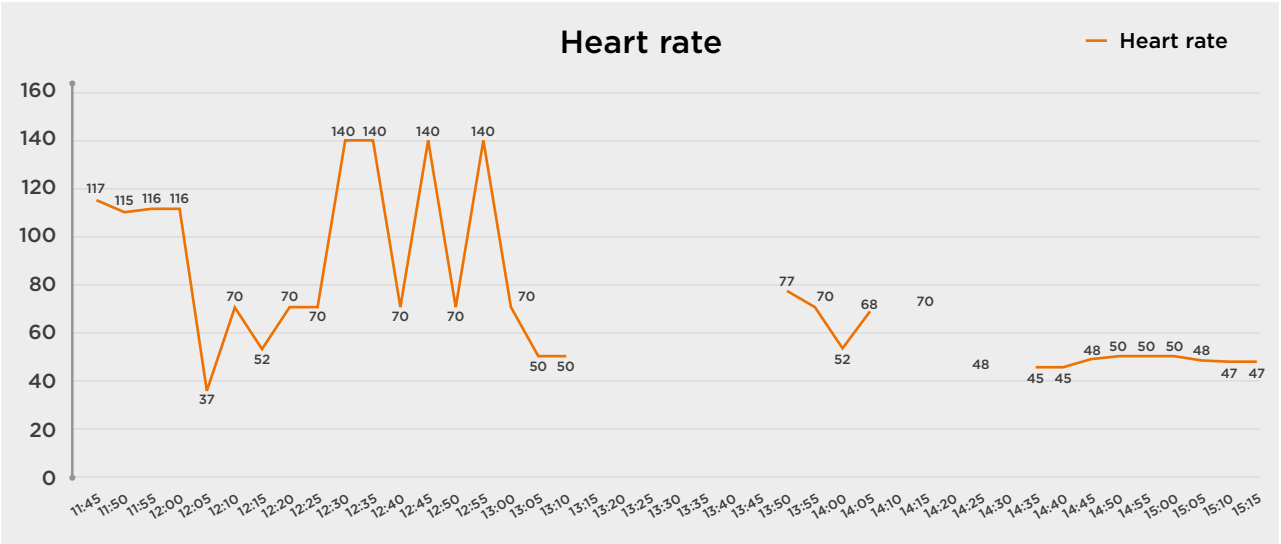


Fig 3 Blood gas test results

Test / Time	12:50	13:50	14:17	14:39	15:43	16:18	17:37	18:41	19:15	Normal (lower)	Normal (upper)	Unit of measurement
Blood pH	7.11	6.91	6.95	6.9	6.91	7	7.03	7.01	7.02	7.35	7.45	NA
pCO2	3.5	6.5	4.5	5.8	5.2	4.6	4.7	4.7	4.1	4.5	6.1	kPa
pO2	52.3	6	17.6	8.7	8.7	10.4	15.6	12.2	18.8	12	15	kPa
Standard Bicarbonate	9.7	6.3	6.5	6.1	5.5	7.8	8.8	8.1	7.8	22	26	mmol/L
Base Excess	-19.5	-22.7	-23.7	-23.7	-24.4	-21.8	-28.7	-21.5	-22	No range		mmol/L
Oxygen Saturation	100	58.9	100	83.7	84.5	93.9	99.1	97.2	99.2	No range		%
Methaemaglobin	0.9	0.3	0.5	0.7	0.6	0.6	0.9	0.5	1.4	No range		%
Oxyhaemaglobin	98.2	58.4	93.3	82.3	82.5	92.2	97.2	93.2	97	No range		%
Carboxyhaemaglobin	0.9	0.6	1.1	1	1.4	1.1	1	1.2	0.9	0	1.5	%
Sodium (gas machine)	134	128	126	128	124	129	131	130	130	135	145	mmol/L
Potassium (gas machine)	5.7	5.2	5.2	5.2	6	5.3	4.4	4.5	4.4	3.5	5.5	mmol/L
Lactate (gas analyser)	11.9	11.3	11.4	10.2	12.2	13.3	14.2	14.8	14.3	0.63	2.44	mmol/L
Glucose (gas analyser)	13.5	8.5	7.6	7	5	4.1	2.9	5	5	No range		mmol/L

- due to Alice's headaches, and the potentially serious cause, the scan and anaesthetic would have to be repeated at a future date

- a subsequent additional scan would likely mean further distress for Alice given her known anxiety regarding medical procedures.

2.4.30 After the second episode of tachycardia, a call was made to a consultant paediatrician for assistance. The consultant paediatrician asked their associate specialist to attend the scanning unit to assess Alice's condition.

2.4.31 On completion of the scan, and on re-entering the MRI scanner room, it was noted that Alice was now pale, and her observations were becoming concerning. Her blood pressure had fallen, her capillary refill time (CRT) [12] was longer than usual (indicating poor blood circulation), and her skin was cold.

2.4.32 On their arrival, the paediatrician commenced an assessment to establish the cause of Alice's deteriorating clinical condition.

2.4.33 The paediatrician noted Alice's increasing CRT, low blood pressure and pallor. The ECG monitoring showed abnormalities in Alice's heart rhythm, suggestive of a cardiac-related cause of her condition. Further tests to investigate her heart were organised.

2.4.34 In parallel with the assessment undertaken by the paediatrician, the anaesthetic team assessed the cause of the problem from an anaesthetic perspective. The anaesthetic team and paediatrician agreed that further clinical support was needed, and a critical care consultant was contacted.

2.4.35 Over the next hour, additional clinical staff arrived at the MRI unit to assist with resuscitating Alice and stabilising her condition.

2.4.36 A blood sample was taken to help determine the severity of her condition. Further blood samples were taken over the following hours (see Figure 3). The results highlighted that Alice was extremely unwell.

2.4.37 The anaesthetic team agreed that, considering Alice's elevated temperature, a potential cause of the collapse and deterioration was malignant hyperthermia [13] (also known as malignant hyperpyrexia), a very rare complication of anaesthesia. They commenced the treatment for this, dantrolene

(British National Formulary, 2019b)), alongside standard resuscitative interventions, including the infusion of intravenous fluids [14].

2.4.38 The consultant anaesthetist decided that an echocardiogram [15] (ultrasound scan) was needed to examine Alice's heart. Common to most hospitals, the hospital in the reference event did not have an emergency paediatric echocardiography service. The echocardiogram technicians were contacted but they were unable to assist. A cardiologist was contacted but was undertaking an interventional procedure at the time and could not leave to attend the MRI unit.

2.4.39 One of the critical care doctors (the consultant anaesthetist) had a special interest [16] and specific competencies in echocardiography and performed a "functional echo" (a functional examination intended to give an overview of the function of the heart, rather than a more detailed, diagnostic examination). This showed a very significant abnormality of Alice's heart. The heart itself was documented as being very enlarged and with a much-reduced ability to pump blood effectively. The investigation was told that Alice's heart-pumping ability (ejection fraction) was estimated as being 20% and that a normal ejection fraction is 60% (the percentage value relates to the amount of blood which is pumped from the left ventricle with each heartbeat).

2.4.40 At 13:45 hours a telephone call was made to the regional children's hospital requesting Alice be transferred by the retrieval (transfer) team to the children's hospital's paediatric intensive care unit.

2.4.41 The retrieval team members spoke with the local hospital using a conference telephone call which allows the whole team to listen and input. This means that the retrieval team was fully briefed about Alice prior to their arrival at the local hospital.

2.4.42 The retrieval team's consultant paediatric intensivist (a children's intensive care specialist) remained in contact with the local hospital while en route. This allowed specialist input to be given by telephone while the team was travelling.

2.4.43 At approximately 15:00 hours, Alice was stable enough to be taken from the MRI unit to the (adult) intensive therapy unit in the local hospital, where her care was continued while awaiting the arrival of the retrieval team.

2.4.44 The retrieval team included a consultant-level paediatric intensivist, a middle grade paediatric anaesthetist [17], and an experienced paediatric transfer nurse. The retrieval team arrived at the local hospital at 16:14 hours.

2.4.45 On arrival at the hospital, the team made its way to the intensive therapy unit with their specialist equipment and ambulance transfer trolley. This approach is consistent with the team's standard operating procedures.

2.4.46 The retrieval team agreed with the medical team at the local hospital that Alice was extremely sick, and that transfer could cause further instability, but was essential.

2.4.47 Responsibility for Alice's care was shared between the hospital team and the retrieval team while in the intensive therapy unit (ITU) [18], and this continued until she was moved to the ambulance at around 19:10 hours, when she became the sole responsibility of the retrieval team.

2.5 Period 3: 19:20 hours on day of event (day 1) until day 4

2.5.1 The paediatric retrieval team was on site at the local hospital between 16:14 hours and 19:20 hours. The retrieval team worked alongside the local hospital team to stabilise Alice's condition before commencing the transfer to the regional children's hospital.

2.5.2 Alice travelled by ambulance, with the three-person retrieval team and her mother, to the regional children's hospital.

2.5.3 Alice was transferred using a conventional land ambulance. Retrieval can also be undertaken using a helicopter air ambulance. Helicopters must be suitable for the task and may be requested from the local HEMS (Helicopter Emergency Medical Service) charity (Association of Air Ambulances, 2019), the military/coastguard, or the national Children's Air Ambulance charity (Children's Air Ambulance, 2019).

2.5.4 A helicopter was not used in the transfer of Alice. This was because the journey involved would have required multiple secondary land ambulance transfers to and from suitable landing sites. The investigation was told that this would have increased the overall journey time.

2.5.5 During the journey to the children's hospital the retrieval team documented that despite Alice being seriously ill, her condition was stable and that the transfer was uneventful.

2.5.6 On arrival at the children's hospital at 21:00 hours, Alice was taken directly to the paediatric intensive care unit.

2.5.7 The following provides a summary of the care at the children's hospital (taken from medical notes).

Day 1

- Alice is settled on the paediatric intensive care unit and is monitored. She received intensive medical and nursing care overnight. The family were told that Alice was unlikely to survive.

Day 2

- At 03:20 hours it was documented that Alice's echocardiogram showed a hypertrophic left ventricle (enlarged heart) and her chest X-ray showed pulmonary oedema (fluid on the lungs). It was also documented that there was evidence from blood tests that she had multiple organ failure.

- Alice's condition was reviewed again at 05:27 hours when it was noted that she needed cardiac support. Her liver was damaged, and she had coagulopathy (a disorder involving blood clotting that causes patients to bleed for extended periods). Her blood tests showed continuing deterioration.

- On discussion with Alice's parents it was agreed to continue treatment.

- At 10:08 hours it was documented that Alice had a 'likely long-standing cardiomyopathy'. Alice needed high doses of adrenaline and noradrenaline – medicines that help maintain blood pressure, which in turn help maintain oxygen supply to tissues/organs. She was cold peripherally, indicating further that her circulation was severely compromised.

- At 16:50 hours, a chaplain met with the family, and he performed a blessing on Alice. The family liaison team explained to Alice's parents how ill she was and that she would not survive.

- At 16:53, it was documented in the notes that the likely cause of Alice's collapse in the MRI scanner was that 'During propofol and sevoflurane she decompensated presumably as her heart was unable to beat faster to compensate for the induced vasoldilation [sic]'. In essence, her underlying cardiomyopathy meant that she was unable to tolerate the anaesthetic needed for her MRI scan. Note: Propofol was not used to induce anaesthesia in this case, but it was used to maintain the anaesthesia/sedation following detection of Alice's deterioration. This is an error in the medical notes.

- The team who cared for Alice overnight received a handover from the day team at 21:00 hours. Several entries were made during the night noting further deterioration, including falling blood pressure and a fluctuating (slow) heart rate.

Day 3

- The medical team explained to Alice's family that if her heart were to stop, any resuscitation attempt would not be successful.

- Overnight, Alice's condition deteriorated further, and this is documented in her notes.

Day 4

- The medical team discussed and agreed with Alice's parents the level of treatment that was now appropriate given her continued deterioration.

- It was agreed with Alice's parents that her condition was not going to improve and that she should receive end-of-life care. Alice died at 14:01 hours with her parents at her side. The doctor wrote in her notes, 'Rest in Peace Alice x'.

2.5.8 A post-mortem examination was carried out to establish the cause of Alice's death. The cause of death was given as:

- '1a Multiple Organ Dysfunction

- 1b Decompensation of cardiac function during general anaesthesia

- 1c Hypertrophic cardiomyopathy with myocardial fibrosis

- 1d Complex I-related mitochondrial disease'
(Taken verbatim from the post-mortem report).

2.5.9 Alice's death was the subject of a Coroner's Inquest. The inquest returned a narrative verdict. The report from the inquest stated that Alice died as a result of four medical conditions which contributed to her death:

'mitochondrial disease, multiple organ failure, myocardial fibrosis and heart failure during the anaesthetic.'

2.5.10 The Coroner issued a Regulation 28 Order (a preventing future deaths report [19]) relating to the care Alice received for her growth hormone deficiency:

'The evidence demonstrated that Alice was under the care of a consultant community paediatrician, a consultant general paediatrician with an interest in endocrinology, and a consultant paediatric endocrinologist presenting with a number of conditions (Growth hormone deficiency, Autistic Spectrum disorder, developmental delay, visual impairment, mobility impairment, poor coordination/dyspraxia and hypermobility) over a 9 year period but was not referred for investigation of an underlying disorder, specifically a clinical geneticist's opinion, despite her parents requesting this on at least 2 separate occasions which are documented and despite such facility being readily available in [location redacted]. The evidence demonstrated that as a result of her underlying condition, and specifically a serious cardiomyopathy, went undiagnosed resulting in her dying unexpectedly and prematurely as a result of a routine general anaesthetic.'

3 Involvement of the Healthcare Safety Investigation Branch

3.1 Notification of reference event

3.1.1 The Healthcare Safety Investigation Branch (HSIB) was notified of the death of a young patient who had undergone an MRI scan under general anaesthetic (MRI GA). During the scan, the patient's condition deteriorated unexpectedly, which was subsequently discovered to have been caused by an undetected heart condition (cardiomyopathy).

3.1.2 The practice of administering general anaesthetic to facilitate MRI scanning is well established in the UK. The Royal College of Anaesthetists (RCoA) has published guidance to minimise the risks associated with carrying out anaesthetics away from the theatre environment. The RCoA publishes information on the risk of death associated with having an anaesthetic, which states that 'death is very rare. An exact figure is not known, but it is around 1 death per 100,000 general anaesthetics' and that 'the risk of a child dying from a general anaesthetic is around 1 in 40,000. However, if the child is healthy and having non-emergency surgery, the risk is much less, probably less than 1 in 100,000' (Royal College of Anaesthetists, 2017).

3.1.3 The preliminary HSIB investigation identified opportunities to improve the way patients are assessed for suitability for anaesthetics and how autism, learning difficulties or learning disabilities may affect this.

3.2 Decision to investigate

3.2.1 Following the preliminary investigation, the Chief Investigator authorised a national investigation based on HSIB's patient safety risk criteria:

Outcome impact – what was, or is, the impact of the safety issue on people and services across the healthcare system?

- Undetected cardiomyopathy can cause sudden unexpected death from activities which put additional strain on the heart. Collapse due to cardiomyopathy may also occur spontaneously.
- When an unexpected death from undetected cardiomyopathy occurs in a hospital setting, this can undermine confidence and trust in healthcare services.

Systemic risk – how widespread and how common a safety issue is this across the healthcare system?

- Pre-anaesthetic assessment is intended to determine patients' suitability for anaesthetic and prevent on-day cancellation of procedures. There is a risk that existing guidance does not sufficiently detail the investigations and examinations that should be undertaken, particularly with children and people with additional needs.
- The sudden death of a child during a routine procedure under anaesthetic is rare.
- The investigation was told by a subject matter advisor for anaesthetics that it is more common for children with autism and/or learning disabilities/difficulties to need general anaesthesia or sedation for medical imaging. As in the reference event, a small number of these children may have diseases that, if undetected, could lead to an adverse outcome.

Learning potential – what is the potential for an HSIB investigation to lead to positive changes and improvements to patient safety across the healthcare system?

- There is limited guidance on the content of pre-anaesthetic assessments, such as the physical observations and examinations that are to be routinely undertaken.
- The guidance for paediatricians or other specialities on seeking consent for patients undergoing non-urgent anaesthetics for diagnostic procedures is limited and the opportunity exists to review these arrangements.
- There is an opportunity to enhance, and make more specific, the guidance on preparing for adverse events in the MRI setting where the patient is under a general anaesthetic.

3.3 Scope of investigation

3.3.1 After preliminary investigation, it was agreed that the national investigation would:

- Analyse the MRI scanning and anaesthetic aspects of the reference event to understand the context and issues associated with these procedures.
- Assess the adequacy of the risk controls in place to mitigate the safety risk to patients undergoing MRI GA and identify where opportunities for error remain. Specifically:
  - review the evidence base and guidance for pre-anaesthetic assessment clinics
  - consent in children
  - considerations for those who are developing differently and may require reasonable adjustments.
- Share learning from organisations that have implemented systems and processes which have reduced the identified risk and improved practice.

3.3.2 The investigation did not explore the management of Alice's short stature and treatment using growth hormone therapy. This aspect of Alice's care did not form part of the safety risk agreed for this national investigation. If in the future this is identified as a safety risk, there may be the opportunity to scope an investigation in the presence of a suitable reference event.

3.4 Method

3.4.1 Investigative approach

3.4.2 HSIB uses a standard process in all its investigations:

- Gather all relevant evidence.
- Establish the factual circumstances leading up to the reference event.
- Analyse the evidence.
- Identify the most significant safety factors and safety issues that contribute to the safety risk being investigated.
  - a safety factor 'is an event or condition that increases safety risk' (Australian Transport Safety Bureau, 2011).
  - a safety issue is a safety factor that 'is a characteristic of an organisation or a system, rather than a characteristic of a specific individual, or … environment at a specific point in time. Safety issues will usually refer to problems with … risk controls' (Australian Transport Safety Bureau, 2011).
- Identify which safety factors are contributory to the reference event.
- Identify which safety issues are likely to contribute to future, similar events nationally. These inform the wider investigation (see section 5).
- Develop safety recommendations and safety observations to reduce identified safety risks.

3.5 Demographics of healthcare organisations

3.5.1 Reference event hospital trust

3.5.2 The trust where the reference event occurred ('the Trust') was a district general hospital which serves a local population of approximately 300,000 people. It employs around 6,000 members of staff and is based at an acute hospital site in a medium-sized town. It also provides community services across the wider locality.

3.5.3 The Trust has an on-site learning disability liaison team.

3.5.4 Organisations visited as part of the national investigation.

3.5.5 The investigation visited three trusts that provide MRI GA services for children. The visits included observing and/or speaking with staff involved with paediatric outpatient MRI scanning under general anaesthetic, learning disability services, and pre-anaesthetic assessment. The three trusts all had learning disability liaison teams.

3.5.6 The investigation also visited a community-based organisation that provides care for patients with learning disabilities.

3.5.7 The trusts were selected to provide the opportunity to see relevant care and practice in different types of hospital. One was a specialist children's hospital, one was a city-centre teaching hospital, and one was a district general hospital similar in size and catchment to the Trust in the reference event.

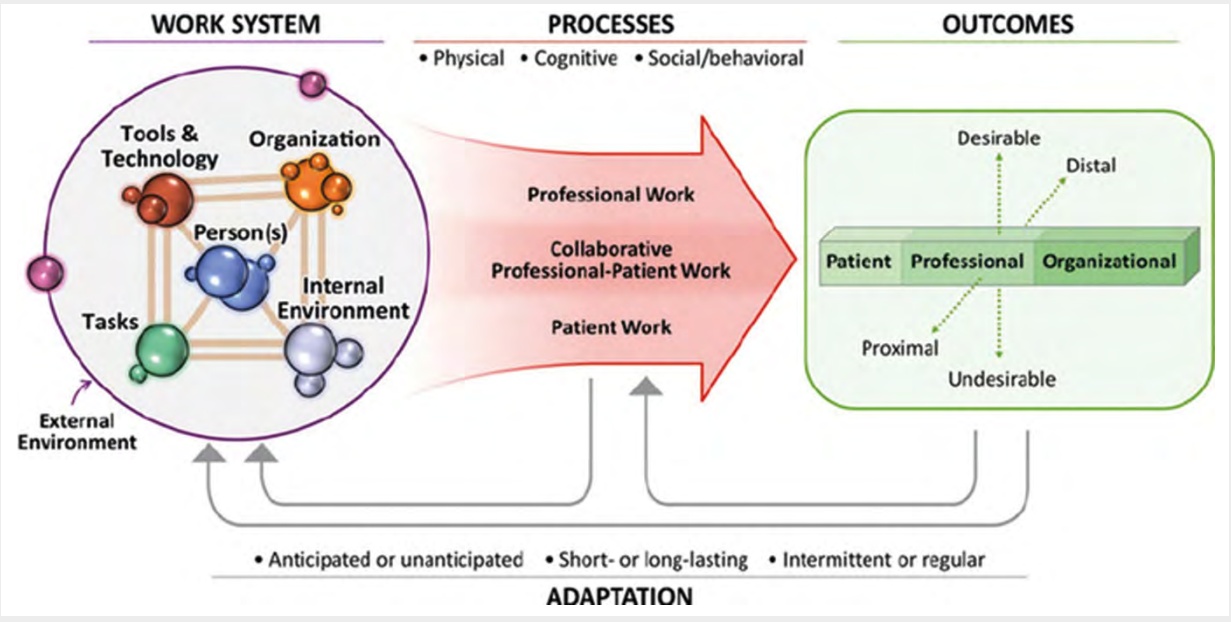
3.6 Evidence gathering and verification of findings

- Review of the patient's clinical records, Trust policies, procedures and practice relating to the referral, pre-anaesthetic assessment, consent, admission and completion of the MRI scan under general anaesthetic.
- Interview and telephone conversations with the patient's family.
- Interviews with staff at the Trust.
- Interviews with two 'Experts by Lived Experience' (see 5.3.7).
- Liaison with subject matter advisors in the areas of anaesthetics and autism/learning disabilities.
- Interviews in person and by telephone with representatives from relevant national organisations and with subject matter advisors (for example, senior leads from the Royal College of Anaesthetists, Association of Anaesthetists, Association of Paediatric Anaesthetists, Royal College of Nursing, College of Operating Department Practitioners, and NHS England and NHS Improvement).
- Observations at the Trust in order to understand the processes and environments in which care was provided.
- Visits to three other trusts to observe their approach to undertaking MRI scanning of children under general anaesthetic.
- Review of the independent serious incident report commissioned by the Trust.
- Review of published guidance and literature relevant to the safety risk.
- Review of Coroner's Inquest and Regulation 28 reports (see 2.5.10).

3.7 Analysis

During the analysis of the investigation, a model called Systems Engineering for Patient Safety (SEIPS) was used to examine the safety factors influencing MRI scanning under general anaesthetic. Figure 4 shows that the structure of a work system affects how safely care is provided (the process); and the means of caring for and managing the patient's case (the process) affects how safe the patient is (outcome).

Fig 4 SEIPS 2.0 (Holden et al., 2013)



4 Findings and analysis

In order to identify the safety factors, safety issues and local risk controls, the investigation reviewed Alice's clinical records and interviewed frontline staff and managers at the Trust where the reference event occurred. In addition, Trust policies and national guidance were reviewed to determine whether actions taken in the reference event aligned with them.

4.1 Decision to undertake MRI under anaesthetic

4.1.1 Alice's paediatrician at the local hospital was concerned her headaches were a side-effect of the growth hormone therapy. The British National Formulary lists headache as a 'common or very common' side-effect of somatropin (British National Formulary, 2019a), the growth hormone therapy taken by Alice. To exclude this cause of the headaches, he referred Alice for an MRI scan.

4.1.2 The paediatrician explained that because the headaches were increasingly recurrent, he was concerned that they may have a serious underlying cause, for example idiopathic intracranial hypertension [20] – an 'uncommon' but serious side-effect of taking somatropin (British National Formulary, 2019a).

4.1.3 An MRI scan of the head typically requires the patient to remain still for around 45 minutes. For some patients, including Alice, this was not possible without a general anaesthetic. Alice had undergone a previous MRI scan under general anaesthetic.

4.1.4 The investigation discussed the decision to request an MRI under general anaesthetic (MRI GA) with representatives from the Royal College of Radiologists and the subject matter advisor (SMA) for anaesthetics for the investigation. They considered the request to be "appropriate" and noted that the presence of headaches in this clinical context was a "red flag" [21].

4.1.5 Summary

- Based on the evidence gathered, including clinical practice guidance and the presence of a 'red flag', the decision to refer Alice for an MRI scan, and perform this under general anaesthetic, was appropriate.

4.2 Adjustments made to support Alice while in hospital

4.2.1 At the hospital where the reference event occurred there was a Children's Learning Disabilities Health Team. This team provides support to patients with learning disabilities who are in hospital, usually for planned care. Alice was not referred to this team. Alice's mother was with her until she was anaesthetised, providing support and minimising her distress.

4.2.2 Guidance by the Royal College of Anaesthetists (RCoA) makes the following recommendation regarding special needs or circumstances:

'In patients with learning disabilities or special needs, there should be close co-operation with other specialists. A learning disability liaison nurse could be available to support patients and carers while attending the hospital either for outpatients, day surgery or as inpatients.' (Royal College of Anaesthetists, 2019a)

4.2.3 It is not known whether involvement of the Children's Learning Disabilities Health Team would have altered the care provided to Alice. The investigation heard from learning disability nurses and the SMA for anaesthetics that consideration may be given to orientation visits, changes to the environment (such as lighting or noise), and the order in which patients are seen in order to minimise waiting time.

4.2.4 Information about patients' needs can be shared using a hospital passport [22] or another similar advance care plan. Alice's autism and her general health history was noted throughout her medical records; however, she was not 'flagged' and did not have a hospital passport. This could have provided information regarding how her autism and learning difficulties affected her behaviour and would have provided an opportunity to plan reasonable adjustments.

4.2.5 Staff described Alice's behaviour as "challenging" although she did comply with having her blood pressure taken when she first arrived on the ward, and her mother told the investigation that she was calm at this point. Staff told the investigation that

later in the morning on the day of the MRI scan Alice showed signs of being extremely distressed and that her physiological changes – tachycardia (fast heartbeat) and hypertension (high blood pressure) – were consistent with this. This was thought to be **"a reasonable judgement"** by the investigation's SMA (anaesthetics). However, the investigation's SMA on autism stated that this may be an example of **"diagnostic overshadowing"**, meaning that other possible causes were not explored.

4.2.6 While anxiety is common in people with a learning disability or autism, it is easy for anxiety to be attributed to a medical condition without proper consideration of other possible causes of either anxiety, or the physiological symptoms of anxiety.

4.2.7 In order to minimise Alice's distress prior to the anaesthetic, she was prescribed a **'pre-med'** (a medicine given to reduce pain or anxiety prior to an anaesthetic). In addition, Alice's mother was invited to lie on the bed and cuddle her while she was being taken to the scanner, and during induction of anaesthesia.

4.2.8 Alice's parents told the investigation that they were concerned that the dose of midazolam given was too high (20mg given in a single dose). The dose of oral midazolam is calculated using the patient's weight (0.5mg per kg). The SMA (anaesthetics) said that as Alice weighed 43.3kg, the 20mg dose was within safe limits. This is supported by the dosage given in the British National Formulary for Children, which states that for premedication children should receive **'500 micrograms/kg (max. per dose 20 mg), to be taken 15–30 minutes before the procedure'** (British National Formulary for Children, 2019b).

4.2.9 Alice was given a 20mg dose of midazolam orally. The SMA (anaesthetics) told the investigation that the oral presentation of midazolam is not always available and therefore the intravenous formulation may be used orally using the same dose as the oral presentation.

4.2.10 There is a known risk with interchanging oral and intravenous presentations of drugs like midazolam [23]. However, as Alice was old enough to take oral medicines using a cup, rather than using an oral syringe, this was not relevant in Alice's care.

4.2.11 The onset of action (the time it takes the drug to take effect) of oral midazolam is 15 to 30 minutes with a duration of action of 45 to 60 minutes (how long the therapeutic effect of the drug lasts). This meant that by the time Alice arrived at the MRI suite the midazolam would be having a sedative effect.

4.2.12 Summary

- Despite being less anxious on admission, Alice's anxiety and distress were judged to be the cause of her raised heart rate and blood pressure.
- Alice was not **'flagged'**, and she did not have a hospital passport. Alice's mother was present until the time of her anaesthetic, provided essential information, and provided care and support to minimise her distress.
- Alice was not seen by a learning disability specialist during her care, but there is no evidence to suggest this would have changed the outcome for Alice and so was not a contributory factor.
- Alice's care may have been influenced by diagnostic overshadowing.
- The combined absence of flagging, a hospital passport or specialist learning disability input meant that the opportunity to consider reasonable adjustments was missed, which is considered a safety issue (see 5.3).

4.3 Referral and consent

4.3.1 Alice was referred for an MRI scan under general anaesthetic by her paediatrician at the same Trust where the scan took place. The request for the MRI scan was sent to the radiology team and the request for the anaesthetic was sent to the anaesthetic department.

4.3.2 All imaging requests were reviewed by the Trust's radiology team. The Royal College of Radiologists told the investigation that MRI scans relating to persistent or increasing headaches are rarely declined as they may indicate serious pathology and are considered **'red flags'**.

4.3.3 Requests for a general anaesthetic are processed by the anaesthetic department. Patients are booked into a dedicated

'paediatric MRI under general anaesthetic' session which occurs every other Tuesday morning. Once a date for the MRI scan is set, patients are invited to attend a pre-anaesthetic assessment clinic appointment.

4.3.4 Written consent for Alice's MRI GA was obtained by Alice's paediatrician and her mother signed the consent form. Consent was gained at the appointment where the referral was made, which took place approximately one month prior to the date of the scan. On the day of the scan, the anaesthetist obtained verbal consent for the anaesthetic on the ward prior to the scan.

4.3.5 Alice was present during the obtaining of consent/assent for her care, but formal written consent was provided parentally. At all stages of her care, verbal consent/assent was obtained.

4.3.6 Department of Health and Social Care guidance states:

'The clinician providing the treatment or investigation is responsible for ensuring that the person has given valid consent before treatment begins … [although the task] … may be delegated to another person, as long as they are suitably trained and qualified. In particular, they must have sufficient knowledge of the proposed investigation or treatment, and understand the risks involved …'
(Department of Health, 2009)

The investigation was told by Alice's family that no serious anaesthetic risks were discussed with them.

4.3.7 The consent form had a section titled 'Significant, unavoidable or frequently occurring risks'. Within this section the paediatrician wrote: 'Significant (but infrequent) – anaesthesia'. The paediatrician told the investigation that usual practice was for written consent to be taken by the paediatrician at the time of the MRI request.

4.3.8 Alice's mother signed page one of the consent form (see Appendix A) during the outpatient appointment with the paediatrician. She also signed page two of the form (titled 'I am the parent') on the day of the scan (see Appendix B).

4.3.9 The paediatrician told the investigation that the consent process involved providing basic information on the commonly occurring risks associated with general anaesthetics (for example, it is common to experience vomiting or a sore throat after an anaesthetic). The paediatrician stated that information regarding serious and significant risks relating to the anaesthetic aspect did not form part of the consent discussion. He noted that an anaesthetist would discuss consent prior to the anaesthetic on the day of the scan.

4.3.10 Reflecting on the situation, the paediatrician said that it was unclear what it was he was taking consent for. Although he believed he was taking consent for the overall procedure (MRI GA) he recognised that imaging such as MRI scanning does not require consent, and therefore the consent element only related to the anaesthetic.

4.3.11 The paediatrician noted that the consent process for MRI GA had become joined as a single entity meaning that paediatricians were routinely taking consent for the risks of anaesthetic. Unlike most anaesthetic scenarios, in the context of MRI GA, the anaesthetic poses a much greater risk than the procedure (MRI scan) the anaesthetic is facilitating (see 5.1).

4.3.12 The investigation was told by the anaesthetic team that given the rarity of serious complications from a general anaesthetic, and in the context of apparently well children, talking to patients and families about serious risks such as death can create undue anxiety. This was supported by the SMA (anaesthetics) who agreed that there needed to be a proportionate approach to discussions regarding risks. Furthermore, the SMA noted that in the reference event this discussion took place (as is common practice) on the day of the scan, giving limited time for Alice's parents to assimilate the information.

4.3.13 Guidance issued by the General Medical Council states:

'The information you share should be in proportion to the nature of their condition, the complexity of the proposed investigation or treatment, and the seriousness of any potential side effects, complications or other risks.' (General Medical Council, 2008)

4.3.14 Summary

- The paediatrician followed common practice and Trust policy in obtaining written consent for MRI GA. Common risks (but not serious risks) associated with general anaesthesia were documented.
- Verbal consent for the anaesthetic was obtained by the anaesthetist on the day of the scan. It appears that the risk of death from anaesthesia may not routinely be discussed for outpatient MRI GA.
- Verbal consent/assent was obtained for the MRI scan.
- The referral and written consent processes take place at the same time. Imaging procedures such as MRI scanning do not require consent, and therefore the consent element only related to the anaesthetic.
- Consent for MRI GA had become part of the referral process, meaning that paediatricians were routinely taking consent for the anaesthetic at the point of referral.
- The consent and referral processes have been identified as a safety issue (see 5.1).

4.4 Pre-anaesthetic assessment process

4.4.1 The hospital's policy required all patients undergoing a general anaesthetic to attend a pre-assessment clinic prior to their procedure. This practice is not common to all hospitals; some may only provide a pre-anaesthetic assessment if the patient is having an operation.

4.4.2 National guidance provided by the Royal College of Anaesthetists (RCoA) states that trusts should have a local policy informing pre-anaesthetic assessment services. This guidance does not define which patients should undergo pre-anaesthetic assessment. The National Institute for Health and Care Excellence publishes guidance on pre-operative assessment, but this is only for adult patients with specified long-term health problems.

4.4.3 In the reference event, the pre-anaesthetic assessment clinic appointment was undertaken by a nurse qualified to care for adults (rather than a specialist children's nurse). The 'pre-operative assessment clinic' was overseen by a consultant anaesthetist whose role was to provide medical leadership and to review patients identified as needing further assessment.

4.4.4 The pre-anaesthetic assessment followed a set process. Alice's health history was taken, and her height and weight recorded. The investigation was told by staff in the clinic that physiological observations, such as heart rate and blood pressure, were not routinely measured in children unless the patient had a relevant history or was judged to be symptomatic (for example, they had chest pain or shortness of breath). Alice's mother pointed out that Alice had headaches and tired easily. However, these signs or symptoms were not commented on by the staff assessing Alice.

4.4.5 Similarly, the investigation was told that examinations such as listening to heart and lung sounds are not undertaken by nurses in the pre-anaesthetic assessment clinic. These examinations are also not routinely undertaken by doctors on the day of the procedure. They will only be carried out if the patient's history or signs and symptoms prompt this.

4.4.6 The investigation was given differing purposes for pre-anaesthetic assessment clinics. The medical and nursing staff running the clinic said it was "to reduce on-day cancellations [for procedures under anaesthetic]". However, anaesthetists at the hospital said it was to determine if patients were fit for anaesthetic. Senior staff at the Trust stated that both these purposes were recognised but do not exist in isolation or cancel one another out.

4.4.7 Patients may either be sent home following their assessment or remain in the clinic to be seen by the anaesthetist. The investigation was advised that between 15% and 20% of patients attending for pre-assessment are reviewed by the anaesthetist. Alice was not referred for review as her case did not trigger any concerns based on the assessment she received.

4.4.8 The RCoA published guidance on the need for trusts to have a policy for pre-assessment services (Royal College of Anaesthetists, 2019a). However, the guidance does not

describe the purpose of pre-assessment or detail which observations and examinations should be carried out.

4.4.9 The local policy at the hospital where Alice had her pre-anaesthetic assessment did not require children to have their heart rate, blood pressure and oxygen saturations taken unless the nurse considered this necessary. These were not recorded for Alice as her history did not raise concerns to the pre-assessment nurse.

4.4.10 The report 'Confidential Inquiry into premature deaths of people with learning disabilities (CIPOLD)' (Heslop et al., 2013) says that patients with additional needs should be 'flagged' [24] to alert healthcare staff of the potential need to make adjustments. Alice was referred from the paediatric team within the hospital (rather than her GP) and was not flagged as having additional needs. Alice also did not have a hospital passport or other form of advance care plan which staff in the pre-anaesthetic assessment clinic could refer to.

4.4.11 Alice's history of autism spectrum disorder (ASD) and learning difficulty was documented in her pre-anaesthetic assessment record but not the way this manifested itself in terms of behaviour and triggers of distress. The CIPOLD report notes that:

'Record-keeping was commonly deficient … little attention was given to predicting potential problems, e.g. when a person was fearful of contact with medical professionals.' (Heslop et al., 2013)

Alice was distressed at the pre-anaesthetic assessment clinic.

4.4.12 Alice's assessment was in keeping with local policy. There is no evidence to suggest that her underlying, undetected cardiomyopathy could have been identified even if physiological observations and physical examinations had been undertaken. It is possible that a paediatric cardiologist may have been able to detect subtle signs during a specialist examination but in the generalist context of a pre-anaesthetic assessment clinic it is unlikely to have been detectable.

4.4.13 Summary

- Alice did not have her physiological observations recorded and a physical examination was not undertaken in the pre-anaesthetic assessment clinic. These tests were not specified in the hospital's policy or in national guidance.
- An important purpose of pre-anaesthetic assessment was described by clinic staff as preventing procedures being cancelled on the day. It was understood by other hospital staff as an assessment of fitness for general anaesthetic.
- Alice's history of ASD and learning difficulties was documented. However, there was no documentation regarding potential reasonable adjustments that might be made to respond to her behaviour and triggers of distress.
- The lack of clarity regarding the purpose and content of pre-anaesthetic assessment is considered a safety issue (see 5.2).

4.5 MRI environment

4.5.1 The MRI scanner in the hospital in the reference event had been installed into an existing building [25]. This is common in older hospitals.

4.5.2 The two radiographers at the Trust who undertook Alice's scan had experience of working in other hospitals. They told the investigation that the MRI suite was "typical" and was in some ways more spacious and better laid out than others they had worked in.

4.5.3 During observations at the reference event hospital, the investigation saw two children having MRI scans under general anaesthetic. The investigation was able to see how the layout of the MRI suite influenced work in practice. The MRI scanning environment (including the anaesthetic area) did not cause problems with care delivery.

4.5.4 MRI scans are conducted by specially trained radiographers. One of the roles of the radiographers is to promote safety within the MRI suite. The national standards 'Safety in magnetic resonance imaging' (The Society and College of Radiographers and

the British Association of MR Radiographers, 2018) provide guidance on key safety considerations. These include the stability of the scanner itself and the prevention of ferrous (metallic) items being taken into the scanning room, which could cause harm to patients and/or staff or damage the scanner.

4.5.5 The radiographers reported that there was a strong team culture and that they felt confident to speak up if they saw anything clinically unsafe or identified any issues relating to safety involving the MRI scanner.

4.5.6 The radiographers told the investigation that they had no previous experience of a patient's condition deteriorating during an MRI scan in the way Alice's had. They described the sort of complications they were more familiar with, such as delayed waking from anaesthetic or patients vomiting excessively during the recovery period.

4.5.7 Summary

- The investigation found no evidence that the MRI environment was a contributory factor in the reference event or a safety issue.

4.6 MRI under general anaesthetic

4.6.1 The anaesthetic room in the MRI suite was in a multi-purpose preparation room (**'prep room'**). A lead operating department practitioner (ODP) provided overall leadership and accountability for its preparation.

4.6.2 The Royal College of Anaesthetists (RCoA) publishes guidance and standards regarding anaesthesia and sedation outside the operating theatre environment (Royal College of Anaesthetists, 2019b). The investigation referenced the standards to assess the anaesthetic environment in the hospital where the reference event occurred (see Appendix C).

4.6.3 The RCoA standards state:

> **'All anaesthetic equipment should be standardised where possible in all areas providing anaesthetic services, including equipment for resuscitation and life support, and such equipment subject to a standardised programme of maintenance.'** (Royal College of Anaesthetists, 2019b)

4.6.4 The anaesthetic equipment in the MRI suite necessarily varied from other anaesthetic equipment in the hospital as it needed to be **'MR safe'** or **'MR conditional'** [26]. The anaesthetic machine used while Alice's scan was in progress was **'MR conditional'**, meaning it had to be kept outside the MRI scan room.

4.6.5 The capnography circuits [27] and ventilator circuits [28] were extended in length, routed through a hole in the wall of the scanning room and connected to the anaesthetic machine. The investigation was advised by the anaesthetists that this was common practice in many hospitals.

4.6.6 The anaesthetic equipment used in the rest of the hospital automatically recorded observations in the patient's electronic anaesthetic chart (within their electronic care record). The equipment used in the MRI unit did not do this and required the anaesthetist to manually annotate a paper anaesthetic chart which they did at five-minute intervals. The clock on the anaesthetic machine was incorrect by 80 minutes, meaning that the anaesthetist had to recalculate the correct time with each set of observations he recorded.

HSIB notes the following safety action

Safety action A/2020/031:
The Trust where the reference event took place has undertaken to resolve the errors with the clocks on the MRI scanner and anaesthetic monitoring equipment.

4.6.7 The investigation was advised by consultant anaesthetists at the hospital that the anaesthetic equipment used did not affect in any way the choice of anaesthetic used for Alice.

4.6.8 The Association of Anaesthetists published guidance titled **'Safe provision of anaesthesia in magnetic resonance units'** (Association of Anaesthetists, 2019). This guidance outlines MRI-specific safety considerations for carrying out anaesthesia in the MRI setting, including leadership, training, equipment, supervision and risk assessment, and management. The guidance was followed by staff at the hospital in the reference event.

4.6.9 Anaesthetists can remain in the scanning room with patients who are under sedation or anaesthetic during MRI scans, if there is

a specific clinical need to do so [29] and they have suitably compatible equipment to take into the room. There was no identified need for an anaesthetist to be in the scanning room during Alice's scan, nor was there MRI compatible equipment available. The investigation was told by those involved in the reference event, and by the SMA (anaesthetics), that accompanying patients during MRI scanning is unusual for routine scans.

4.6.10 The RCoA guidance includes information on the special considerations required for paediatric patients, and includes the following statement:

'Children presenting for anaesthesia outside the operating room may present challenges relating to the procedure, the environment, or physical, physiological and psychological challenges. Children may often require repeat treatments or investigations ...'
(Royal College of Anaesthetists, 2019b)

4.6.11 The RCoA provides a voluntary accreditation scheme called ACSA (Anaesthesia Clinical Services Accreditation) (Royal College of Anaesthetists, 2019c). The hospital in the reference event is a member of the ACSA scheme and held a current accreditation at the time.

4.6.12 The anaesthetic environment within the MRI scanning suite did not appear to have contributed to the incident in the reference event, based on the published standards. However, nationally there is variation in the approach to equipping MRI suites for anaesthetics (see 5.4).

4.6.13 Summary

- The anaesthetic equipment used in the MRI suite differed from that used in the rest of the hospital as it needed to be MR conditional.
- The clocks on the MRI scanner and anaesthetic equipment were incorrect. The anaesthetist had to manually record observations and other timings during Alice's MRI scan.
- Guidance regarding the safe provision of anaesthetic while undertaking MRI scanning was followed.
- The hospital held the RCoA ACSA accreditation for anaesthetic services.

4.7 Decision to complete the MRI scan

4.7.1 Alice's condition deteriorated unexpectedly while she was under anaesthetic. The post-mortem report concluded that her collapse, which was triggered by the anaesthetic, was secondary to undiagnosed cardiomyopathy.

4.7.2 While anaesthetised, Alice had four separate events involving her heart rate. In the first episode her heart rate dropped (bradycardia), and on the other occasions her heart rate was abnormally fast (tachycardia). On each occasion, her heart rate was normalised, either using medication or a manual intervention.

4.7.3 During the management of the third episode of tachycardia, consideration was given to terminating the scan and waking Alice up. The investigation was told by the consultant anaesthetist that the decision was taken to continue with the scan due to previous resolution of the episodes of tachycardia, Alice's distress at being in hospital and the need to repeat the anaesthetic and MRI scan if it was aborted.

4.7.4 The investigation was told that a radiologist was available while imaging is taking place but that they are rarely contacted to assist with adverse events. The Royal College of Radiologists told the investigation that radiologists can provide guidance on the progress of imaging and decide whether a scan has sufficiently progressed to provide the diagnosis required. A radiologist was not contacted in the reference event.

4.7.5 On completion of her scan, Alice's condition was found to have deteriorated. Alice's cardiomyopathy was not known about at this point. The deterioration was initially attributed to a condition called malignant hyperthermia as Alice did have a raised temperature. This is an emergency which requires treatment to be urgently initiated. When it was established that malignant hyperthermia was not the cause, the treatment was ceased, and cardiovascular resuscitation, which had already commenced, continued.

4.7.6 There is no specific published guidance available to support clinicians with decision making regarding the termination of imaging, such as MRI, taking place under general

anaesthetic. It is therefore left to the clinical judgement and agreement of the anaesthetic team on a case-by-case basis. There is guidance in the Quick Reference Handbook published by the Association of Anaesthetists (Association of Anaesthetists, 2019) on the specific conditions (for example, bradycardia and tachycardia) and this was followed.

4.7.7 Summary

- There is no national guidance for terminating imaging procedures taking place under general anaesthetic. The investigation considered this to be a safety issue (see 5.4).

4.8 Response to deterioration

4.8.1 Once it was recognised that Alice's condition had deteriorated, escalation of her care was rapidly undertaken and specialist clinical input was summoned. A paediatrician was contacted initially and following their assessment the decision to escalate to critical care was agreed.

4.8.2 It was not possible to move Alice to a critical care environment for several hours due to her clinical instability. There was no paediatric intensive care facility at the local hospital and Alice was transferred to the adult intensive therapy unit in accordance with hospital policy.

4.8.3 The regional children's hospital was contacted and a specialist paediatric retrieval team was sent to bring Alice back to its paediatric intensive care unit. The investigation was told by the retrieval team that telephone contact for clinical advice and support was maintained between the local hospital and the retrieval team while the team was en route to the hospital.

4.8.4 When the retrieval team arrived at the local hospital, it worked alongside staff in the adult intensive therapy unit prior to transferring Alice to the regional children's hospital.

4.8.5 The investigation was told by the retrieval team members that they considered the management of Alice's deteriorating health to be appropriate. They reported good communication between the clinical teams throughout and the investigation heard that there were ongoing/real-time conversations with the retrieval team regarding Alice's evolving clinical condition. This was echoed by the senior clinical team at the local hospital.

4.8.6 Summary

- Internal escalation by the anaesthetic team was initiated rapidly following the detection of Alice's deteriorating condition at the end of the MRI scan.
- Alice remained in a critical condition but was stabilised to allow her to be transferred to the regional children's hospital.

4.9 Actions resulting from the Trust's internal investigation

4.9.1 The Trust's internal investigation resulted in several safety actions to reduce the risk of recurrence.

HSIB notes the following safety action

Safety action A/2020/031:
The Trust where the reference event took place has undertaken to resolve the errors with the clocks on the MRI scanner and anaesthetic monitoring equipment.

5 Analysis and findings from the wider investigation

This section lays out the investigation's findings in relation to the identified safety issues affecting patients having magnetic resonance imaging (MRI) scans under general anaesthetic (MRI GA).

5.1 Consent

5.1.1 The investigation was told by representatives of the Royal College of Anaesthetists (RCoA) that written consent for patients having an MRI scan under general anaesthetic is commonly obtained at the point of referral. Written consent is not usually required for diagnostic imaging [30], nor is it required for anaesthesia (Association of Anaesthetists, 2017).

5.1.2 The paediatrician makes the referral for a child to have an MRI scan under general anaesthetic. This involves two separate requests; one to the radiology department for the scan, and another to the anaesthetic department for the anaesthetic.

5.1.3 The investigation spoke to clinical staff and managers in several hospital trusts regarding the issue of consent. Staff reported that the request process for MRI GA is consistent with many other clinical scenarios, but the consent aspect differed, specifically when compared to obtaining consent for surgical procedures where the clinician carrying out the intervention takes written consent.

5.1.4 In children, consent is sought from the patient's parent(s) or guardian unless the child is able to demonstrate capacity to consent (see 1.6.2).

5.1.5 The Association of Anaesthetists (AoA) guidelines on consent state:

'A separate consent form, signed by the patient, is not required for anaesthetic procedures that are done to facilitate another treatment.'

However, the AoA guidelines relating to MRI scans state:

'For diagnostic scanning the only intervention is the anaesthetic; however, the referring clinician or radiologist is responsible for seeking formal written consent for the MR [MRI] scan itself, as (s)he will have discussed other options including not performing the imaging, and the impact on diagnosis and prognosis of that omission. The anaesthetist explains the anaesthesia to facilitate the scan, but currently this does not require separate written consent in addition to that taken for the scan.' (Association of Anaesthetists, 2019a)

Thus, written consent for MRI is not needed unless the scan requires a general anaesthetic in order to facilitate it. In this scenario, the guidance states that the consent is for the MRI scan, rather than the anaesthetic, despite the anaesthesia being the 'only intervention'.

5.1.6 There appeared to be a belief among referrers interviewed that MRI GA was a discrete procedure requiring written consent. In reality, it comprises two separate procedures, one being the MRI scan and the other being the general anaesthetic. Neither of these require written consent if undertaken in isolation but do require verbal consent.

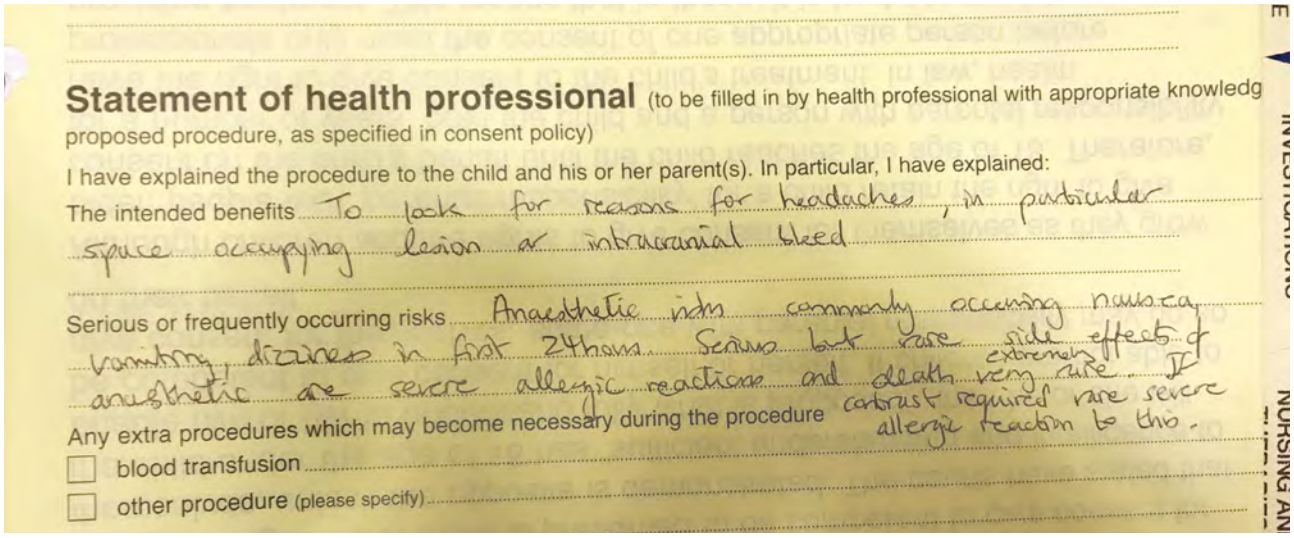
5.1.7 Evidence gathered by the investigation identified that there appeared to be confusion regarding which aspect of MRI GA consent was being sought for. During observation visits to other hospitals the investigation saw examples of completed consent forms (Figure 5 and Figure 6). There was variation between consent forms completed by different doctors in the same trust. It was clear from speaking with clinicians during observation visits that some referrers believed they were gaining consent for the anaesthetic as well as the MRI scan.

5.1.8 Referring clinicians interviewed cited reasons why they take written consent for MRI GA. These included organisational policy, adopted good practice from other trusts, or a perception that MRI GA was a single procedure requiring consent.

5.1.9 The Department of Health and Social Care (DHSC) guidance on consent states:

'The clinician providing the treatment or investigation is responsible for ensuring that the person has given valid consent before treatment begins, although the consultant responsible for the person's care will remain ultimately responsible for the quality of medical care provided. The GMC [General Medical Council]

Fig 5 Consent form example seen during observation visit with detailed information on anaesthetic risks



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

I have explained the procedure to the child and his or her parent(s). In particular, I have explained:

The intended benefits To look for reasons for headaches, in particular space occupying lesion or intracranial bleed

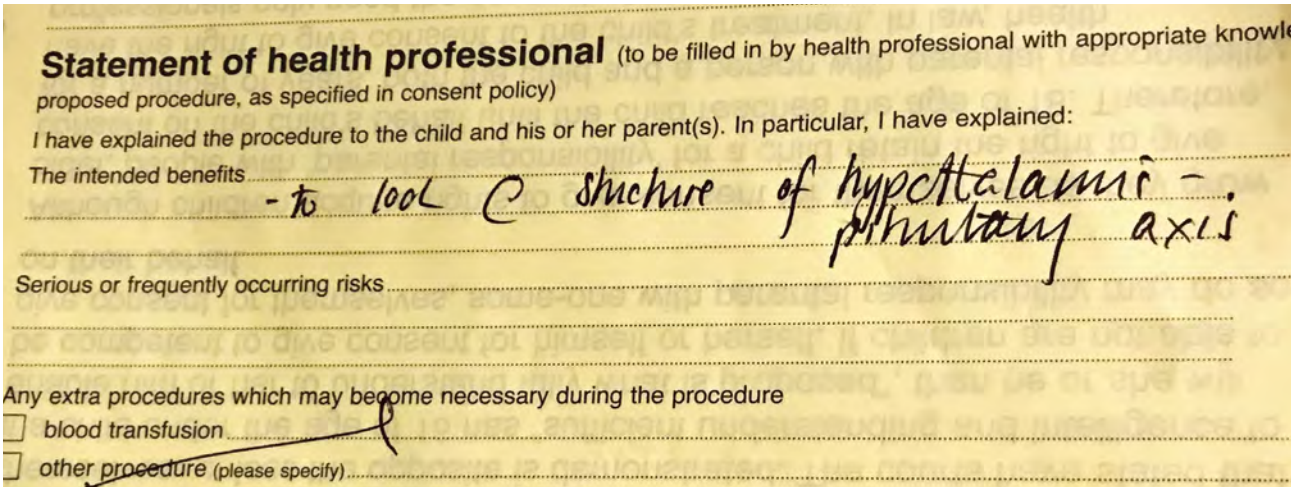
Serious or frequently occurring risks Anaesthetic risks commonly occuring nausea, vomiting, dizziness in first 24hours. Serious but rare side effects of anaesthetic are severe allergic reactions and death extremely rare. If contrast required rare severe allergic reaction to this.

Any extra procedures which may become necessary during the procedure

☐ blood transfusion

☐ other procedure (please specify)

Fig 6 Consent form example seen during observation visit with no information on anaesthetic risks



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

I have explained the procedure to the child and his or her parent(s). In particular, I have explained:

The intended benefits - to look @ structure of hypothalamic - pituitary axis

Serious or frequently occurring risks

Any extra procedures which may become necessary during the procedure

☐ blood transfusion

☐ other procedure (please specify)

guidance states that the task of seeking consent may be delegated to another person, as long as they are suitably trained and qualified.

In particular, they must have sufficient knowledge of the proposed investigation or treatment, and understand the risks involved, in order to be able to provide any information the patient may require.'
(Department of Health, 2009)

In relation to seeking consent for anaesthetic, the guidance states that the clinician taking consent should have this task delegated to them. They must also be suitably trained and have knowledge and experience such that they can provide the patient/family with any information they request.

5.1.10 DHSC guidance implies that it would not be appropriate for a paediatrician to obtain consent for a general anaesthetic unless they meet the requirements (as stated in 5.1.9). The DHSC guidance supports the AoA guidance that consent obtained by referrers is solely for the MRI scan. However, if the referring clinician is not taking written consent for the anaesthetic at the time of the referral for the MRI, this means that consent for this intervention would only be sought on the day of the procedure, immediately prior to the anaesthesia.

5.1.11 Guidance published by the DHSC (Department of Health, 2009), which cites the guidance issued by the General Medical Council, states that consent should be an ongoing process and patients should have time to assimilate information to assist with making an informed decision about their care.

'You should see getting their consent as an important part of the process of discussion and decision-making, rather than as something that happens in isolation.' (General Medical Council, 2008)

5.1.12 During observation visits, the investigation sought anaesthetists' views on whether the referring paediatrician was taking consent for the anaesthetic or solely for the scan, as the AoA guidance suggests. Overall, there was a perception that the consent process for the anaesthetic was commenced by the referrer.

5.1.13 As one senior anaesthetist said:

"We need to know that a benefit/risk assessment has been done by the referring consultant, [that is, the risk of the general anaesthetic compared to the clinical benefit of the MRI] and we have agreed that by receiving this consent form and referral, this has been done."

5.1.14 The investigation was told by anaesthetists during observation visits that the practice of consent being taken by referrers (non-anaesthetists), and the short time available for anaesthetists to assess patients on the day of the MRI scan, meant that there was limited assurance that patients/parents understood the risks of the anaesthetic.

5.1.15 The Head of Patient Safety at one trust told the investigation that "the issue regarding consent has come up regularly over the last 10 years in terms of who should be taking consent for GA" and that "improvements and clarification would be very helpful".

5.1.16 The RCoA said that the practice of written consent being sought by referring clinicians, and the lack of clarity regarding the medico-legal position, left anaesthetists in a potentially vulnerable position. In addition, it means patients may not be given the opportunities to make an informed decision about the risks of anaesthesia. These concerns were echoed by the investigation's subject matter advisor (SMA) for anaesthetics who stated that MRI GA typifies the issues associated with anaesthetics used for diagnostics.

5.1.17 The SMA (anaesthetics) and representatives from the RCoA expressed concern regarding an anaesthetist not being involved in, or influencing, the consent process prior to the day of the procedure. Suggestions were given during these discussions to help mitigate this risk, such as a two-part consent form; pre-agreed written information regarding risks which the referrer would include in their consent discussion; and providing a patient advice leaflet.

5.1.18 Summary

- Written consent is not usually required for diagnostic imaging nor is it required for anaesthesia specifically when undertaken prior to a surgical procedure.
- There is a gap between national guidance and practice regarding obtaining written consent when referring patients for MRI scans under general anaesthetic.
- There is variation in the information given to patients regarding anaesthesia at the point of referral.

HSIB makes the following safety recommendation

Safety recommendation R/2020/079:
It is recommended that the Royal College of Anaesthetists convenes a working group to provide additional guidance regarding the responsibilities for obtaining consent for MRI and other non-invasive diagnostic and/or therapeutic procedures under general anaesthetic in children.

5.2 Pre-anaesthetic assessment

5.2.1 The content of pre-anaesthetic assessment is not set nationally. As with the findings from the reference event, nursing and medical staff told the investigation during observation visits that pre-anaesthetic assessment is used to prevent on-day cancellations of procedures, for example, by providing patients with information on fasting. Other staff suggested that the pre-anaesthetic assessment process was intended to identify patients who were not fit for an anaesthetic.

5.2.2 A theme from interviews with staff was that they perceived children coming into hospital as a day-case (i.e. not planned to have an overnight stay), such as for MRI GA, as being "well". Commenting on this, the representative from the Association of Paediatric

Anaesthetists of Great Britain and Ireland stated that by definition **"no child undergoing MRI is well"**, albeit that they may be fit for anaesthetic. He said this perception of wellness is unhelpful given the risks associated with any anaesthetic. Furthermore, many patients may appear outwardly well, yet if they are having an MRI scan, it is for a potentially serious condition. Added to which, as in the reference event, there is always the potential for the existence of an underlying, undiagnosed pathology without obvious signs and symptoms.

5.2.3 The perception of wellness was reflected in a comment made by one of the day-unit nurses spoken with during an observation visit. Her role involved the admission of children on the day of their scan. She said that she **"knows nothing about them before they arrive"** and that these children are **"coming in** [to hospital] **well"**.

5.2.4 The approach to pre-anaesthetic assessment for day-case procedures under general anaesthetic (including MRI scanning) varied among the different hospitals visited by the investigation. For example, some hospitals assessed all patients in a clinic, others undertook telephone-based assessment. One hospital did not undertake any form of pre-anaesthetic assessment, relying on information received from the referrer; information about fasting was sent to the patient as part of their admission letter. In all cases, a final decision about suitability for general anaesthetic is made on the day of the procedure by the anaesthetist.

5.2.5 Guidance published by the RCoA states that **'assessment should be standardised and consist of establishing a rapport with the patient, followed by the gathering of information to establish the patient's medical, nursing and social needs in the perioperative period** [before, during and after an operation]' (Royal College of Anaesthetists, 2019a). During observation visits, the investigation found that at an organisational level trusts did have local policies, in line with the guidance, but there was variation regarding the purpose and intent of pre-anaesthetic assessment, and how this should inform care on the day of the procedure.

5.2.6 RCoA guidance states that pre-anaesthetic assessment clinics should have an **'examination couch and equipment such as computers, scales for measuring height and weight, blood pressure, pulse oximeter and electrocardiography machines'** (Royal College of Anaesthetists, 2019a). However, the guidance does not state which observations should be undertaken for which patients. As in the reference event, there is variation regarding the observations and examinations undertaken in child and adult patients. Overall, more detailed assessments are undertaken in adult patients, particularly those with known pre-existing conditions.

5.2.7 The National Institute for Health and Care Excellence (NICE) guidance **'Routine preoperative tests for elective surgery'** (NG45) (National Institute for Health and Care Excellence, 2016) advises clinicians to avoid unnecessary investigations. It does not include guidance on basic physiological measurements that should be taken routinely in pre-anaesthetic/pre-operative assessment, such as for patients undergoing MRI scanning under general anaesthetic.

5.2.8 Similarly, guidance from the AoA does not state which investigations and examinations should be undertaken routinely and says this should be determined locally and based on individual patient factors:

'History and examination performed by appropriately trained and competent personnel remains the most efficient and accurate way of initially detecting significant morbidity. Local departmental protocols should determine which additional tests should be used based upon patient age, comorbidity and complexity of the surgery.' (Association of Anaesthetists, 2010).

5.2.9 If a standard set of observations was taken routinely in the pre-anaesthetic assessment clinic this would provide a baseline. This could be referred to on the day of the procedure and inform decisions regarding whether further assessment and monitoring was required.

5.2.10 The investigation was told by the SMA (anaesthetics) that it can be challenging to obtain accurate observations in patients who are distressed. These patients may include very young children, or those who are developing differently (for example those with autism or a learning disability). The SMA (anaesthetics)

told the investigation that while such patients may not co-operate, this should never be assumed and there should be an attempt to obtain these important observations. Input from a learning disability specialist may assist staff in obtaining these observations (see 5.3).

5.2.11 Summary

- The observations and examinations to be carried out routinely in pre-anaesthetic assessment are not defined nationally. The investigation found variation in the hospitals visited.
- A theme from interviews with staff was that they perceived children coming into hospital as a day-case who had attended pre-anaesthetic assessment as being "well".

HSIB makes the following safety recommendation

Safety recommendation R/2020/080:
It is recommended that the Royal College of Anaesthetists reviews standards for pre-assessment services, including their purpose, the required observations and examinations, and competencies of staff undertaking this work.

5.3 Adjustments for children who are developing differently

5.3.1 The Disability Discrimination Act (1995) (UK Government, 1995) and the Equality Act (2010) (UK Government, 2010) includes a requirement for organisations to make reasonable adjustments for people with disabilities. Reasonable adjustments must be made if the individual affected would be placed at a disadvantage if the adjustments were not made.

5.3.2 The report 'Confidential inquiry into premature deaths of people with learning disabilities (CIPOLD)' states:

'The lack of reasonable adjustments to facilitate healthcare of people with learning disabilities, particularly attendance at clinic appointments and investigations, was a contributory factor in a number of deaths. GP referrals commonly did not mention learning disabilities, and hospital 'flagging' systems to identify people with learning disabilities who needed reasonable adjustments were limited.' (Heslop et al., 2013)

5.3.3 The potential for clinical environments to cause distress to some patients means that staff may not look for alternative explanations for abnormal observations. This is known as 'diagnostic overshadowing'.

5.3.4 Diagnostic overshadowing can also happen if healthcare professionals make assumptions that a person's behaviour is a part of their disability without exploring other reasons (Blair, 2017).

5.3.5 Children who are developing differently, as well as adults with diagnoses of autism, learning disability or learning difficulties, often find hospitals and clinical environments distressing. This may be reflected in their physiological observations, for example anxiety can cause a raised heart rate or blood pressure and may lead to diagnostic overshadowing.

5.3.6 Having prior information about patients who have additional needs may help mitigate the risk of diagnostic overshadowing. The investigation was told that "the biggest risk [is] assuming everything is down to their LD/ASD [learning difficulty/autism spectrum disorder]. For example, worsening behaviour is [attributed] to ASD, but it could be pain or hypoglycaemia".

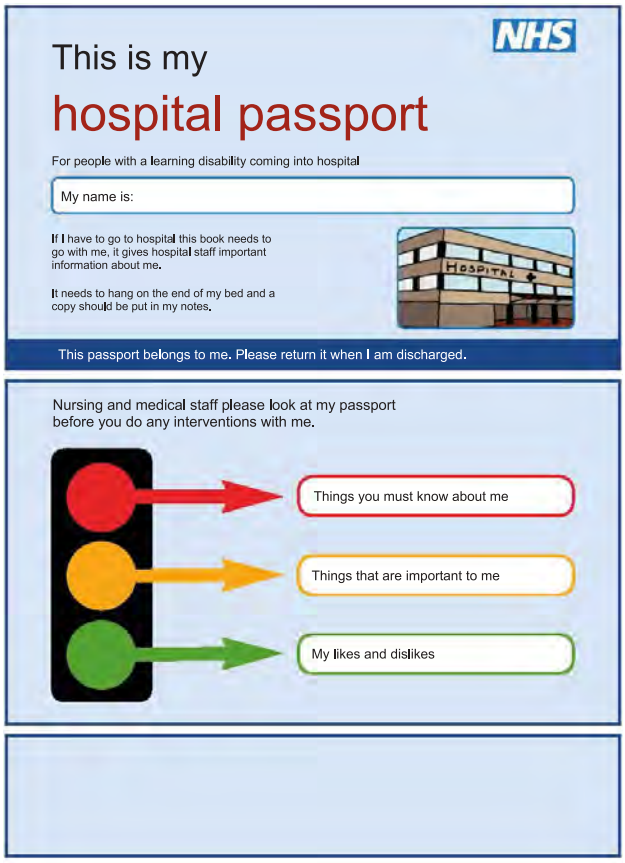
5.3.7 The investigation spoke with the parents of two young people who had autism. These Experts by Lived Experience (EbLEs) told their stories of the care their children had received. Each gave examples of good experiences and examples where they believed there could have been improvements.

5.3.8 One EbLE explained that their daughter needed an operation on her knee. The hospital used a system where each patient who had additional needs or was developing differently was given a 'hospital passport'. This document provides a single point of reference where key information can be recorded and shared with healthcare providers, and from which reasonable adjustments can be planned for the day of the patient's admission.

5.3.9 Hospital passports were developed as a result of the white paper 'Valuing people' (Department of Health, 2001) and are now the accepted tool to assist hospital staff to better understand the individual needs of autistic people or those who have a learning disability.

5.3.10 Hospital passports may differ in design, layout and content (see Figure 7 for an example), but all seek to assure that the person's often highly complex needs are understood, and can guide the reasonable adjustments that need to be made for them.

Fig 7 Front page of a hospital passport (full example can be found in Appendix D)



Hospital staff can read the contents of the passport and make adjustments to the environment, time of admission, and the methods of communication used with the patient.

5.3.11 The investigation visited the hospital referred to by the EbLE. The Learning Disabilities Liaison Team, managers and ward staff spoke about the use of hospital passports and the practice of flagging patients with additional needs. Redacted examples of passport documents were shown to the investigation, and the flagging (alerting) system was also demonstrated (Figure 8, Figure 9). This flagging system was linked to the internal electronic patient records system only and did not communicate with primary care or other external organisations such as mental health trusts.

Fig 8 Example of flagging/alert used in a trust visited by the investigation

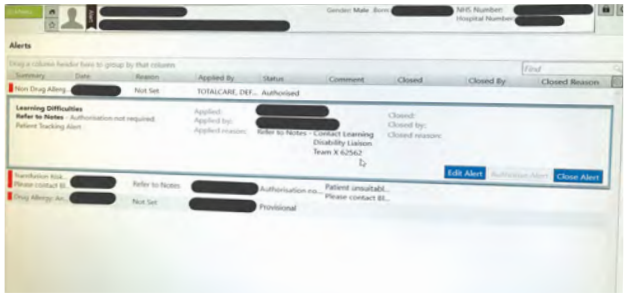
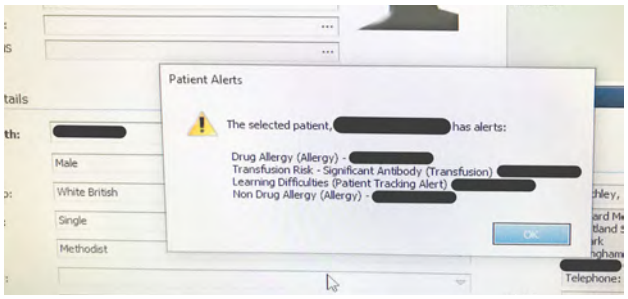


Fig 9 Example of 'pop-up' flag/alert



5.3.12 Nursing staff spoken to during an observation visit who used the flagging system and hospital passports said they were "**extremely helpful and improved patient care and safety**". An example was shared regarding a patient who requested a portable radio, which would normally not be allowed as the ward was used for neurological patients. As the patient was in a side room and the hospital passport explained that the radio helped the patient to remain calm, the request was fulfilled.

5.3.13 One nurse told the investigation that alerts (flagging) and hospital passports "**save time**" and that you have to "**take time to save time**". He explained that making reasonable adjustments to optimise a patient's wellbeing results in greater satisfaction levels and can improve individuals' outcomes. He also said that they are quicker in the long run than trying to resolve situations which can occur in the absence of adjustments.

5.3.14 The CIPOLD report (Heslop et al., 2013) states that GP referrals and hospital systems '**did not routinely 'flag' people with learning disabilities who might need reasonable adjustments made for them**'. The investigation found that systems for flagging patients, either when being referred from primary care, or between departments within secondary care, was variable. The Summary Care Records

[31] on the NHS's digital network Spine can be accessed in both primary and secondary care settings, so could provide a mechanism for flagging patients with additional needs. The investigation was made aware of a pilot scheme to assess the functionality of a flagging system within one geographical area. However, this pilot does not include a template for, or sharing of, a hospital passport within the Summary Care Record.

5.3.15 NICE guidance (CG170) details adjustments that may be made to optimise care environments for children and young people with autism:

- "providing visual supports, for example, words, pictures or symbols that are meaningful for the child or young person
- making reasonable adjustments or adaptations to the amount of personal space given
- considering individual sensory sensitivities to lighting, noise levels and the colour of walls and furnishings."

(National Institute for Health and Care Excellence, 2013)

5.3.16 Members of the Learning Disability (LD) Liaison Team at one trust told the investigation of the importance of their role in co-ordinating care for patients coming into hospital. They also spoke about the wider aspects of their role, such as providing education for staff. Education provided by that team covered reasonable adjustments, awareness of the different conditions, and the use of hospital passports.

5.3.17 The investigation observed that the availability of LD liaison teams was inconsistent across the trusts visited. This included variations in age limits for accepting referrals, the size of LD teams and availability of these teams. This echoed the findings in the Royal College of Nursing's 'Connect for change' report (Royal College of Nursing, 2016). Data from the first year of 'The learning disability improvements standards for NHS trusts' shows that 55% of acute hospital trusts directly employ acute liaison nurses (NHS England/Improvement, 2019). The NHS Long Term Plan (NHS England, 2019) focuses on tackling health inequalities and aims to increase uptake of 'annual health checks' and increase the number of LD liaison nurses.

5.3.18 The investigation found that there was no national guidance which informed a standardised model of care or work plans for LD teams. Hence, there was variation reported in aspects such as the amount of direct patient input, referral management, staff education/leadership, and co-ordination of patients coming into hospital. Learning generated from policy documents over the past 10 years suggests the need for a competency framework for practitioners working in LD teams.

5.3.19 The CIPOLD report states that 'reviews found little evidence that reasonable adjustments were being made for people with learning disabilities on a day-to-day basis' (Heslop et al., 2013). Subsequently, the Learning Disabilities Mortality Review programme report found that the 'good practice demonstrated by ward staff and the Learning Disability Liaison Nurse service needs to be replicated across other services. The examples of best practice as evidenced in this review will be shared' (University of Bristol, 2019).

5.3.20 The investigation heard examples of adjustments being made. One example was given by staff in an MRI suite who described making adjustments for a patient who found waiting rooms and waiting for procedures extremely distressing. They were able to arrange a preferred time for the procedure to start and allowed the patient's carer to bring them directly into the scanning area through a fire exit, thus avoiding the waiting room. In this example, the co-ordination of patients with additional needs was organised by a radiography assistant practitioner who had taken on this additional responsibility as part of their role. They were not overseen or supported by the trust's LD team.

5.3.21 An SMA who works with children with autism and learning disabilities told the investigation that "hospitals appeared to operate in a default mode". This means that staff in mainstream health services may fail to recognise the additional needs of patients with autism or who have a learning disability and may not apply the necessary reasonable adjustments the patients need.

5.3.22 A Learning Disability Acute Liaison Nurse at one trust said that there are "huge gaps in service for patients with autism who do not have a diagnosis of a learning disability".

This was reflected in a meeting with LD nurse consultants who agreed that nationally services for patients varied depending on whether the patient had a formal diagnosis, particularly in older children.

5.3.23 Summary

- Children who are developing differently often find clinical environments distressing, which may be reflected in their physiological observations. This may result in diagnostic overshadowing.
- Children who are developing differently may require, and are entitled to, reasonable adjustments being made when attending hospital.
- Flagging patients and using hospital passports may support staff in making timely and responsive interventions tailored as reasonable adjustments to effectively meet the person's needs.
- There is no national guidance to inform a standardised model of care or work plan for learning disability teams.

HSIB makes the following safety recommendations

Safety recommendation R/2020/081:
It is recommended that NHS England and NHS Improvement strengthens its 'Learning disability improvement standards for NHS trusts' by including metrics which enable organisations to assess their progress against the outcomes for specialist learning disability teams.

Safety recommendation R/2020/082:
It is recommended that as part of the work to support the NHS Long Term Plan, NHS England and NHS Improvement should develop a role and competency framework for learning disability liaison nurses, to ensure that people with learning disabilities and autistic people receive optimal care which respects and protects their rights.

Safety recommendation R/2020/083:
It is recommended that NHSX develops a system for sharing care plans for patients with autism, learning disabilities or learning difficulties to enable reasonable adjustments to be made.

Safety recommendation R/2020/084:
It is recommended that NHSX develops a standardised care passport, which should include sections to support patients with autism, learning disabilities or learning difficulties.

5.4 Preparing for unexpected adverse events

5.4.1 Serious complications in patients who are anaesthetised for MRI scanning are rare. This is particularly true in the context of children attending as a day-case.

5.4.2 Staff in MRI suites told the investigation that unexpected deterioration was very unusual in their experience and usually occurred when the patient had a known underlying condition. None of the staff interviewed during reference event or during observation visits had experienced a scenario similar to that in the reference event.

5.4.3 Guidance for invasive procedures requiring a general anaesthetic is considered within the National Safety Standards for Invasive Procedures (NatSSIP). NatSSIPs defines an invasive procedure as:

- 'Making a cut or a hole to gain access to the inside of a patient's body – for example, when carrying out an operation or inserting a tube into a blood vessel, or
- Gaining access to a body cavity (such as the digestive system, lungs, womb or bladder) without cutting into the body – for example, examining or carrying out treatment on the inside of the stomach using an instrument inserted via the mouth, or
- Using electromagnetic radiation (which includes X-rays, lasers, gamma-rays and ultraviolet light) – for example, using a laser to treat eye problems.' (NHS England, 2015)

5.4.4 General anaesthesia to facilitate MRI scanning does not meet these criteria (see 5.4.5), and does not meet the extended criteria used in the NatSSIP guidance:

- 'All surgical and interventional procedures performed in operating theatres, outpatient treatment areas, labour ward delivery rooms, and other procedural areas within an organisation.

- Surgical repair of episiotomy or genital tract trauma associated with vaginal delivery.
- Invasive cardiological procedures such as cardiac catheterisation, angioplasty and stent insertion.
- Endoscopic procedures such as gastroscopy and colonoscopy.
- Interventional radiological procedures.
- Thoracic interventions such as bronchoscopy and the insertion of chest drains.
- Biopsies and other invasive tissue sampling.' (NHS England, 2015)

5.4.5 NatSSIPs specifically excludes minimally invasive procedures such as the insertion of cannulae or airway adjuncts [32]:

"It is not intended that NatSSIPs and LocSSIPs [Local Safety Standards for Invasive Procedures, which are developed by individual trusts and are used where relevant invasive procedures are carried out in that organisation] address procedures that involve the simple penetration of the skin or entry of a body cavity, such as the insertion of an intravenous line ..." (NHS England, 2015)

5.4.6 When a general anaesthetic is given to facilitate a procedure that does not meet the NatSSIP criteria, such as MRI scanning under general anaesthetic, the anaesthesia may be considered as an invasive procedure in its own right, as the risk of the anaesthetic exceeds the risks of the procedure being facilitated (see 5.1.5).

5.4.7 For invasive procedures, it is expected that local safety standards are developed, based on the NatSSIP guidance. These safety standards are intended to provide additional safeguards.

5.4.8 Local Safety Standards for Invasive Procedures (LocSSIPs) are only required where the procedure being carried out meets the NatSSIPs criteria. MRI GA is not included in the NatSSIP criteria, therefore LocSSIPs are not required.

5.4.9 The Association of Anaesthetists (AoA) produces a 'Quick reference handbook' (QRH). This online handbook contains guidance intended to assist anaesthetic teams to prepare for, and respond to, emergencies and adverse events (see Appendix E for a list of its contents). The QRH does not currently include specific guidance on the management of emergencies which occur in settings such as MRI scanners but does provide guidance on emergencies.

5.4.10 There was variation among staff regarding their knowledge and awareness of the guidance by the Royal College of Anaesthetists and other professional associations. The investigation was told by the Association of Anaesthetists that they have concerns about the implementation of theirs and others' published guidance.

5.4.11 In addition to the QRH, the investigation was advised by the SMA (anaesthetics) of the value of professional networks in sharing learning, including following adverse events. One anaesthetist interviewed who belonged to a professional network within their region, described how discussions at the network meetings promoted consensus and consistency in practice. The RCoA and the SMA (anaesthetics) said that "adequately resourced" networks were beneficial for increasing consistency in practice across regions.

5.4.12 The lead for professional standards at the RCoA said:

"Professional networks are an invaluable tool to standardise and optimise medical care across the NHS. The proposed Operational Delivery Networks (ODNs) [33] for paediatric critical care and surgery in children should include all procedures, interventions and investigations that require children to receive sedation or general anaesthesia. Examples of which include: radiological interventions, radiotherapy and proton beam therapy."

5.4.13 The RCoA administers a voluntary accreditation scheme called Anaesthesia Clinical Standards Accreditation (ACSA). The ACSA scheme publishes standards against which trusts can self-assess and submit their results to the RCoA. The ACSA standards include declarations regarding the provision of policies and procedure which cover aspects of care (such as handover and resuscitation). There is a specific ACSA standard for anaesthetics undertaken in non-

theatre settings which requires 'policies for the anaesthetic management of adults and children in remote sites e.g. radiology, MRI suites, endoscopy'.

5.4.14 The RCoA told the investigation that only 63% of NHS trusts in the UK are registered with the ACSA scheme and of these around one third of anaesthetic departments have progressed to full accreditation. The scheme is supported by the Care Quality Commission. Within the independent sector, fewer than 1% of hospitals are registered and only one independent sector hospital that provides some NHS-funded services is accredited by the ACSA scheme.

5.4.15 Anaesthetic and monitoring equipment used in MRI scanning environments differ from those used in other settings, such as operating theatres, due to the electromagnetic field that the MRI scanner generates. The RCoA guidance states:

'All anaesthetic equipment should be standardised where possible in all areas providing anaesthetic services, including equipment for resuscitation and life support, and such equipment subject to a standardised programme of maintenance.'
(Royal College of Anaesthetists, 2019b)

Due to the requirement for anaesthetic machines to be MR safe or MR conditional (see 4.6.4), it may not be possible for trusts to comply with this aspect of the guidance (for example, due to the additional expense of MRI-specific equipment).

5.4.16 Summary

- Medical emergencies are rare during MRI scanning under general anaesthetic.
- General anaesthesia for MRI scanning is not considered an invasive procedure within the National Safety Standards for Invasive Procedures.
- The Association of Anaesthetists' 'Quick reference handbook' does not include specific guidance on emergencies specifically arising during MRI GA.
- Professional bodies and associations publish guidance to support anaesthetists, but this may not be consistently adopted in practice.
- Professional networks may be beneficial for sharing learning and consensus regarding best practice among anaesthetists.
- Equipment standards for anaesthetic machines and monitoring do not fully consider the particular requirements of MRI environments.

HSIB makes the following safety recommendation

Safety recommendation R/2020/085:
It is recommended that the Centre for Perioperative Care considers the remit of the National Safety Standards for Invasive Procedures (NatSSIPs) to cover the administration of general or regional anaesthesia for non-invasive diagnostic procedures.

Safety recommendation R/2020/086:
It is recommended that the Association of Anaesthetists reviews the dissemination and implementation of its 'Quick reference handbook' on managing adverse events during anaesthesia.

HSIB makes the following safety observation

Safety observation O/2020/065:
There are likely to be benefits for all organisations delivering anaesthesia to gain Anaesthesia Clinical Services Accreditation (ACSA) as this is likely to reduce unwarranted variation in practice.

HSIB notes the following safety actions

Safety action A/2020/030:
The recommendation for standardised anaesthetic equipment in the Royal College of Anaesthetists' 'Guidelines for the provision of anaesthetic services' is challenging within the MRI environment given the need for MR-safe/MR-conditional equipment. The Royal College of Anaesthetists has clarified this recommendation accordingly.

Safety action A/2020/031:
The Trust where the reference event took place has undertaken to resolve the errors with the clocks on the MRI scanner and anaesthetic monitoring equipment.

6 Summary of findings, safety recommendations, safety observation and safety actions

6.1 Findings

The investigation identified:

- There is an opportunity to clarify the consent requirements for diagnostic imaging facilitated by a general anaesthetic.
- There is variation in the information given to patients regarding anaesthesia at the point of referral for a magnetic resonance imaging (MRI) scan under general anaesthetic.
- The observations and examinations to be routinely performed in pre-anaesthetic assessment are not defined nationally. The investigation observed variation in the hospitals visited.
- Children coming into hospital for an MRI scan, who had been assessed as fit for anaesthetic, were perceived as "well" by staff.
- Children who are developing differently often find clinical environments distressing which may be reflected in their physiological observations. This may result in diagnostic overshadowing.
- Children who are developing differently may benefit from reasonable adjustments being made when attending hospital.
- Electronic flagging systems can help staff identify patients who may benefit from reasonable adjustments. Hospital passports provide valuable information to assist with implementation of these adjustments.
- The model of care for learning disability nursing teams is not standardised nationally.
- There is an opportunity to enhance the dissemination and implementation of guidance published to assist clinicians to prepare for adverse events in the MRI scanning environment.
- Professional networks for anaesthetists provide the opportunity for shared learning and consensus regarding best practice.
- It is challenging to fully comply with the existing standards for anaesthetic equipment used in MRI environments.

HSIB makes the following safety recommendations

Safety recommendation R/2020/079:
It is recommended that the Royal College of Anaesthetists convenes a working group to provide additional guidance regarding the responsibilities for obtaining consent for MRI and other non-invasive diagnostic and/or therapeutic procedures under general anaesthetic in children.

Safety recommendation R/2020/080:
It is recommended that the Royal College of Anaesthetists reviews standards for pre-assessment services, including their purpose, the required observations and examinations, and competencies of staff undertaking this work.

Safety recommendation R/2020/081:
It is recommended that NHS England and NHS Improvement strengthens its 'Learning disability improvement standards for NHS trusts' by including metrics which enable organisations to assess their progress against the outcomes for specialist learning disability teams.

Safety recommendation R/2020/082:
It is recommended that as part of the work to support the NHS Long Term Plan, NHS England and NHS Improvement should develop a role and competency framework for learning disability liaison nurses, to ensure that people with learning disabilities and autistic people receive optimal care which respects and protects their rights.

Safety recommendation R/2020/083:
It is recommended that NHSX develops a system for sharing care plans for patients with autism, learning disabilities or learning difficulties to enable reasonable adjustments to be made.

Safety recommendation R/2020/084:
It is recommended that NHSX develops a standardised care passport, which should include sections to support patients with autism, learning disabilities or learning difficulties.

Safety recommendation R/2020/085:
It is recommended that the Centre for Perioperative Care considers the remit of the National Safety Standards for Invasive Procedures (NatSSIPs) to cover the administration of general or regional anaesthesia for non-invasive diagnostic procedures.

Safety recommendation R/2020/086:
It is recommended that the Association of Anaesthetists reviews the dissemination and implementation of its 'Quick reference handbook' on managing adverse events during anaesthesia.

HSIB makes the following safety observation

Safety observation O/2020/065:
There are likely to be benefits for all organisations delivering anaesthesia to gain Anaesthesia Clinical Services Accreditation (ACSA) as this is likely to reduce unwarranted variation in practice.

HSIB notes the following safety actions

Safety action A/2020/030:
The recommendation for standardised anaesthetic equipment in the Royal College of Anaesthetists' 'Guidelines for the provision of anaesthetic services' is challenging within the MRI environment given the need for MR-safe/MR-conditional equipment. The Royal College of Anaesthetists has clarified this recommendation accordingly.

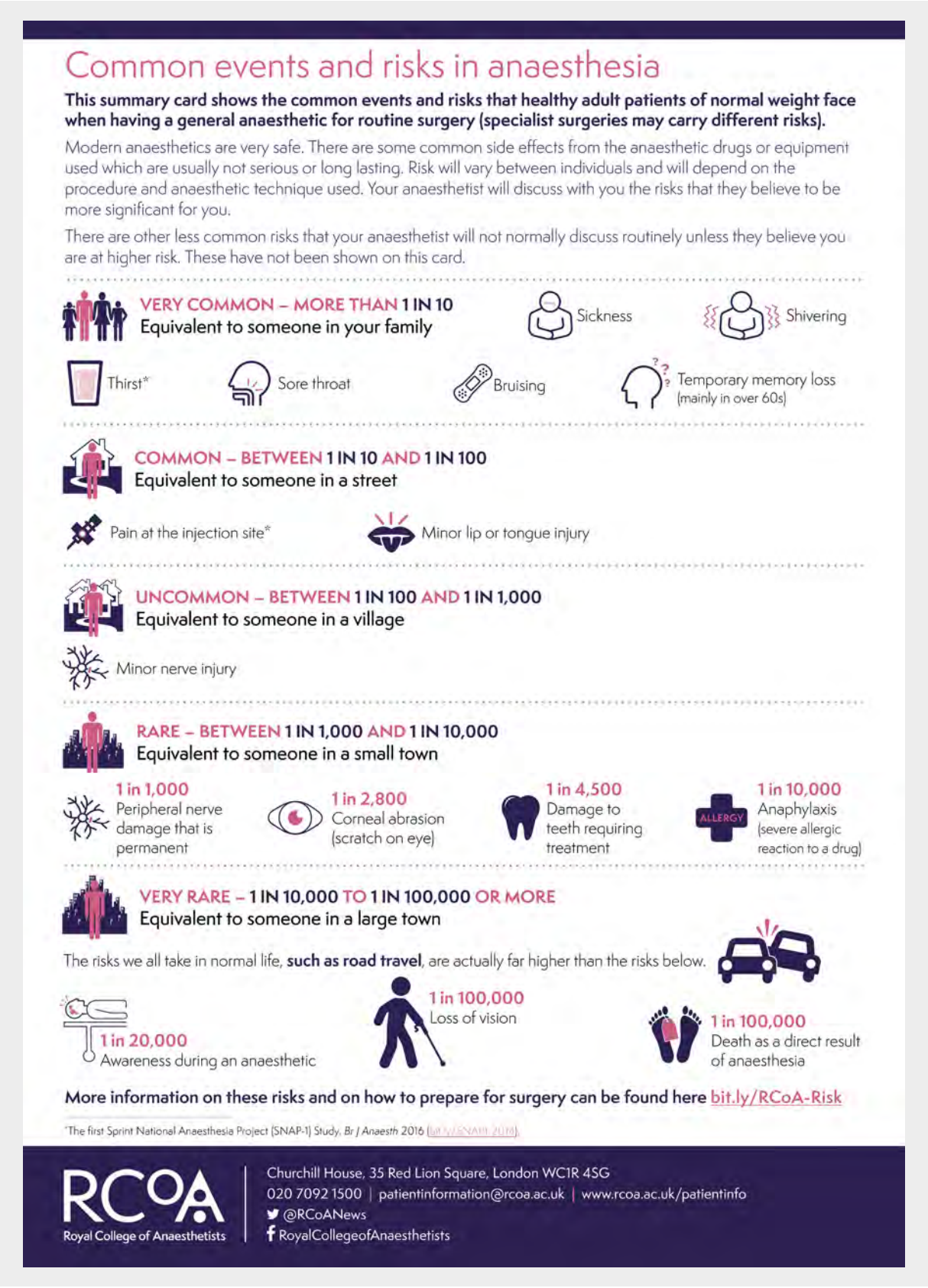
Safety action A/2020/031:
The Trust where the reference event took place has undertaken to resolve the errors with the clocks on the MRI scanner and anaesthetic monitoring equipment.

7 Appendices

Appendix A

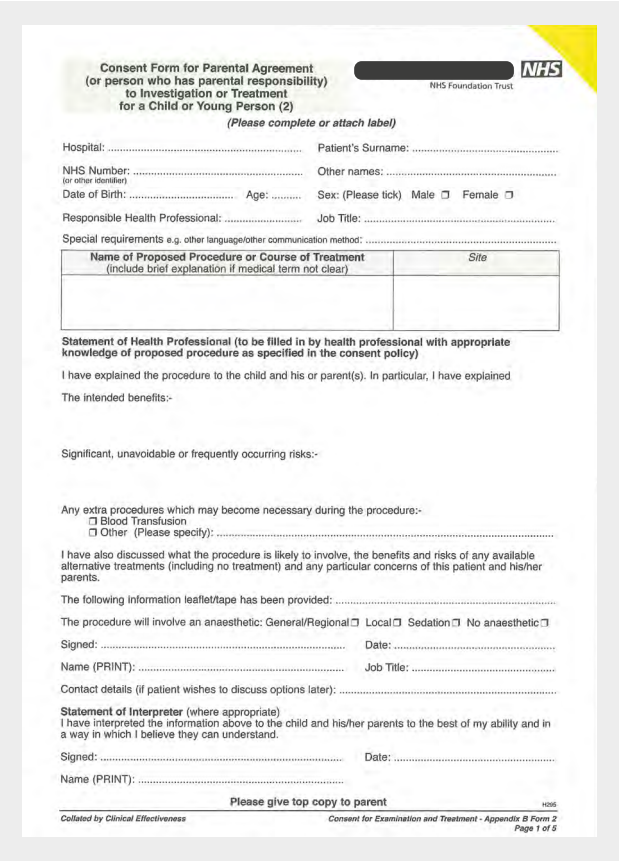
Common events and risks in anaesthesia

Fig 10 Poster produced by the Royal College of Anaesthetists regarding the common risks relating to anaesthesia



Appendix B

Fig 11 Copy of Trust consent form



Consent Form for Parental Agreement
(or person who has parental responsibility)
to Investigation or Treatment
for a Child or Young Person (2)

[redacted] NHS
NHS Foundation Trust

(Please complete or attach label)

Hospital: ..... Patient's Surname: .....

NHS Number: ..... Other names: .....
(or other identifier)

Date of Birth: ..... Age: ..... Sex: (Please tick) Male ❒ Female ❒

Responsible Health Professional: ..... Job Title: .....

Special requirements e.g. other language/other communication method: .....

Name of Proposed Procedure or Course of Treatment (include brief explanation if medical term not clear)	*Site*

Statement of Health Professional (to be filled in by health professional with appropriate knowledge of proposed procedure as specified in the consent policy)

I have explained the procedure to the child and his or parent(s). In particular, I have explained

The intended benefits:-

Significant, unavoidable or frequently occurring risks:-

Any extra procedures which may become necessary during the procedure:-
❒ Blood Transfusion
❒ Other (Please specify): .....

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

The following information leaflet/tape has been provided: .....

The procedure will involve an anaesthetic: General/Regional ❒ Local ❒ Sedation ❒ No anaesthetic ❒

Signed: ..... Date: .....

Name (PRINT): ..... Job Title: .....

Contact details (if patient wishes to discuss options later): .....

Statement of Interpreter (where appropriate)
I have interpreted the information above to the child and his/her parents to the best of my ability and in a way in which I believe they can understand.

Signed: ..... Date: .....

Name (PRINT): .....

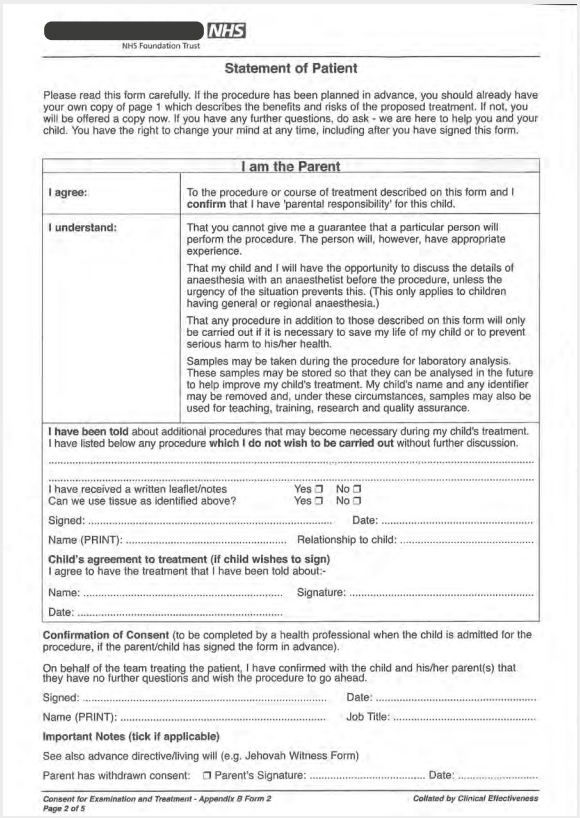
Please give top copy to parent

H295

Collated by Clinical Effectiveness *Consent for Examination and Treatment - Appendix B Form 2* *Page 1 of 5*

Appendix C

Fig 12 Copy of Trust consent form, parental responsibility section



[redacted] NHS
NHS Foundation Trust

Statement of Patient

Please read this form carefully. If the procedure has been planned in advance, you should already have your own copy of page 1 which describes the benefits and risks of the proposed treatment. If not, you will be offered a copy now. If you have any further questions, do ask - we are here to help you and your child. You have the right to change your mind at any time, including after you have signed this form.

I am the Parent

I agree:	To the procedure or course of treatment described on this form and I **confirm** that I have 'parental responsibility' for this child.
I understand:	That you cannot give me a guarantee that a particular person will perform the procedure. The person will, however, have appropriate experience. That my child and I will have the opportunity to discuss the details of anaesthesia with an anaesthetist before the procedure, unless the urgency of the situation prevents this. (This only applies to children having general or regional anaesthesia.) That any procedure in addition to those described on this form will only be carried out if it is necessary to save my life of my child or to prevent serious harm to his/her health. Samples may be taken during the procedure for laboratory analysis. These samples may be stored so that they can be analysed in the future to help improve my child's treatment. My child's name and any identifier may be removed and, under these circumstances, samples may also be used for teaching, training, research and quality assurance.

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

.....

.....

I have received a written leaflet/notes Yes ❒ No ❒
Can we use tissue as identified above? Yes ❒ No ❒

Signed: ..... Date: .....

Name (PRINT): ..... Relationship to child: .....

Child's agreement to treatment (if child wishes to sign)
I agree to have the treatment that I have been told about:-

Name: ..... Signature: .....

Date: .....

Confirmation of Consent (to be completed by a health professional when the child is admitted for the procedure, if the parent/child has signed the form in advance).

On behalf of the team treating the patient, I have confirmed with the child and his/her parent(s) that they have no further questions and wish the procedure to go ahead.

Signed: ..... Date: .....

Name (PRINT): ..... Job Title: .....

Important Notes (tick if applicable)

See also advance directive/living will (e.g. Jehovah Witness Form)

Parent has withdrawn consent: ❒ Parent's Signature: ..... Date: .....

Consent for Examination and Treatment - Appendix B Form 2 *Collated by Clinical Effectiveness*
Page 2 of 5

Appendix D

Healthcare Safety Investigation Branch (HSIB) analysis of hospital in reference event using Royal College of Anaesthetists (RCoA) standards for equipment, services and facilities

RCoA standards	HSIB analysis	
	Evidence of Standard met	Analysis/Comments
Facilities		
2.1 Access to lifts for easy trolley transfer should be available.	Yes	
2.2 Procedure rooms should be large enough to accommodate equipment and personnel, with enough space to move about safely and to enable easy access to the patient at all times.	Yes	Prep room observed by investigation team during routine general anaesthetic (GA). During stabilisation, room was described as "crowded".
2.3 Environments in which patients receive anaesthesia or sedation should have full facilities for resuscitation available, including a defibrillator, suction, oxygen, airway devices and a means of providing ventilation.	-19.5	
2.4 The procedure room should be easily accessible to the resuscitation team and large enough to accommodate them and appropriate equipment if required.	Yes	Access via MRI control room and external corridor. Room became crowded during stabilisation but large enough for normal conditions.
2.5 It should also be possible to arrange transfer of a patient from the procedure room to other areas within the institution if necessary.	Yes	Observed by HSIB under normal conditions (arrival in prep room, move to transfer area, taken into MRI scanner).
2.6 A PACU [post anaesthetic care unit] or equivalent should be available for each patient at the end of the procedure.	Yes	Post anaesthetic care undertaken in prep room after each case, and before the next case is called.
2.7 Facilities to allow access to online information, such as electronic patient records, local guidelines and clinical decision aids, should be available.	Yes	Hospital computers in MRI scanner. It was noted that the monitoring was not connected to main hospital critical care system as is the case in theatres and intensive therapy unit (ITU).
Equipment		
2.8 All patient trolleys should be capable of being tipped into the head-down position and be easily transferable to the rest of the hospital.	Yes	
2.9 Equipment for monitoring should be available at all sites where patients receive anaesthesia or sedation. For patients receiving conscious sedation, this should include pulse oximetry [heart rate monitoring].	Yes	Includes continuous pulse oximetry applied on ward. And during transfer to MRI suite.
2.10 Continuous waveform capnography [carbon dioxide monitoring] should be available for all patients undergoing general anaesthesia and moderate or deep sedation.	Yes	
2.11 The anaesthetist should ensure that an adequate supply of oxygen is available before starting any procedure. Many of the sites where anaesthesia is provided outside the main operating theatres do not have piped oxygen; if anaesthesia is provided frequently in such a location, the use of the location should be reviewed or piped oxygen provided.	Yes	Piped supply.
2.12 Where piped oxygen is available, back-up cylinders should always be available and appropriately stored.	Yes	

RCoA standards	HSIB analysis	
	Evidence of Standard met	Analysis/Comments
2.13 All anaesthetic equipment should be standardised where possible in all areas providing anaesthetic services, including equipment for resuscitation and life support, and such equipment subject to a standardised programme of maintenance.	Partial	Monitoring not the same as in main theatres – not connected to electronic patient record system.
2.14 All staff should be provided with opportunities to familiarise themselves with all equipment by way of documented formal training sessions.	Yes	Assurance given by Lead Operating Department Practitioner (ODP) who leads on MRI GA services.
2.15 Equipment standards where anaesthesia is planned, including with controlled ventilation, should replicate the facilities available in the main theatre suites as outlined in chapter 3 and commensurate with local hospital anaesthetic facilities.	Yes	Same anaesthetic machines used in MRI suite.
2.16 All anaesthetic equipment should be checked before use in accordance with the Association of Anaesthetists published guidelines. Anaesthetic machine checks should be recorded in a log and on the anaesthetic chart.	Yes	Daily checks reported to the investigation. Designated lead (Lead ODP).
2.17 All procedures should be compliant with National Safety Standards for Invasive Procedures (NatSSIPs) and the Safe Surgery Checklist.13,14 An appropriate 'pre list check' of the anaesthesia systems, facilities, equipment, supplies and resuscitation equipment should be performed prior to the start of each list.	Yes	Safety huddle/briefing undertaken in MRI suite before list.
Medication		
2.18 Wherever anaesthesia or sedation is undertaken, a full range of emergency drugs including specific reversal agents such as naloxone, sugammadex and flumazenil should be made available.	Yes	All relevant drugs available. During event, atropine and glycopyrrolate available rapidly.
2.19 In remote locations where anaesthesia is undertaken, drugs to treat rare situations, such as dantrolene for malignant hyperthermia, or intralipid for local anaesthetic toxicity should be immediately available and located in a designated area.	Yes	Dantrolene available rapidly.
2.20 There must be a system for ordering, storage, recording and auditing of controlled drugs in all areas where they are used, in accordance with legislation.	Yes	Controlled drugs cupboard in MRI prep room.
2.21 Robust systems should be in place to ensure reliable medicines management, including storage facilities, stock review, supply, expiry checks, and access to appropriately trained pharmacy staff to manage any drug shortages.	Yes	As discussed with Lead ODP.
2.22 All local anaesthetic solutions should be stored separately from intravenous infusion solutions, to reduce the risk of accidental intravenous administration of such drugs.	Not known	Not seen, as out of scope.
2.23 All drug containing infusions and syringes should be clearly labelled.	Yes	Labelled syringes witnessed during observation.

RCoA standards	HSIB analysis	
	Evidence of Standard met	Analysis/Comments
2.24 The anaesthetist should consider all environmental factors when planning administration of anaesthesia or sedation.	Yes	Team report being very aware of remote location (different floor to theatres/ ITU).
2.25 When rooms are darkened hindering direct observation of the patient, availability of an alternative light source to record notes and observe the patient should be considered.	Not seen	Room not darkened for scan.
2.26 Appropriate equipment should be available to minimise heat loss by the patient and to provide active warming.	Yes	
Services		
2.27 Patients should be appropriately monitored during their recovery.	Yes	Recovery witnessed during observations by investigation.
2.28 The care of the patient remains the responsibility of the anaesthetist up to discharge for ambulatory procedures or ward transfer for inpatient procedures.	Yes	Witnessed during routine conditions.

Appendix E

Fig 13 Front page of example hospital passport

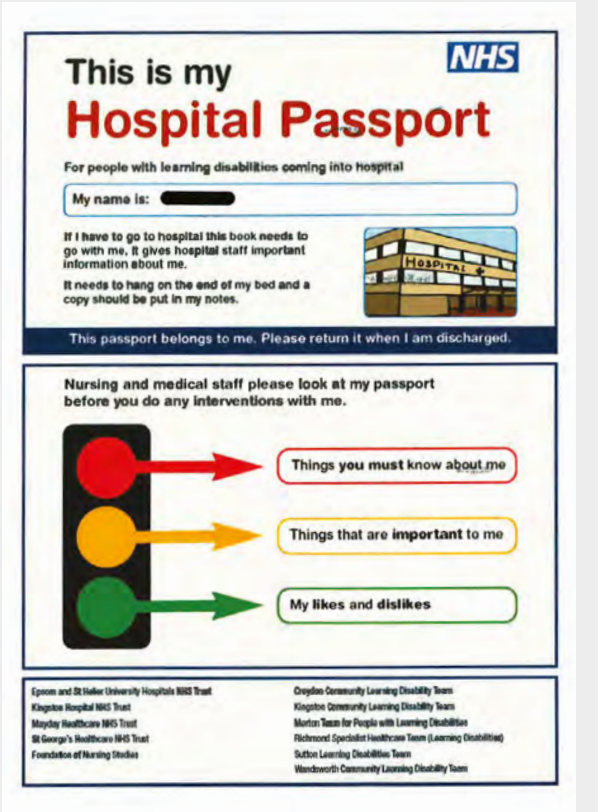


Fig 14 Page 2 of example hospital passport

Fig 15 Page 3 of example hospital passport

Things you must know about me

Current medication:
This is current on the day of completing the passport. Please ensure you check with GP or medication sheet. Prior to administering.

Levetiracetam 500 mgs twice a day

Buccal Midazolam 10 mgs PRN

Rectal Diazepam 10 mgs PRN

My medical history and treatment plan:

Focal Epilepsy (see attached care plan)

Severe Neurological Disability

Microcephaly

What to do if I am anxious:
Please reassure me, speak in calm simple language. Say its OK, [redacted] Stroke my arm in a reassuring manner. It would be better if my family can be with me as they know me well. If I am distressed I may attempt to push you away, my left hand is strong.

Date completed [redacted] by [redacted] 3

Fig 16 Page 4 of example hospital passport

Things that are important to me

How to communicate with me:
Please use simple language. I can understand Bengali and English. When you meet me, please offer your hand for me to shake.

How I take medication: (whole tablets, crushed tablets, injections, syrup)
I am able to take my medication with support. I may need encouragement. If I have a prolonged seizure it is often difficult to administer buccal midazolam as I may try to push you away. My family prefer to administer rectal diazepam as it is easier and more effective.

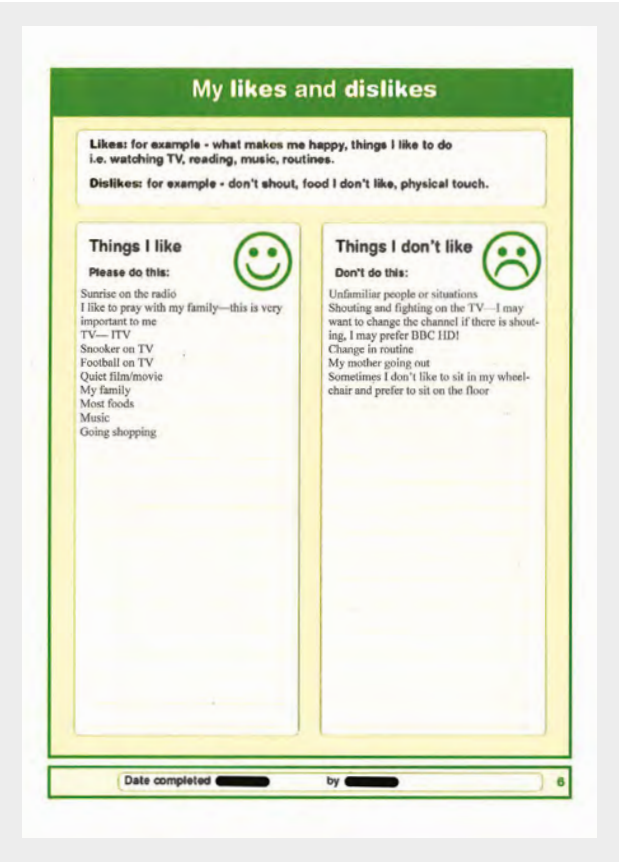
How you know I am in pain:
It may be difficult to know if I am in pain. My behaviour may change. I may appear distressed. I may push you away.

Moving around: (Posture in bed, walking aids)
I use a wheelchair. I cannot walk but I can sit upright on the floor. I need to be hoisted out of bed and into my chair using a sling, by 2 people. I use a downstairs shower, I do not use a bath. I need to use a hospital bed as I would not be safe in a normal bed.

Personal care: (Dressing, washing, etc)
I need complete care with all personal care. My right hand is paralysed so it is difficult to clean this as my fist is clenched.

Date completed [redacted] by [redacted] 4

Fig 17 Page 5 of example hospital passport



My likes and dislikes

Likes: for example - what makes me happy, things I like to do i.e. watching TV, reading, music, routines.

Dislikes: for example - don't shout, food I don't like, physical touch.

Things I like

Please do this:

Sunrise on the radio
I like to pray with my family—this is very important to me
TV— ITV
Snooker on TV
Football on TV
Quiet film/movie
My family
Most foods
Music
Going shopping

Things I don't like

Don't do this:

Unfamiliar people or situations
Shouting and fighting on the TV—I may want to change the channel if there is shouting, I may prefer BBC IID!
Change in routine
My mother going out
Sometimes I don't like to sit in my wheelchair and prefer to sit on the floor

Date completed [redacted] by [redacted] 6

Fig 18 Page 6 of example hospital passport

Things that are important to me

How to communicate with me:
Please use simple language. I can understand Bengali and English. When you meet me, please offer your hand for me to shake.

How I take medication: (whole tablets, crushed tablets, injections, syrup)
I am able to take my medication with support. I may need encouragement. If I have a prolonged seizure it is often difficult to administer buccal midazolam as I may try to push you away. My family prefer to administer rectal diazepam as it is easier and more effective.

How you know I am in pain:
It may be difficult to know if I am in pain. My behaviour may change. I may appear distressed. I may push you away.

Moving around: (Posture in bed, walking aids)
I use a wheelchair. I cannot walk but I can sit upright on the floor. I need to be hoisted out of bed and into my chair using a sling, by 2 people. I use a downstairs shower, I do not use a bath. I need to use a hospital bed as I would not be safe in a normal bed.

Personal care: (Dressing, washing, etc)
I need complete care with all personal care. My right hand is paralysed so it is difficult to clean this as my fist is clenched.

Date completed [redacted] by [redacted] 4

Appendix F

Content of Association of Anaesthetists 'Quick reference handbook'

Fig 19 Content list taken from 'Quick reference handbook'

Contents

August 2019 edition (Check currency/download latest at https://anaesthetists.org/Quick-Reference-Handbook)

8 Endnotes

[1] Children aged between 2 and 18 may have their growth recorded on a growth chart. This chart is mainly intended to assess the growth of school age children and young people in primary or secondary care. Centiles represent the distribution of height and weight among the population. (Royal College of Paediatrics and Child Health, 2019)

[2] Raised intracranial pressure (ICP) can be acute or chronic and be caused by problems such as tumours or fluid around the brain. This is a dangerous problem as the skull is a closed structure meaning that a rise in pressure cannot be relieved and instead compresses the brain causing signs and symptoms, including headaches. (Patient, 2019)

[3] Electrocardiograms (ECGs) record the electrical signal coming from the heart and are used to assess the rate and rhythm of the heart and can be used to detect and diagnose certain abnormalities.

[4] 'Assistant practitioners are a growing part of the health care workforce. Sometimes known as associate practitioners, they take on more responsibilities than healthcare assistants, under the delegation of registered [nurse] colleagues in a range of different settings.' (Royal College of Nursing, 2019)

[5] Pre-med is short for pre-medication; medicines given prior to an anaesthetic/operation to address any issues prior to the procedure commencing. This may include pain relief, drugs to reduce stomach acid/reflux, or to relieve anxiety.

[6] Operating department practitioners (ODPs) are healthcare professionals registered with the Health and Care Professions Council and primarily qualified in perioperative care (care of patients before, during and after an operation). They may work as part of the anaesthesia or surgical teams and in post-anaesthesia recovery care.

[7] Gas induction involves using gases and/or anaesthetic vapour to achieve anaesthesia, rather than using an intravenous anaesthetic drug. Anaesthetic vapours are volatile agents (a liquid which rapidly vaporises when exposed to air).

[8] Sevoflurane is documented as being a modern volatile anaesthetic vapour which has a safer profile and fewer and rarer side effects.

[9] The normal heart rate for a child of 14 years is between 60 and 100 beats per minute. If the heart rate falls below 60, this is known as bradycardia. This is not uncommon during anaesthesia and anaesthetic teams commonly pre-prepare medicines (such as atropine and glycopyrrolate) which can be used to treat this.

[10] Tachycardia (not involving hypovolaemia/shock) can be caused by high blood pressure, reduced blood supply to the heart muscle, heart valve disease, heart disease and cardiomyopathy.

[11] Carotid massage and the Valsalva manoeuvre are techniques intended to stimulate the Vagus nerve, increasing electrical signals to the heart causing it to beat more slowly.

[12] Capillary refill time (CRT) is a manual procedure where blood is evacuated from the capillary bed, usually under a fingernail or on the forehead achieved by pressing or squeezing that area. The time it takes for blood to return to the area is the capillary refill time. This is normally less than three seconds in healthy patients and is often almost instantaneous. A delay in CRT indicates issues with the patient's circulation.

[13] Malignant hyperthermia is caused by a sudden release of calcium stored in diseased muscle and causes a cascade in the body which leads to increased temperature and an increased oxygen requirement. (Association of Anaesthetists, 2011)

[14] Intravenous fluids are used to increase the circulating volume in a patient's cardiovascular system. The purpose is to help maintain the blood pressure and prevent organ failure. (National Institute for Health and Care Excellence, 2015)

[15] An echocardiogram is an examination of the heart using ultrasound imaging to view the structure of the heart, the heart valves, and blood flow through the chambers of the heart.

[16] Some doctors have a special interest in other areas of speciality or develop a specialist interest prior to undertaking their main speciality. For example, a general practitioner may have a special interest in pre-hospital care, or an anaesthetist may have a special interest in dermatology (the branch of medicine relating to skin, hair and nails). The doctor must have structured competency in their area of their special interest.

[17] A middle grade doctor is a qualified doctor working at registrar level. They may be undergoing speciality training, be practicing as a clinical fellow, or be employed in a staff grade post (grade below consultant).

[18] Intensive therapy unit (ITU) and intensive care unit (ICU) are often used interchangeably but are essentially the same. These specialist units care for the most unwell patients who need to be ventilated or receive other support.

[19] The Coroners and Justice Act 2009 'provides coroners with the duty to make reports to a person, organisation, local authority or government department or agency where the coroner believes that action should be taken to prevent future deaths'. (Courts and Tribunal Judiciary, 2019)

[20] The investigation noted the findings of the expert opinion included in the Trust's independently commissioned serious incident report. The opinion was that some children will experience idiopathic intracranial hypertension within a few weeks of commencing treatment with Somatropin.

[21] A 'red flag' is a serious clinical finding identified in the patient's health history, following a physical examination or via a diagnostic test. A red flag is a finding that is either always associated with a particular disease or prompts the need for more specialised tests to rule in or rule out the suspected serious condition. An example of a red flag is a patient with sudden central chest pain.

[22] A hospital passport is a document which is completed by individuals and/or their family/carers with support from a learning disability liaison team. The passport contains information on a person's individual needs and any reasonable adjustments needed when attending healthcare settings. This differs from a medical care plan in that its focus is to inform healthcare staff about adjustments rather than technical/medical care needed.

[23] See 'Inadvertent administration of an oral liquid medicine into a vein'. (Healthcare Safety Investigation Branch, 2019)

[24] The report 'Confidential Inquiry into premature deaths of people with learning disabilities (CIPOLD)' describes flagging as 'systems to identify people with learning disabilities'. (Heslop et al., 2013)

[25] MRI suites are often installed into older hospitals, and this often results in the imaging environment being a compromise rather than being designed around the scanner, as would happen with new-build hospitals.

[26] 'MR safe' means that the equipment can be in the vicinity of an MRI scanner and will function normally but cannot be in the actual scanning room. 'MR compatible' means the equipment can be in the scanning room itself. 'MR safe' is defined as 'an item that poses no known hazards resulting from exposure to any MR environment. MR safe items are composed of materials that are electrically nonconductive, non-metallic, and nonmagnetic'. 'MR conditional' is defined as 'an item with demonstrated safety in the MR environment within defined conditions. At a minimum, address the conditions of the static magnetic field, the switched gradient magnetic field and the radiofrequency fields. Additional conditions, including specific configurations of the item, may be required'. (Society and College of Radiographers, 2019)

[27] Capnography is the measurement of carbon dioxide in expired air and can be used to indicate if a patient's body is becoming too acidic.

[28] Ventilator circuits are the pipes which carry air and oxygen and, where applicable, anaesthetic gases from the ventilator to the breathing tube placed in the patient's airway.

[29] Some MRI scans require additional interventions to be carried out at the same time as the scan. This can differ depending on the type of intervention and the type of anaesthetic machine. For example, scans of the chest may require a 'breath-hold' which needs to be done by pausing the ventilator.

[30] Diagnostic imaging procedures, such as X-ray, CT and MRI scanning, do not need written consent as they are not considered invasive.

[31] Summary Care Records are 'an electronic record of important patient information, created from GP medical records. They can be seen and used by authorised staff in other areas of the health and care system involved in the patient's direct care'. (NHS Digital, 2019)

[32] Airway adjuncts include items such as Guedel airways. They are not invasively inserted and are usually not considered a definitive airway management strategy such as tracheal intubation or surgical cricothyroidotomy.

[33] 'Operational Delivery Networks (ODN) are focussed on coordinating patient pathways between providers over a wide area to ensure access to specialist resources and expertise.' (NHS England, 2013)

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HEALTHCARE SAFETY INVESTIGATION BRANCH

Further information

More information about HSIB – including its team, investigations and history – is available at **www.hsib.org.uk**

If you would like to request an investigation then please read our **guidance** before submitting a safety awareness form.

@hsib_org is our Twitter handle. We use this feed to raise awareness of our work and to direct followers to our publications, news and events.

Contact us

If you would like a response to a query or concern please contact us via email using **enquiries@hsib.org.uk**

We monitor this inbox during normal office hours - Monday to Fridays (not bank holidays) from 0900hrs to 1700hrs. We aim to respond to enquiries within five working days.

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