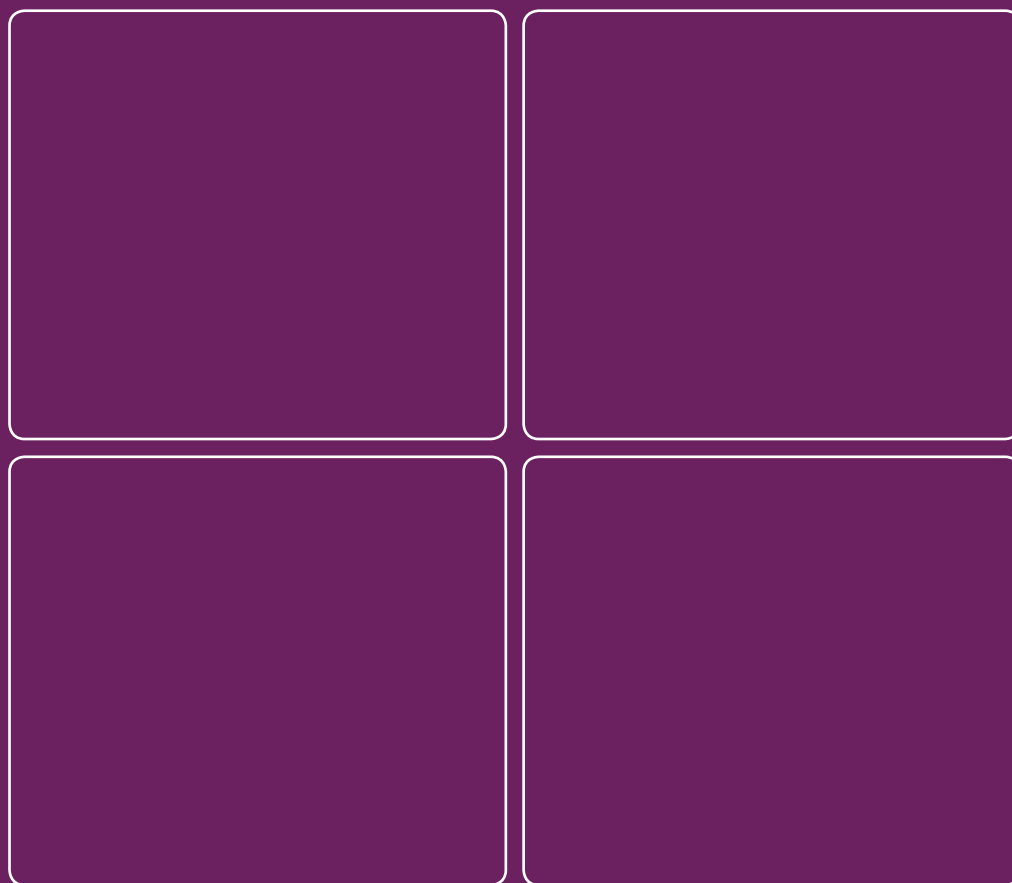


Guidance about compliance

Judgement framework



How we will judge providers' compliance with the section 20 regulations of the Health and Social Care Act 2008

December 2009

About the Care Quality Commission

The Care Quality Commission is the independent regulator of health and adult social care services in England. We also protect the interests of people whose rights are restricted under the Mental Health Act.

Whether services are provided by the NHS, local authorities, private companies or voluntary organisations, we make sure that people get better care. We do this by:

- Driving improvement across health and adult social care.
- Putting people first and championing their rights.
- Acting swiftly to remedy bad practice.
- Gathering and using knowledge and expertise, and working with others.

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A new system of registration

As the regulator of health and adult social care in England, we make sure that the care people receive meets essential standards of quality and safety and we encourage ongoing improvements by those who provide or commission care.

The new registration system for health and adult social care will make sure that people can expect services to meet essential standards of quality and safety that respect their dignity and protect their rights. The new system is focused on outcomes rather than systems and processes, and places the views and experiences of people who use services at its centre.

We will continuously monitor compliance with essential standards as part of a new, more dynamic, responsive and robust system of regulation. Our assessors and inspectors will frequently review all available information and intelligence we hold about a provider. We will seek information from patients and public representative groups, and from organisations such as other regulators and the National Patient Safety Agency.

If we have concerns that a provider is not meeting essential standards of quality and safety, we will act quickly, working closely with commissioners and others, and using our new enforcement powers if necessary.

Promoting improvement

In addition to the assurance about compliance with essential standards that registration will provide, we have an important function in promoting improvement by providing independent, reliable and timely information about the quality of care in providers above essential standards, and about the quality of care secured by commissioners for their local communities, which we describe as assessments of quality.

These assessments include: our periodic reviews of the performance of all health and adult social care providers, and of councils and primary care trusts as commissioners of care; our special reviews and studies of particular aspects of care, on economy, efficiency and effectiveness; and information issues.

The judgement framework

The judgement framework is written for staff of the Care Quality Commission to help them make decisions and reach judgements about the registration status of providers.

The framework will improve consistency in the decisions and judgements we make about a provider's registration, and will provide a transparent method that can be used to check our judgements. Although it will be used to promote consistency, it will not be a substitute for the professional judgement of inspectors and assessors, and individual circumstances will always be taken into account.

It explains how a decision should be reached by considering evidence about compliance. It focuses on the 16 regulations and associated outcomes that most directly relate to the quality and safety of care.

The framework is split into four stages:

Stage 1: Determining whether there is enough evidence to make a judgement.

Stage 2: Checking whether or not the evidence demonstrates compliance, or whether there are concerns about the provider's compliance with the regulations.

Stage 3: If concerns are found, making a judgement about the impact on people using services and the likelihood of the impact occurring.

Stage 4: Validating the judgement.

How to use the judgement framework

When should you use the judgement framework?

You should use the judgement framework when making any decisions about a provider's registration status.

You should use it alongside the guidance about compliance for providers and apply it when looking at evidence to check a provider's compliance, or to identify concerns relating to their compliance with the relevant regulations.

You do not have to use it for every piece of evidence or information that you have about a service or provider. You should be proportionate and targeted in your approach.

Which regulations does it cover?

The essential standards of safety and quality consist of the 28 regulations and associated outcomes that are described in the guidance about compliance for providers.

The judgement framework is concerned with the 16 regulations (out of the 28) that come within Part 4 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2009. These are the ones most directly relate to the quality and safety of care.

When we are checking a provider's compliance, these are the regulations that we will focus on.

Section	Outcome	Regulation*	Title
Information and involvement	1	17	Respecting and involving people who use services
	2	18	Consent to care and treatment
Personalised care, treatment and support	4	9	Care and welfare of people who use services
	5	14	Meeting nutritional needs
	6	24	Cooperating with other providers
Safeguarding and safety	7	11	Safeguarding people who use services from abuse
	8	12	Cleanliness and infection control
	9	13	Management of medicines
	10	15	Safety and suitability of premises
	11	16	Safety, availability and suitability of equipment
Suitability of staffing	12	21	Requirements relating to workers
	13	22	Staffing
	14	23	Supporting workers
Quality and management	16	10	Assessing and monitoring the quality of service provision
	17	19	Complaints
	21	20	Records
Suitability of management	N/A		

* Regulations of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2009.

What does compliance look like?

The guidance about compliance for providers describes, in detail, the expected outcomes when a provider complies with each regulation.

When assessing whether a provider complies with the regulations, the guidance about compliance should be the main reference point.

The judgement framework provides case studies of what compliance may look like in practice to help validate your decision.

Does every element described in the guidance about compliance for providers need to be met?

No, you should not use the elements detailed for each of the relevant regulations in the guidance about compliance as a tick box exercise. You should use and consider all the relevant information only.

If the provider has innovative ways of meeting the needs of people using their service that demonstrate compliance with the regulations but are not included in the guidance about compliance, then this is acceptable. The most important aspect is that CQC is satisfied that providers comply with the regulations.

If evidence suggests concerns, how do you use the judgement framework?

If the evidence shows that a provider is not meeting the outcomes in the guidance about compliance, then this suggests that there are concerns about meeting the 16 regulations covered by the judgement framework.

In this situation, use **stage 2** of the framework. Consider what is reasonably practicable and proportionate. If you still feel the evidence demonstrates a concern, use the prompts in stage 2 and the guidance about compliance for providers as a reference, to identify what the concerns are.

Use **stage 3** of the judgement framework to determine the impact of the concerns on people who use services and the likelihood that the impact will occur.

When you have determined the impact and its likelihood, use the matrix in **stage 3** to determine whether the concerns identified are minor, moderate or major.

Use **stage 4** to validate the judgement, using the descriptors and the case studies to help you.

You only need to identify the elements of the descriptor for each level of concern; every element does not need to have occurred for that level of concern to be determined.

The case studies are not exhaustive and can include elements relevant to other regulations. When assessing concerns, use the regulation that is most relevant.

Although the judgement framework is split into stages, the process will not always be linear. For example, during any part of **stage 2** or **stage 3**, you may find you do not have enough evidence. In this instance, you can refer back to the prompts in **stage 1** to gather more evidence. You may also find it helpful to go through **stage 2** and **3** together in order to come to a judgement.

Taking account of other influencing factors

When making your decisions, take into account other influencing factors, such as situations in which people may be more vulnerable.

For example, if regulation 15, safety and suitability of premises (outcome 10) is not being achieved in a secure mental health hospital, this may have more of an impact on people using that service than in a home care agency.

Does it matter what evidence is used?

Yes, the source of evidence can determine what weight you will attach to it when making a decision. Also, you must attempt to triangulate evidence with other sources before you rely on it.

You also need to ensure that you have sufficient evidence about the quality of outcomes that people experience.

What if I have conflicting evidence?

When assessing any evidence, you should consider the outcome for people using services as described in the guidance about compliance.

For example, if a service has not handed out their written complaints procedure this could be assessed as being **'possible'** that there will be a **'medium'** impact on people who use services resulting in a **'moderate concern'**.

However, the focus should be on the outcome for people using the service. For example, people using a complaints process could be fully satisfied with the experience even though the service did not have a written complaints procedure. This could be because the process was managed very well and the manager and staff were approachable and helpful when dealing with complaints. Therefore, the likelihood could be assessed as **'possible'** with a **'low'** impact on people who use services resulting in a **'minor concern'**.

What do our judgements look like?

You will make the following judgement for each of the 16 regulations:

- Compliance
- Minor concern
- Moderate concern
- Major concern.

These judgements are taken at a point in time. Subsequent follow-up activity requires you to reconsider the judgements in light of any other information gathered. This way, our system is dynamic and current and we have an up-to-date picture of a provider's provision of care in line with the relevant regulations.

How do our judgements affect the decision about registration?

The judgement framework determines whether there are concerns with a provider's compliance with the 16 regulations that most directly relate to the quality and safety of care.

It does not describe the registration actions you should take once a judgement has been reached. For guidance on registration actions, you should read the 'Setting the Bar' document.

Where do I record my decisions?

Use the assessment record to document all evidence you use and any decisions you make. It will provide you with an audit trail demonstrating how you have reached your judgement.

Putting the judgement framework into practice

Stage 1: Determining whether we have enough evidence to make a judgement about compliance

First, you need to consider the following question when looking at your evidence:

Do I have enough robust evidence to reach a judgement about compliance with the relevant regulations?

To determine whether the evidence you have is adequate and robust, consider the following points:

- Is it **current**? (within 12 months or longer if a long-term focus)
- Is it **reliable**? (is the source credible, is the evidence consistent, can it be validated or triangulated with another source)
- Is it **relevant**? (is it related to the regulations, the regulated activities and CQC's remit)
- Is it **sufficient**? (is there an adequate amount of evidence with enough detail to make an assessment)
- Does it **demonstrate** the quality of outcomes and/or experiences of people who use services?
- Does it **demonstrate** what controls (processes) the provider has in place?
- Is **specialist input** (eg pharmacy, medical etc) required?

You should consider all relevant information on the provider's Quality and Risk profile.

If you conclude '**yes**', you do have enough information, you should progress to **stage 2**.

If you conclude '**no**', you should collect further information and/or seek expert advice if needed. Then repeat **stage 1**.

You can collate additional information in various ways including:

- Telephoning or writing a letter to the provider or third parties.
- Making a provider compliance assessment.
- Making a site visit.

Stage 2: Checking whether the evidence demonstrates compliance with the regulations

In stage 2, use the evidence collected and the guidance about compliance to make a decision about compliance with the outcome statements.

Does the evidence demonstrate compliance?

If you are satisfied that the evidence identifies compliance with the outcomes described in the guidance about compliance for providers, you should go straight to **stage 4** for validation.

If you think that the provider is not meeting the outcomes described in the guidance about compliance, you must consider what is 'reasonably practicable' and apply 'proportionality'. In your assessment, you should consider whether the provider has done all that is reasonably practicable and that you have made a proportionate decision.

If you still think that the provider is not meeting the outcome statements, **or** it is an assessment of a new application, consider the prompts below to identify the concerns.

Do not use the prompts as a tick box exercise. You do not have to have evidence for every prompt.

Once you have done this, you should progress to **stage 3** to identify the impact of the concerns on people using the service and the likelihood of the concerns happening or recurring in the future.

Note: All regulations are from the Health and Social Care Act 2008 (Regulated Activities) Regulations 2009

Outcome 1 (Regulation 17): Respecting and involving people who use services	
Prompts	<ul style="list-style-type: none"> ● Are there processes in place to ensure that people’s <ul style="list-style-type: none"> – choices – human rights – dignity, privacy, diversity and independence needs are considered and respected? ● Are people supported and enabled to make informed decisions about the management of their care and treatment through the provision of appropriate information? ● Are people involved in how the service is planned and run? ● When people are making decisions about their care and treatment are they informed of the risks and benefits? ● Are people enabled to make choices about how they live their lives in a way that reflects their individual preferences and diverse needs? ● Does the provider monitor to make sure that all the above arrangements are operating effectively? ● Are people given opportunities to become involved in the local community?

Outcome 2 (Regulation 18): Consent to care and treatment	
Prompts	<ul style="list-style-type: none"> ● Are there processes in place to ensure that people are able to give informed consent to their treatment and care? ● If people lack capacity, do staff know how to comply with the Mental Capacity Act 2005? ● Is the consent process reviewed and monitored to make sure that staff are following it? ● Do the systems for consent to care and treatment take into account any guidance issued (Government and Expert)?

Outcome 4 (Regulation 9): Care and welfare of people who use services	
Prompts	<ul style="list-style-type: none"> • Has every person been actively involved in an assessment to identify their individual needs and choices? • Does everyone have a written personalised care plan, which details their individual needs and choices? • Is care and/or treatment delivered in accordance with the person’s care plan to ensure their individual and diverse needs are met? • Is everyone’s care plan reviewed on an ongoing basis with the involvement of the person? • Do the assessment and care planning processes take account of guidance and research relating to the care and treatment of people in the service? • Does the application of all policies and procedures ensure that people are protected from unlawful discrimination? • Are there procedures in place for dealing with emergencies that may impact on people? • Does the care delivered encourage the prevention and early detection of ill health and enable the person to make healthy living choices?

Outcome 5 (Regulation 14): Meeting nutritional needs	
Prompts	<ul style="list-style-type: none"> • Are there processes in place to make sure people do not experience poor nutrition and hydration? • Is there ongoing assessment, planning and monitoring of nutritional and hydration needs and intake? • Is the food and hydration provided nutritious and available in sufficient quantities? • Is there a choice of food and drink (if relevant) that takes account of people’s individual preferences and diverse needs, including timing and location (when appropriate)? • Are people offered support and enabled to eat and drink when necessary?

Outcome 6 (Regulation 24): Cooperating with other providers	
Prompts	<ul style="list-style-type: none"> • Are there processes in place to ensure that when people are admitted, transferred or discharged, relevant and appropriate information about their care and treatment is shared between providers and services? • Is the information shared in a timely way and in an appropriate format so that people receive their planned care and/or treatment? • Do staff work with other providers and/or other services to ensure that people’s care plans reflect their individual and diverse needs? • Is there a process for sharing and coordinating information with other providers and/or services in an emergency? • Are there robust arrangements to make sure that information sharing systems comply with the Data Protection Act 1998? • Do people receive coordinated health and social care support to meet the needs described in their care plan?

Outcome 7 (Regulation 11): Safeguarding people who use services from abuse	
Prompts	<ul style="list-style-type: none"> • Is there an effective process for identifying and responding appropriately to signs and allegations of abuse? • Do staff understand what constitutes abuse and restraint? • Do staff respond appropriately to signs and allegations of abuse? • Is there an effective process for preventing abuse before it occurs, and minimising the risks of further abuse once it has occurred? • Do staff understand the circumstances in which restraint can and cannot be used and how? • When restraint is used, is there a process to follow that is safe, lawful and not excessive? • Do the systems for both safeguarding and restraint take into account any guidance issued including <i>No secrets</i> and <i>Working together to safeguard children</i> and the requirements of the Mental Capacity Act 2005 and the Mental Health Act Code of Practice (Government and Expert)? • Are people respected and supported following the allegation of abuse?

Outcome 8 (Regulation 12): Cleanliness and infection control	
Prompts	<ul style="list-style-type: none"> • Are there processes in place to operate monitoring and management arrangements intended to prevent and control infections? • Do these processes take account of people’s susceptibility, the risks posed by their environment and other people who use the service? • Is this process informed by risk assessment? • Is the environment clean and maintained to prevent and control infections? • Is suitable and accurate information on infections provided to people who use services, their relatives or carers? • Is suitable and accurate information on infections provided in a timely manner to any other provider or person responsible for the ongoing care of a person using the service? • Is there a process to identify and manage people that have developed an infection? • Is the appropriate treatment offered to people with an infection to reduce the risk of passing the infection on? • Are all staff and people providing care involved in the process of preventing and controlling infection? • Are adequate isolation facilities available? • Is there adequate access to laboratory support? • Are there policies in place, that are adhered to, that help to prevent and control infections, and that are reviewed and amended in line with lessons learned? • Are there processes in place that protect staff from exposure to infections? • Are all staff suitably educated in the prevention and control of infection?

Outcome 9 (Regulation 13): Management of medicines	
Prompts	<ul style="list-style-type: none"> • Are there effective processes for the safe and secure handling of medicines and are these in line with the relevant guidance and legislation? • Are there clear processes in place for the handling of controlled drugs? • Are there clear processes to take account of new guidance and alerts relating to the safe handling and use of medicines? • Are there clear processes in place to ensure a person’s medicines prescription is up to date and reviewed as their needs or conditions change in relation to their medicine? • Are staff trained and competent in the handling of medicines?

Outcome 10 (Regulation 15): Safety and suitability of premises	
Prompts	<ul style="list-style-type: none"> • Is the design, layout and security of the premises fit for purpose to safely meet the needs of everyone receiving care and treatment including those with disabilities? • Does the design and layout of the premises promote people’s dignity, independence and wellbeing? • Have all reasonable steps been taken to ensure that premises are accessible to all those who need to use them in keeping with the requirements of the Disability Discrimination Act 1995? • Are the premises and grounds well maintained and risks to safety identified and managed? • Are there arrangements in place to comply with all legislative requirements relating to the classification, collection, segregation, storage, handling, transport, treatment and disposal of waste? • Are there arrangements in place to provide safe and effective care in the event of a failure in major utilities, fire, flood or other emergencies? • Are all staff, people who use services and others provided with information on the risks to their health and safety, protective measures and what to do in the event of an emergency, for example fire? • Are there arrangements for learning from relevant safety incidents, safety alerts and national guidance relating to premises and taking action to minimise risk in the future? • Are there emergency evacuation procedures in place and are they practised? • Does the provider risk assess when he is not responsible for the premises in which care is delivered?

Outcome 11 (Regulation 16): Safety, availability and suitability of equipment	
Prompts	<ul style="list-style-type: none"> • Do people have access to appropriate equipment to safely meet their needs? • Does the equipment promote their independence and comfort? • Is the equipment fit for purpose? • Is there a process for ensuring that all equipment is properly installed, used, maintained, tested, serviced and replaced in accordance with relevant legislation, manufacturer’s instructions and relevant expert guidance? • Are all people using or maintaining equipment trained and competent to do so? • Is the equipment stored safely and securely? • Are there arrangements in place to identify and manage risks related to equipment? • Are there arrangements in place to report and learn from equipment-related safety incidents, including relevant national safety alerts and guidance to minimise the risks in the future? • Are there arrangements in place to manage emergencies, such as, power failures where necessary?

Outcome 12 (Regulation 21): Requirements relating to workers	
Prompts	<ul style="list-style-type: none"> • Are there effective recruitment procedures that include checking and recording all required information? • Are the procedures followed for all staff, including temporary and agency staff, students and volunteers? • Are there effective processes to ensure people are not discriminated against during recruitment? • Do the recruitment processes include: <ul style="list-style-type: none"> – checking and recording that a person is of good character – checking whether there are any pending enquiries about fitness to practise or breaches of code of conduct – checking that a person has the right skills and qualifications needed for work – checking and recording that the person is fit to do the role and that any reasonable adjustments are made – checking and recording the requirements listed in Schedule 3 of the Regulations; and – ensuring and monitoring that people are not discriminated against during recruitment? • Do all relevant members of staff have an up-to-date registration with the relevant professional body, if this is required, for their role or for them to use a given title? • Is there an effective and proportionate process to identify and take action if a person is no longer fit to practise or if they breach codes of conduct, including how and when to refer a registered professional to their regulatory body? • Does the service have a documented disciplinary procedure?

Outcome 13 (Regulation 22): Staffing	
Prompts	<ul style="list-style-type: none"> • Are there sufficient staff with the right skills, qualifications and experience to meet the assessed needs of the people who use the service at all times? • Is staffing provision reviewed both routinely and in response to the changing needs of people using the service? • Does the service address any gaps in staff numbers and skills when needed, including at short notice? • Are staff appropriately managed at all times? • Do staff who are on duty have access to other staff with appropriate specialist skills and knowledge if required?

Outcome 14 (Regulation 23): Supporting workers	
Prompts	<ul style="list-style-type: none"> • Are staff competent to deliver care and treatment to people in the service because their learning and development needs have been met (including mandatory training, updating skills, professional development and any further qualifications)? • Do staff have access to supervision that meets both their needs and the needs of the people who use the service? • Do all staff receive appraisals at an agreed interval that is in line with any professional requirements? • Do the clinical governance and audit systems enable healthcare professionals to demonstrate that they continue to meet professional standards?

Outcome 16 (Regulation 10): Assessing and monitoring the quality of service provision	
Prompts	<ul style="list-style-type: none"> • Does the provider effectively assess and monitor the quality of its service delivery to ensure that people receive safe and appropriate care and treatment? • Are there clear lines of reporting/accountability/responsibility and are these implemented? • Is that covers all risks relating to health, welfare and safety of people who use the service? • Is a system implemented for reporting and learning from incidents? • Does the provider seek views and comments from people who use services, their carers, staff and other third parties, and use these views to help them assess quality and manage risks? • Are there effective processes in place for staff, people who use services and their carers to raise concerns and for the service to act on them? • Does the provider evaluate, take action on, and learn from relevant findings and recommendations from: <ul style="list-style-type: none"> – CQC – expert bodies – professional bodies – national reports and audits – bodies representing the views of people who use services?

Outcome 17 (Regulation 19): Complaints	
Prompts	<ul style="list-style-type: none"> • Is there an effective complaints system? • Are people made aware of the complaints system and what to do if they are dissatisfied with the response? • Is the complaints process accessible and available in an appropriate manner and formats to meet the needs of people using the service? • Are people provided with support to raise a complaint or make comments, and protected from discrimination? • Are complaints fully investigated, resolved if practicable, and the outcome communicated to the complainant and other interested parties? • Is a coordinated investigation and response undertaken if there is more than one service specified in the complaint? • Is a record made of all complaints, investigations, responses and outcomes? • Are there processes in place to implement learning from complaints?

Outcome 21 (Regulation 20): Records	
Prompts	<ul style="list-style-type: none"> • Do the records kept for each person include clear, accurate and up-to-date information about their care and treatment? • Are all the relevant records listed in the guidance about compliance kept? • Are records stored securely (in accordance with the Data Protection Act 1998) and able to be located promptly when required? • Is there an effective records management system that staff understand? • Are staff given induction training about the principles of confidentiality and the Data Protection Act? • Are records securely destroyed in keeping with the Data Protection Act?

Stage 3: Determining the impact on people who use services and the likelihood that this will happen

Step 1: Impact

For stage 3, the first question you need to answer is:

What is the impact on the people who use the service?

The impact can either be “low”, “medium” or “high”, as follows:

Impact	Definition
Low	No or minimal level of impact on people who use services in one or more areas.
Medium	A moderate impact but no long-term effects on people who use services in one or more of the areas.
High	A significant or long-term impact on people who use services in one or more of the areas.

When determining the impact on people who use services, all of the following areas are important:

- Safety
- Independence
- Experience
- Outcomes
- Dignity
- Human rights
- Accessibility.

Also, consider who is using the service and what their situation is, as these factors may influence the impact. For example:

Capacity: A lack of understanding of the Mental Capacity Act would be more significant in a service providing care to people with dementia than it would in a health screening service that primarily deals with fit, healthy adults.

Diversity: Failing to have information available in an audible format or in Braille would be more significant for a service that specialises in care for people with impaired vision than a service that does not.

Circumstances where people are more vulnerable: A poor and uncomfortable environment would be more significant for people that are detained than for people using an outpatient clinic.

The concern may impact on one or many of the above areas, and all relevant areas should be considered.

The examples below describe the impact for people who use services for each regulation.

Please note: The impact may not have happened. These examples describe the level of impact that could happen if the concern is not rectified.

When you have considered the examples and any influencing factors, select the appropriate level of impact for people using the service.

Note: All regulations are from the Health and Social Care Act 2008 (Regulated Activities) Regulations 2009

Outcome 1 (Regulation 17): Respecting and involving people who use services	
Low	<ul style="list-style-type: none"> • People understand the majority of the choices they have that are related to their care, treatment and support, so that they can make decisions. • People feel uncomfortable when expressing decisions about their care, treatment and support. • People can only influence significant decisions about the running of their service, not everyday aspects.
Medium	<ul style="list-style-type: none"> • People do not fully understand the choices they have that are related to their care, treatment and support, which limits their ability to make informed decisions. • People find it difficult to express their decisions about their care, treatment and support. • People’s modesty is not protected while receiving intimate personal care.
High	<ul style="list-style-type: none"> • People do not understand the choices they have that are related to their care, treatment and support, so their decisions are not informed. • People cannot express their decisions about their care, treatment and support. • People cannot influence decisions about the running of a service and are not consulted.

Outcome 2 (Regulation 18): Consent to care and treatment	
Low	<ul style="list-style-type: none"> • People feel reasonably informed when giving consent but not all information is provided.
Medium	<ul style="list-style-type: none"> • People do not feel fully informed when giving consent. • People are not supported to change a consent decision.
High	<ul style="list-style-type: none"> • People are not informed and feel pressurised to give consent. • People feel they cannot change their care or treatment once they have given consent.

Outcome 4 (Regulation 9): Care and welfare of people who use services	
Low	<ul style="list-style-type: none"> • People experience discomfort because serious and significant needs are cared for, but the less important needs are not always considered.
Medium	<ul style="list-style-type: none"> • People experience pain or are put at risk because they do not receive all the care, treatment and support in their care plan. • People are not able to have the care, treatment and support they would like if it is a riskier option.
High	<ul style="list-style-type: none"> • People who use services experience harm through care and treatment that does not meet their needs or is in their care plan and develop conditions such as pressure sores or DVT. • People who use the service receive care and treatment that conflicts with their religious beliefs. • People receive inappropriate care and treatment because it is not best practice and outdated.

Outcome 5 (Regulation 14): Meeting nutritional needs	
Low	<ul style="list-style-type: none"> • People do not have the choice of food they expect. • People frequently receive a substitute food rather than what they choose. • People feel they cannot make an informed choice when choosing their meals.
Medium	<ul style="list-style-type: none"> • People are not able to finish eating during the allotted mealtime. • People do not feel supported to eat independently and are not given the equipment to enable them to eat independently. • People do not have access to food 24 hours a day, seven days a week.
High	<ul style="list-style-type: none"> • People do not know when food they are eating contains substances they are allergic to. • People are unable to eat and drink and become malnourished or dehydrated.

Outcome 6 (Regulation 24): Cooperating with other providers	
Low	<ul style="list-style-type: none"> • People can be confused because their care is uncoordinated between services and they receive unnecessary visits. • People experience continuation of care for serious and significant needs, but smaller needs are not always considered. • People are not supported to access services they would like.
Medium	<ul style="list-style-type: none"> • People have to proactively follow up changes to their care and treatment due to delays in amendments. • People experience continuation of care but are not transferred with the necessary medication. • People do not feel confident about asking to access services other than the ones suggested by staff.
High	<ul style="list-style-type: none"> • People do not receive the necessary input into their care planning from all relevant providers. • People do not experience continuation of care for serious and significant needs. • People are unable to access other services.

Outcome 7 (Regulation 11): Safeguarding people who use services from abuse	
Low	<ul style="list-style-type: none"> • People’s preferred techniques for restraint are not used although an appropriate level is used. • People that experienced abuse were not offered support.
Medium	<ul style="list-style-type: none"> • People suffer subtle levels of abuse that are not recognised by staff. • People’s dignity is not maintained during restraint. • People reporting abuse are not immediately removed from the situation. • People lend money and belongings to staff because staff ask and allow it to happen.
High	<ul style="list-style-type: none"> • People suffer abuse for extended lengths of time because the signs are not recognised. • People reporting abuse do not have their concerns acted on. • People are harmed when being restrained as the most appropriate techniques are not used. • People are placed with other people that pose a risk to them. • People are pressured into giving money and belongings to staff.

Outcome 8 (Regulation 12): Cleanliness and infection control	
Low	<ul style="list-style-type: none"> • People are treated by staff dressed inappropriately to offer the level of care required. • People using the service and visitors feel ill-informed about how they reduce the risk of infection. • People do not know when cleaning has been undertaken.
Medium	<ul style="list-style-type: none"> • People receive inappropriate treatment because staff are not up to date on their training. • People feel vulnerable because the environment is unpleasant.
High	<ul style="list-style-type: none"> • People are exposed to infection because appropriate decontamination does not take place. • People are put at risk because the environment is unclean. • Staff and others are exposed to infection because the appropriate systems are not in place to protect them.

Outcome 9 (Regulation 13): Management of medicines	
Low	<ul style="list-style-type: none"> • People’s individual lifestyles are not taken into account when prescribing. • People are not supported to manage their own medication. • People do not receive their medication at regular times.
Medium	<ul style="list-style-type: none"> • People’s medication is administered infrequently with long delays. • People do not manage their own medication as it is not an option. • People do not understand what medication they are taking or why. • People’s medication is not reviewed and remains the same.
High	<ul style="list-style-type: none"> • People’s medication is not administered appropriately allowing for duplication or errors. • Medication is prescribed and administered to people that is not specific to their needs. • People do not receive their medication.

Outcome 10 (Regulation 15): Safety and suitability of premises	
Low	<ul style="list-style-type: none"> • People cannot easily access buildings or facilities without asking for help. • People are uncomfortable because the environment is not pleasant. • People that have a strong presence can influence the environment, but not all people that use the service are listened to.
Medium	<ul style="list-style-type: none"> • People are inconvenienced because poor arrangements exist and prevent them from accessing buildings and facilities. • People’s routine for example, sleep, is repeatedly disrupted because of an unpleasant environment. • People feel exposed as the environment does not offer any facilities allowing privacy i.e. family time. • People are restricted within their environment because it has limiting factors.
High	<ul style="list-style-type: none"> • People are harmed or seriously disturbed because the environment is not fit for purpose. • People cannot receive the necessary care, treatment or support because facilities and buildings are not accessible. • People are put at risk because the environment is unsafe.

Outcome 11 (Regulation 16): Safety, availability and suitability of equipment	
Low	<ul style="list-style-type: none"> • People are in some discomfort as equipment is not designed for their specific needs. • People receive equipment for significant and serious needs in a timely manner, but experience delays or do not receive equipment for less significant needs. • People do not have a full understanding of the equipment they have been provided with.
Medium	<ul style="list-style-type: none"> • People experience pain or are put at risk from equipment or the use of it. • People's independence is restricted due to equipment not supporting them. • People's routine is affected because equipment does not provide the support and functionality required.
High	<ul style="list-style-type: none"> • People suffer harm and injury from equipment that is not fit for purpose. • People experience delays in receiving equipment that is for serious or significant needs.

Outcome 12 (Regulation 21): Requirements relating to workers	
Low	<ul style="list-style-type: none"> • People's serious and significant needs are cared for by qualified staff but their less significant needs cannot be met by the volunteers offering support. • People are uncomfortable when receiving care because staff cannot communicate effectively.
Medium	<ul style="list-style-type: none"> • People experience pain or are put at risk when receiving care because agency staff are not inducted appropriately. • People's independence is restricted because staff were not checked and are physically unable to use certain equipment for example, hoists.
High	<ul style="list-style-type: none"> • People are verbally and emotionally abused by staff that have a previous record of abuse because CRB checks were not carried out. • People experience harm or injury because repeated failings by staff were not managed or reported to the professional body.

Outcome 13 (Regulation 22): Staffing	
Low	<ul style="list-style-type: none"> • People feel isolated and confused because staff do not have the skills to communicate in a specialist centre. • People experience discomfort that is not recognised by inexperienced staff.
Medium	<ul style="list-style-type: none"> • People’s routine is repeatedly disrupted because skilled staff are not routinely available. • People’s independence and ability to communicate is restricted because the number of staff is not appropriate to offer the necessary support.
High	<ul style="list-style-type: none"> • People suffer harm or injury because of the lack of staff on duty. • People experience delays in receiving care for serious or significant needs because of unskilled staff. • People receive inappropriate care and treatment due to a heavy reliance on agency staff without the necessary skills.

Outcome 14 (Regulation 23): Supporting workers	
Low	<ul style="list-style-type: none"> • People feel some discomfort when receiving care because of the lack of knowledge of the staff. • People’s individual plan of care is not always followed because staff management is this training or monitoring? does not include implementing a care plan. • People feel anxiety when interacting with staff due to low morale in the workplace.
Medium	<ul style="list-style-type: none"> • People experience pain or are put at risk when receiving care because of the lack of mandatory update training. • People are exposed to unnecessary risk because competencies are not checked and addressed.
High	<ul style="list-style-type: none"> • People are seriously harmed when receiving care because the necessary management is not provided. • People experience abuse because concerns about staff members are not identified or supervised.

Outcome 16 (Regulation 10): Assessing and monitoring the quality of service provision	
Low	<ul style="list-style-type: none"> • People with a strong voice influence the provision of care, but staff do not seek input. • People are not fully informed of any risks, preventative measures or own responsibilities relating to their care.
Medium	<ul style="list-style-type: none"> • People’s independence is restricted because the necessary professional input has not been sought. • People experience pain or are put at risk when receiving care because issues raised about staff competencies were not followed up.
High	<ul style="list-style-type: none"> • People receive inappropriate care and treatment because the quality assurance process is limited and fails to identify problems. • People suffer harm or injury because risk is not assessed or managed. • People experience delays in receiving care that is for serious or significant needs because lessons are not learned from incidents.

Outcome 17 (Regulation 19): Complaints	
Low	<ul style="list-style-type: none"> • People feel uncomfortable when making a complaint or comment and are not supported.
Medium	<ul style="list-style-type: none"> • People are frustrated about repeated comments not being acted on. • People feel threatened when making a complaint.
High	<ul style="list-style-type: none"> • People’s concerns and complaints are not acknowledged or responded to. • People who make complaints or raise concerns experience bullying.

Outcome 21 (Regulation 20): Records	
Low	<ul style="list-style-type: none"> • People are upset about incorrect information that is documented on their records. • People’s personal information in their records is kept for an unnecessary length of time by a service.
Medium	<ul style="list-style-type: none"> • People experience delays in treatment due to records not being available when requested. • People’s confidentiality is not fully protected, sensitive matters are discussed openly.
High	<ul style="list-style-type: none"> • People’s confidentiality is breached as records are not secure or disposed of appropriately.

Step 2: Likelihood

The second question in stage 3 is:

What is the likelihood that the impact will happen to people using the service?

The likelihood can either be “unlikely”, “possible” or “almost certain”, as follows:

Likelihood	Definition
Unlikely	This will probably never happen/recur, as there are control measures and processes in place.
Possible	This may happen/is probable/recur, but it is not a persisting issue.
Almost certain	This will probably happen/recur frequently. This is could be due to a breakdown in processes, or serious concerns about control measures.

Consider the evidence using the following prompts to reach a decision about how likely it is that the impact will happen:

- Has the concern happened before?
- How long will the concern last for?
- How many people are exposed to the concern?
- Has the provider identified and assessed the concern?
- Are measures in place to control the concern?
- Are the relevant people involved in managing the concern?

Example

People using services have had a poor experience when making complaints. This has raised concerns about whether the provider is meeting regulation 19 (outcome 17).

Has the concern happened before?

If complaints have not been listened to and acted on previously, the likelihood is increased as it shows that there may be a recurring problem. However, if this is a one-off occurrence and complaints are usually responded to and acted on, there would be less likelihood of it recurring.

How long will the concern last for?

If no action is taken to resolve the impact on people who use services and they continue to experience a poor response to complaints, the likelihood is greater than if the concern only occurs for a limited period.

How many people are exposed to the concern?

If complaints are listened to and action taken for all but one small area of the service, that deals say with less than 2% of the people using the service, the likelihood is less than if people across 100% of the service do not have their complaints listened to and action taken.

Has the provider identified and assessed the concern?

If the provider has assessed its complaints process to identify why people who use the service have not been listened to and their complaints not acted on, this will reduce the likelihood of it happening again, as this can inform what they will do to resolve the concern.

Are measures in place to control the concern?

If the provider has put in place some measures, such as an audit of all recent complaints to check the responses and what actions were taken, with a follow-up for any complaints that have not been resolved or acted on, this would reduce the likelihood. The provider has tried to control the concern and its impact on people who use services.

Are the relevant people involved in managing the concern?

If responsibility for dealing with the concern is at the appropriate level, this will ensure that the necessary changes are completed and the likelihood will be reduced. However the likelihood will be increased if the person tasked with making the changes is unable to exert enough influence and does not have the necessary impact.

Step 3: Level of concern

When you have determined the impact for people using the service, including any influencing factors, and the likelihood that the impact will happen, you should apply these to the matrix below to determine the overall level of concern.

Likelihood:	Impact:		
	Low	Medium	High
Unlikely	Minor concern	Minor concern	Moderate concern
Possible	Minor concern	Moderate concern	Major concern
Almost certain	Moderate concern	Major concern	Major concern

Stage 4: Validating the judgement

For each of the relevant regulations, you need to check your assessment and validate it against the descriptor and case studies set out in the rest of this document.

If you have judged compliance with outcomes described in the guidance about compliance at **stage 2**, refer to the 'compliance' case study to validate the decision.

If you identified concerns and proceeded to **stage 3**, refer to the relevant descriptor (minor, moderate or major concern) and associated case studies.

We have included case studies for each variation of concern. Use the case study relevant to the level of concern assessed. The case studies are not exhaustive and only illustrate what concerns can look like in practice.

This stage is to validate and confirm that the level of concern is similar to those defined in the descriptor and case studies. Not all aspects of the descriptor need to be identified to determine the level of concern. You should ensure that you use the most relevant regulation, although it is likely that some aspects of concern may relate to elements of other regulations, as seen in the case studies below.

Note that all regulation numbers in stage 4 are from the Health and Social Care Act 2008 (Regulated Activities) Regulations 2009.

Outcome 1 (Regulation 17)

Respecting and involving people who use services

Outcome 1 Compliance

The provider has met all aspects of this safety and quality regulation as the outcome described in the guidance about compliance is fully met (refer to the guidance about compliance for detail).

Case study 1

The manager of a care home has worked with staff and people who use the service to develop and implement a range of policies and training. This means that staff know how to promote people's human rights, privacy, dignity and independence, including how to promote wellbeing and prevent deterioration of existing health problems.

People living in the care home told us they run their own monthly meetings to identify any issues, and there is a clear system for giving feedback to the manager. The manager said that she relies on these meetings to ensure that people can express their views, as well using a variety of other methods to ensure that people using the service, and their carers or relatives, can comment on and influence the service (for example, comment and suggestion forms, one-to-one discussions with members of staff, enabling people to access advocacy support when necessary or requested).

Outcome 1**Minor concern**

Where minor concerns are identified, people who use the service are safe, but the provision of care may not always meet this safety and quality regulation.

The service tends to involve people and their carers in all aspects of planning their treatment and support, which affects their outcomes (including clinical) and may affect their lifestyle and quality of life, but it does not proactively seek comments. Staff understand the importance of people (and their families, as appropriate) being given good quality, timely information about every aspect of their care, treatment and support in order to help them make informed choices. Staff also understand the importance of people being informed and supported to take control of their own lives, and people are encouraged to make their own decisions, even where there are risks involved in the decisions they make.

People's privacy and dignity is recognised and staff seek their views, and those of nominated representatives where necessary, to influence the care, treatment and support offered. However, this practice is not always followed and inconsistencies can occur. Most people understand that their privacy, dignity and human rights should be respected and are aware of policies that staff should follow. These take account of government advice but are not all up to date or audited and changes occur ad hoc. Most staff are aware of these.

Information is available in a range of formats and languages, but this is not always easily accessible. People using the service generally have an understanding about their care, treatment and support, and the potential risks involved, although full explanations are not always given without prompting. People can usually access advocacy services for support if needed, but access can sometimes be difficult.

People are involved and listened to by staff and requests made about their care are considered but are not always accommodated. Generally, people's privacy, dignity and human rights are respected and their diversity needs are understood, although there are some inconsistencies in practice.

A key principle for the service is to consult with and involve people who use services and their carers in developing a plan of care that successfully meets their needs, as far as reasonably possible, by respecting and accommodating people's choices. This principle is adopted by most staff but some inconsistencies occur, resulting in varied outcomes for people.

Most staff are aware of the equality, diversity and human rights agenda and contribute to developments.

There are procedures to ensure that people using the service are informed of their right to confidentiality. Most people understand when staff may have to share personal information but some are unclear.

Case study 2

Some of the bedrooms in a community home for people with complex physical and learning disabilities are too small to manoeuvre hoists with the doors closed. Staff work around this by positioning screens across the doorways while people are being hoisted, to protect their privacy and dignity. Staff are always vigilant about doing this.

The manager has been told that she cannot replace hoists with ceiling track systems, because the home is due to close within the next six months. Two people are moving on to new homes shortly, and the manager has agreed with the remaining residents that those who use a hoist will move into the larger rooms.

- This has a **low** impact on people using the service, because alternatives have been implemented to respect people's dignity and privacy.
- The likelihood of it recurring is **unlikely**, because the environment is being changed to meet individual needs.
- This means it is a **minor** concern.

Case study 3

In a care home, staff are trained to make sure that people who use the service are involved in their care planning. Staff are able to give a clear explanation about how they do this. However, a few residents have some difficulty understanding English, as it is not their first language. Previously there was regular access to interpretation facilities but, due to a member of staff leaving, this service is restricted and only offered at certain times, so care planning can be delayed for those people whose first language is not English.

- This has a **low** impact on people using the service, as their right to be involved in care planning is met, although delayed on occasion.
- The likelihood of it recurring is **possible**, because the interpretation facilities are limited.
- This means it is a **minor** concern.

Case study 4

People with impaired mobility commented that grab rails in the toilets at their GP surgery are not positioned at the correct height, making it difficult for them to use the toilet independently. There have been several instances of people having to ask for help, which has caused embarrassment. The GP surgery invested in changes to its premises to comply with the Disability Discrimination Act, but did not seek input from its patient reference group. Therefore, they were unaware of the problem with the grab rails and made no changes.

The practice manager has been made aware of the problem, and has made urgent arrangements to reposition the rails. The manager has also arranged for regular sessions with the reference group as part of the management meetings to ensure that their views are regularly sought.

- This has a **medium** impact on people using the service, because people's independence and dignity has been compromised.
- The likelihood of it recurring is **unlikely**, because prompt remedial action has been taken and people who use services will be involved more closely with future changes.
- This means it is a **minor** concern.

Outcome 1

Moderate concern

Where moderate concerns are identified, people who use the service are generally safe, but there are risks to their outcome, health and wellbeing. Provision of care is inconsistent and may not always meet this safety and quality regulation.

The service generally does not involve people or their carers in the planning of care, treatment and support, which affects their outcomes (including clinical) and may affect their lifestyle and quality of life. Staff do not always provide appropriate information and only have some understanding of the importance of people (and their families, as appropriate) being given good quality, timely information about every aspect of their care, treatment and support in order to help them make informed choices. Staff are more likely to inhibit people from taking control of their own lives or making decisions and choices rather than encourage.

The concepts of privacy, dignity and human rights are not understood by all staff or people using the service, resulting in a variation of practice for people using services. Not all people have their privacy and dignity accommodated or their diversity needs met.

Few staff are aware of the policies and procedures about respecting people's privacy, dignity and human rights, they are unclear and do not take account of all government advice.

Information is available, but there are inconsistencies among people using the services about whether they understand their care, treatment and support, including potential risks. Few people feel confident to ask for further information or clarification about their planned care, treatment and support. There is limited access to advocacy services for support.

People feel that they are involved and listened to by staff occasionally, and some requests made about their care are considered, but these are infrequently accommodated.

The culture of the service is not proactive about consulting with and involving people who use the service and their carers in developing a plan of care that meets their needs or accommodates their choices. This occurs on an exceptional basis.

Some staff are aware of the equality, diversity and human rights agenda but do not contribute or develop the agenda.

The procedure to ensure that people using the service are informed of their rights to confidentiality is unclear. Many people using the service do not have a clear understanding about how to access advocacy services or when staff may have to share personal information.

Case study 5

People attending an ophthalmology clinic for diagnostic tests are not told before they arrive about the short-term side effect of retinal angiography. This is the sudden onset of nausea as the fluorescent dye circulates through the bloodstream. Patients have told staff that they would have liked to have been warned about this before their appointment. Staff said that they will consider adding it to the next update of their patient information sheet. However, most staff agree that it's better not to give too much information in advance, because not everyone experiences this side effect and, when it does happen, it passes quickly.

- This has a **low** impact on people using the service, because they have not been given all the information about the treatment they are receiving.
- The likelihood of it recurring is **almost certain**, because staff are not listening to people who use the service.
- This means it is a **moderate** concern.

Case study 6

Men at a prison say that they are told in advance about attending a hospital appointment. However, they are not provided with information in a format that they understand. Also, they are not given the opportunity to have input into their care and treatment options. In response to this, staff said that the most important thing was to ensure that the person attends the appointment and that care planning is for the professionals to manage.

- This has a **medium** impact on people using the service, because people are not given the opportunity to input into their care planning.
- The likelihood of it recurring is **possible**, because staff do not recognise people's rights to be involved.
- This means it is a **moderate concern**.

Case study 7

Uptake of breast screening among women of a particular minority ethnic group has recently increased, following a targeted community health promotion initiative. Few of the women speak English, and the screening unit has an unreliable interpreting service. Some of the women who attended told their community leaders that they were distressed by the screening process because nobody was available to explain what would happen to them, therefore they may not attend again. This has been fed back to the unit through the local LINK. The interpreting service contract has been strengthened to ensure that someone is available to interpret in the required languages.

- This has a **high** impact on people using the service, because people's needs were not fully met and some women may not continue to attend screening.
- The likelihood of it recurring is **unlikely**, because the unit has acted promptly and effectively to improve access to an appropriate interpreter.
- This means it is a **moderate concern**.

Outcome 1

Major concern

Where major concerns are identified, people who use the service are not protected from unsafe or inappropriate care. The provision of care does not meet this safety and quality regulation.

The service generally does not involve people or their carers in the planning of care, treatment and support. Little information is given that people can use to make an informed choice about things that affect their lifestyle and quality of life. Staff are more likely to inhibit people from taking control of their own lives or making decisions and choices rather than encouraging them.

The concept of privacy, dignity and human rights is not clearly understood by people or staff, which results in regular disregard by staff and misunderstanding by people using the service of what to expect.

Staff are not aware of policies and procedures about respecting people's privacy, dignity and human. Policies and procedures are either absent or of poor quality and do not take account of government advice.

Information for people using the service is available in a limited format and people do not have a full understanding of their care, treatment or support and the potential risks involved. Advocacy services are rarely available to give support.

People do not feel involved or listened to by staff and are encouraged not to engage or discuss changes to their care, treatment or support. Practice does not encourage respecting people's privacy and dignity. People using the service and staff do not fully understand the meaning of privacy and dignity, which supports continuing poor practice.

The ethos of the service is for staff not to consult with or involve people who use the service or their carers in developing a plan of care. Few staff are aware of the equality, diversity and human rights agenda or contribute to it.

People using the service are not informed of their rights to confidentiality. They do not have an understanding about when personal information should be shared or know how to access advocacy services for support.

Case study 8

The families of people living in a care home have expressed concerns that the home is not doing enough to maintain their relatives' independence. People who can walk with help are not offered support, and they are informed they must use wheelchairs, especially at mealtimes, principally to save time. The manager explained that several people had fallen in the past few months and the number of staff is too low to offer people help when residents want to walk around. In her opinion, safety is more important than independence and she insists on the use of wheelchairs unless they can walk without help.

- This has a **medium** impact on people using the service, because their independence is not being promoted.
- The likelihood of it recurring is **almost certain**, because the manager is prioritising ease and safety over independence.
- This means it is a **major concern**.

Case study 9

A number of people who underwent liposuction at a cosmetic surgery clinic have contacted their MP after experiencing the same complication, which they had not been told about prior to surgery. Information leaflets provided by the clinic do not mention this complication, and there are no agreed protocols for what should be discussed at consultation. Surgeons are not closely involved in governance issues and there is no regular review of written information for patients. The clinic has now updated its information leaflets to include information about possible complications, and the manager is arranging for the surgeons to meet to develop common protocols for all procedures.

- This has a **high** impact on people using the service, because they have not been informed of all possible complications.
- The likelihood of it recurring is **possible**, because the clinic does not have protocols for consultation.
- This makes it a **major concern**.

Case study 10

People living at a care home for people with a learning disability told us they are not involved in how the service runs and that staff do not listen to them. People told us they would like to go to the local pub quiz but staff said that this could not be arranged as it was at the same time the shifts changed. Staff said that people's needs would be accommodated as long as it fits with the staff and their rota.

- This has a **high** impact on people using the service, because their rights to choice are not being respected.
- The likelihood of it recurring is **almost certain**, because staff prioritise their needs over people using the service.
- This means it is a **major concern**.

Outcome 2 (Regulation 18)

Consent to care and treatment

Outcome 2 Compliance

The provider has met all aspects of this safety and quality regulation as the outcome described in the guidance about compliance is fully met (refer to the guidance about compliance for detail).

Case study 1

There is a comprehensive welcome pack for people detained on an acute mental health ward, explaining the law around detention, appeal, and consent to treatment. This is given to people, or a named advocate where necessary, on admission to the unit and a member of staff said that she always goes through the pack in detail with new people admitted. Patients are aware of their consent status and care plan, and these are documented in their files. The legal authority for treatments being administered under the Mental Health Act is clear and correct in every case.

Outcome 2**Minor concern**

Where minor concerns are identified, people who use the service are safe, but the provision of care may not always meet this safety and quality regulation.

Staff with the appropriate knowledge and understanding of the care, treatment or support required for a person seek and record their consent, however they may not have access to all relevant information.

Processes are in place to assess and manage people who use services, including people detained. Processes meet the requirements of the Mental Health Act 1983, the Mental Capacity Act 2005 and the Children Act 1989, and other recommended guidance e.g. from professional/regulatory bodies. However, these are not reviewed frequently.

People feel informed when giving consent and do not feel under-pressure; however staff do not proactively encourage autonomy in decisions. People who use the service are able to make a decision of their choice, but this is not always reviewed. People are able to change their decision but this is not proactively encouraged by staff.

Information to ensure that people understand the implications of the care, treatment or support being offered is provided in a range of formats but this is not always available. Carers or advocates are usually involved where needed.

Decisions about consent are recorded and where written consent is sought, appropriate and correct forms are used. The consent process is audited but improvements are not always made.

Case study 2

An independent mental health hospital undertakes regular reviews of patients' consent decisions, taking into account their changing needs. A recent audit of consent documentation shows a higher than usual number of records with the date field left blank, making it impossible to determine how often consent is being reviewed. However, a separate audit of patients' experience of consent revealed no concerns. Further analysis of the incomplete records showed that it was newly-appointed staff who were failing to complete them correctly. They have since received training on documenting consent. Further audits are scheduled for the remainder of the year.

- This has a **low** impact on people using the service, because the audit of their experiences showed people are involved in consent decisions.
- The likelihood of it recurring is **unlikely**, because all staff have received training and documentation audits continue to be undertaken on a regular basis.
- This means it is a **minor concern**.

Case study 3

Staff at a care home told us they always seek consent before using bed rails to keep people safe. People using the service and their advocates told us that they made informed decisions to consent to this. Records always reflect the discussions, but a signature is not always obtained from the person giving consent.

- This has a **low** impact on people using the service, because people are involved in the decision to use bed rails.
- The likelihood of it recurring is **possible**, because staff are not seeking consent appropriately.
- This means it is a **minor concern**.

Case study 4

Staff at a care home for people with dementia have given a flu vaccination to a new person without seeking their consent, after incorrectly assessing her capacity to refuse consent. Further discussion with the woman and her family confirmed that she did, in fact, have the capacity to refuse consent. The member of staff involved had not received training in the Mental Capacity Act. All staff have now been trained, and individual assessments of capacity are fully documented and clearly visible in care plans.

- This has a **medium** impact on people using the service, because consent was not sought.
- The likelihood of it recurring is **unlikely**, because all staff are now fully trained on the Mental Capacity Act and documentation about capacity is clearly visible in care plans.
- This means it is a **minor concern**.

Outcome 2**Moderate concern**

Where moderate concerns are identified, people who use the service are generally safe, but there are risks to their outcome, health and wellbeing. Provision of care is inconsistent and may not always meet this safety and quality regulation.

Consent is not always sought and recorded by staff with the appropriate knowledge and understanding of the care, treatment or support needed for the person. Staff are not fully briefed and have limited information about the person.

Processes to manage people using the service that meet the requirements of the Mental Health Act 1983, Mental Capacity Act 2005 and Children Act 1989 are unclear and infrequently checked.

People do not always feel informed when giving consent and staff do not encourage autonomy when people are making a decision. People can feel under pressure about what option they choose and are not always given the opportunity to change this decision.

Information to ensure people understand the implications of their care, treatment or support is available in a limited range of formats and is not easily accessible. Carers or advocates are not consistently involved where needed.

Decisions about consent are recorded, but some records are not accurate or kept up to date. The consent process is infrequently audited, resulting in limited improvements.

Case study 5

A care home that is experiencing an unusually rapid turnover of staff has been unable to ensure 100% compliance with staff training on the Mental Capacity Act. Therefore, managers try to ensure that staff who have not attended training do not take consent. This is monitored regularly and found to be working.

- This has a **low** impact on people using the service, because a process is in place to ensure that only trained staff are seeking consent.
- The likelihood of it recurring is **almost certain**, because until all staff are trained and staffing turnover stabilises, there is a risk of untrained staff seeking consent.
- This means it is a **moderate concern**.

Case study 6

The parents of an eight-year old boy signed a consent form on his behalf for a minor surgical procedure. No assessment was made of the child's ability to understand the process, and staff did not attempt to include him in the discussions or provide information in a format relevant for a young child.

- This has a **medium** impact on people using the service, because the person was not involved in the consent process.
- The likelihood of it recurring is **possible**, because local processes do not accommodate the need to include the views and opinions of minors when obtaining consent.
- This means it is a **moderate concern**.

Case study 7

People attending an acute hospital for treatment for a skin condition, who are taking part in a clinical research trial, were given consent forms to sign. However, the forms contained incomplete information. The manager explained that this was a printing error that had not been identified. Some people described how they had given consent, which they would not have done if they had received more information.

Doctors were unable to say what the effects of the trial would have on these people in the future. However, they confirmed that the incident had been formally reported, systems had been amended to prevent this recurring and the volunteers had been told about the mistake and provided support if needed.

- This has a **high** impact on people using the service, because they had been ill-informed when giving consent.
- The likelihood of it recurring is **unlikely**, because systems of monitoring have been put in place.
- This means it is a **moderate concern**.

Outcome 2**Major concern**

Where major concerns are identified, people who use the service are not protected from unsafe or inappropriate care. The provision of care does not meet this safety and quality regulation.

Consent is regularly sought by staff who do not have the appropriate knowledge and understanding of the care, treatment or support needed by the person they are seeking consent from. They have no access to information about the person and may not record consent appropriately.

Processes to manage people using the service that meet the requirements of the Mental Health Act 1983, Mental Capacity Act 2005 and Children Act 1989 are limited and practices are not checked.

People do not feel informed when giving consent and staff do not encourage autonomy when people are making a decision. People feel under pressure and are not given the opportunity to change their decision.

Information to ensure that people understand the implications of their care, treatment or support is not available. Carers or advocates are rarely involved where needed.

Records of decisions about consent are poor or absent. Where written consent is sought, the forms are inappropriate or incorrect. The consent process is not audited.

Case study 8

A woman attends an appointment for a surgical procedure. During the consent process, it becomes apparent that she does not speak English and does not understand what is happening. Her partner who normally attends to interpret for her is not available and they do not have interpreters or documentation in her first language. As the surgery is already booked and staff have previously discussed the procedure with her and her partner, they continue with the consent process, which the patient signs.

- This has a **medium** impact on people using the service, as consent information cannot be shared with people whose first language is not English.
- The likelihood of it recurring is **almost certain**, because a system is not in place to help people whose first language is not English.
- This means it is a **major concern**.

Case study 9

A mother has recently given consent for her daughter, who has a learning disability, to undergo a sterilisation operation. No assessment was made of the daughter's capacity to give consent. After the operation, she told her advocate that she would have liked to have had children, but her mum has stopped her. The doctor said that he had not had any training on the Mental Capacity Act 2005 and thought the woman understood what she was signing.

- This has a **high** impact on people using the service, because people's understanding or capacity to consent is not assessed.
- The likelihood of it recurring is **possible**, because doctors do not have the appropriate understanding of the Mental Capacity Act.
- This means it is a **major concern**.

Case study 10

A young woman aged 14 signed consent form for a termination of pregnancy procedure. No assessment was made to verify the woman's age or capacity to consent. After the procedure, the woman commented that she had not understood what would happen to her during the treatment, she felt frightened and unable to ask questions from staff seeking consent and was worried whether she would be able to have children in the future.

- This has a **high** impact on people using the service, because staff do not verify personal details of people giving consent.
- The likelihood of it recurring is **almost certain, because** the processes do not include checking personal details.
- This means it is a **major concern**.

Outcome 4 (Regulation 9)

Care and welfare of people who use services

Outcome 4 Compliance

The provider has met all aspects of this safety and quality regulation as the outcome described in the guidance about compliance is fully met (refer to the guidance about compliance for detail).

Case study 1

In a small care home for people with learning disabilities, there is recorded evidence that all people using the service have an ongoing assessment and that their care plans cover all needs, including maximising health and wellbeing, advocacy and support for social activities. Feedback from people living in the home shows that people feel all of their needs, including those relating to their diversity and culture, are being met and are happy with the service.

Outcome 4

Minor concern

Where minor concerns are identified, people who use the service are safe, but the provision of care may not always meet this safety and quality regulation.

People using the service have an assessment and plan of care, but the practice of involving people or their representative in the planning of care can be variable. The assessment and plan of care includes the necessary information to deliver the person's care.

Care plans are reviewed involving all relevant staff and people using the service. But, while significant needs are accommodated, people's less significant needs are not always accounted for.

Risk assessments are completed but these are basic and can be delayed.

The delivery of care – although safe, effective, and appropriate – is not always flexible enough to meet individual needs.

The service takes steps to use appropriate, accepted guidance in practice, but this is not always done in a consistent way.

Case study 2

Radiographers in an acute hospital review and report on certain emergency department x-rays, for which they are trained and qualified. Some team members are working towards their qualification and their reports are routinely checked by a consultant radiologist. However, there have been some problems in the hospital caused by a batch of reports from radiographers who have not completed their specialist training that were not checked by a consultant. The problem arose when a new system of reporting was put in place.

The hospital recognised the problem after a couple of weeks and immediately reviewed all the reports, finding no significant disagreement. Also, the new process has been reviewed and amendments made to prevent the same problem arising.

- This has a **low** impact on people using the service, because there was a delay in checking the reports.
- The likelihood of it recurring is **unlikely, because** the new process has been implemented and the issue rectified.
- This means it is a **minor concern**.

Case study 3

A mental health NHS trust has recently started to hold multidisciplinary care programme approach (CPA) meetings in a small community hospital, situated in a rural area with poor public transport links. This is to provide a service for people living in the area who find it difficult to travel to the main trust site. All members of the multidisciplinary team attend on a regular basis, but people's notes are sent ahead using the internal transport system.

On two occasions notes have not arrived in time for the meeting. However, in line with agreed trust policy, care co-ordinators bring copies of the agreed CPA and take responsibility for transferring any changes made at the meeting to the main notes at a later date.

- This has a **low** impact on people using the service, because information is made available.
- The likelihood of it recurring is **possible**, because the transport process is ineffective.
- This means it is a **minor concern**.

Case study 4

Mrs S receives personal care in her own home. It was agreed in her care plan that her home visits should be increased from two to four a week. However, this took four weeks to change. When this was raised with the manager of the service, she said that there had been problems in keeping track of changes to people's care plans and that a central reporting and recording process had recently been put in place to address this issue.

- This has a **medium** impact on people using the service, because the frequency of visits has not increased.
- The likelihood of it recurring is **unlikely, because** a new process has been implemented to resolve the issue.
- This means it is a **minor concern**.

Outcome 4

Moderate concern

Where moderate concerns are identified, people who use the service are generally safe, but there are risks to their outcome, health and wellbeing. Provision of care is inconsistent and may not always meet this safety and quality regulation.

Most people using the service have an assessment and plan of care, but not all. The assessment and plan is basic and means the delivery of care is not reliable. There is very limited inclusion of prevention in the assessment and plan of care.

Although reviews are carried out, they are not done regularly with the involvement of all appropriate staff, and changes that have been highlighted at the review do not always feed back into the plan of care. People who use services are not encouraged to be involved in the review process.

Risk assessments are usually completed, but do not cover all aspects of ensuring that someone is cared for and supported in a safe way. Staff are not always aware of the risk assessments.

The delivery of care is not always safe, effective, appropriate and flexible enough to meet individual needs.

The service uses appropriate, agreed guidance sporadically and the changes in practice are audited infrequently limiting improvements.

Case study 5

Following the publication of an annual survey of people using community mental health services, a local assessor briefly mentions the survey results at a routine discussion with the service manager in the local mental health trust. The trust has been doing its own quarterly audits of the implementation of the refocused care programme approach (CPA). Each of its last three audits have shown some clear inconsistencies in practice within some teams, including ensuring that review meetings are held and care plans are updated, although overall satisfaction among people who use the service seems good and that most aspects of the CPA are being implemented.

- This has a **low** impact on people using the service, because they are receiving an adequate service.
- The likelihood of it recurring is **almost certain**, because the trend has not shown improvements over time.
- This means it is a **moderate concern**.

Case study 6

When Mr B was transferred to his local community hospital for rehabilitation, his care plan identified that he was at risk of falling. The community hospital did not put protective rails on his bed and Mr B had a fall during the night. While there was a policy of reassessing people's risk of falling on admission, feedback from staff indicate that these assessments can be delayed.

- This has a **medium** impact on people using the service, because their needs are not being accommodated following admission.
- The likelihood of it recurring is **possible**, because the risk assessment process is regularly delayed.
- This means it is a **moderate concern**.

Case study 7

A trust has no mechanism for ensuring that it follows the National Institute for Health and Clinical Excellence's guidance on interventional procedures, and that the right checks are made if new interventional procedures are carried out within the trust. The trust says that because of the services it provides, none of its staff currently undertake any interventional procedures. Therefore, they feel they do not need to have the relevant mechanisms in place.

- This has a **high** impact on people using the service, because of the lack of appropriate governance and awareness, therefore procedures may be carried out in an unsafe way or by staff who are not appropriately trained.
- The likelihood of it recurring is **unlikely**, because of the type of procedures that are carried out.
- This means it is a **moderate** concern.

Outcome 4**Major concern**

Where major concerns are identified, people who use the service are not protected from unsafe or inappropriate care. The provision of care does not meet this safety and quality regulation.

Not all people using the service have an assessment or plan of care. Where these exist they are very basic, and only record simple health and personal care needs.

There is no evidence of appropriate staff or people using the service being involved in the development of their plan of care, and it does not reflect their diverse needs, current situation or discuss any future plans.

Because there are only basic plans in place, care delivery can be inconsistent and variable. This can lead to practice that is unsafe.

Reviews do not take place regularly. There is little evidence of risk assessments. Those that exist are generic and out of date and do not address key safety or welfare concerns. People are not allowed to make informed choices or to take risks.

The safety, effectiveness and appropriateness of care delivery is insufficient, and there is no flexibility to meet individual needs.

The service does not use appropriate, accepted guidance to help inform their practice, and does not keep up to date with current policy or developments. This can mean their practice is dated.

Case study 8

A care home provides care for older people with a variety of needs. Some have long-term illnesses that are usually managed by the district nurse or GP. The home has recently appointed a 'care manager' with a vocational qualification in care as its clinical lead; the registered manager does not have a clinical background. The care manager has made amendments to the care plans (previously developed with input from the district nurse). This has included changing the times that medication is given and not changing dressings of leg ulcers as recommended.

Members of staff and some residents have raised concerns with the registered manager. The registered manager has supported the changes, as she feels the care manager is acting in line with his job description. The care manager is not suitably qualified to make alterations in the planning and delivery of care and those alterations could put residents at risk.

- This has a **medium** impact on people using the service, because these changes directly impact on their care and needs.
- The likelihood of it recurring is **almost certain, because** the registered manager is supporting the care manager and the changes that are being made.
- This means it is a **major concern**.

Case study 9

The mortality rate for pulmonary embolism following surgery at a hospital is significantly higher than expected. Enquiries found that the hospital does not follow any evidence-based guidance about preventing blood clots (for example, clinical guidelines from the National Institute for Health and Clinical Excellence) and overall there is very limited communication to staff about how to implement recognised good practice guidance.

- This has a **high** impact on people using the service, because they are not protected from unsafe or inappropriate care
- The likelihood of it recurring is **possible**, because the process to circulate and implement evidence is poor.
- This means it is a **major concern**.

Case study 10

People with suspected skin cancer are being referred by their GP to a plastic surgeon at an acute hospital who does not have a specialist interest in skin cancer. The trust has a specialist dermatologist, but its custom and practice means that people are only seen by the specialist dermatologist once a diagnosis of cancer has been confirmed. This practice is not in keeping with published evidence-based guidelines, and could mean that some skin cancers are missed. The trust does not have a clear referral protocol for people with potential skin cancer.

- This has a **high** impact on people using the service, because their needs are not being safeguarded and practice does not follow evidence-based guidelines.
- The likelihood of it recurring is **almost certain, because** the process does not allow referrals to be sent to the appropriate specialist.
- This means it is a **major concern**.

Outcome 5 (Regulation 14) Meeting nutritional needs

Outcome 5 Compliance

The provider has met all aspects of this safety and quality regulation as the outcome described in the guidance about compliance is fully met (refer to the guidance about compliance for detail).

Case study 1

A community hospital uses a multidisciplinary approach to nutritional assessment. There is a nutritional screening tool for identifying the nutrition and hydration needs for all its patients. These are recorded in the care plans. There is a protected meal time in operation, which allows patients to eat without interruption. Patients who need help with eating and drinking are identified and help is provided with due regard to dignity and respect. Senior staff carry out audits to ensure that there is adequate choice and availability of nutritious food and drink at all times, which meets people's diverse needs.

Outcome 5**Minor concern**

Where minor concerns are identified, people who use the service are safe, but the provision of care may not always meet this safety and quality regulation.

People's nutritional and hydration needs are understood and accounted for in their plan, including any medical dietary requirements. The plan is reviewed and monitored, but not regularly, and staff do not proactively seek people's input. Diverse needs are accommodated and a healthy balanced diet is offered at all times (i.e. up to 24 hours everyday). However, the range is limited.

Food is generally presented in an appetising manner and people's dignity is considered at mealtimes. Support is offered to people when eating and drinking and if a person using the service requests facilities to enable independence when eating this will be provided, but there is not a proactive attitude to promoting independence.

People are generally allowed sufficient time to enjoy their meals, but may sometimes be interrupted.

Case study 2

A care home has clear procedures in place to identify and meet nutritional requirements for all its residents. On a visit, residents tell us that recently there was a short period when the menu was very limited. The service manager reports that there was an unexpected problem with the oven and as a result staff had to provide sandwich meals and some meals warmed up in the microwave. This meant the choices of meals were limited, but none of the residents went hungry and the options were healthy. There was some delay in getting the oven fixed, but this was completed with no further problems.

- This has a **low** impact on people using the service, as they receive a healthy meal.
- The likelihood of it recurring is **unlikely**, because the issue was the broken cooker, which has been repaired.
- This means it is a **minor concern**.

Case study 3

One person using the service told us they had indicated that they needed halal food on admission to hospital. This was noted in the care plan. Staff had ordered the meals accordingly. When the meal arrived, the person wanted to confirm that the food was halal. Staff were not available to follow this up as they were busy helping other people to eat and drink as indicated in their care plan and the kitchens were not able to answer the query. The person felt that staff should have confirmed that the food was halal, as it would have compromised his religious beliefs if he had eaten food that was not.

- This has a **low** impact on people using the service, because the halal food had been ordered.
- The likelihood of it recurring is **possible**, because staff may be unavailable to follow up and there is poor communication with the kitchen.
- This means it is a **minor concern**.

Case study 4

A community hospital provides rehabilitation for people with fractures. Many of the patients need adapted cutlery and beakers to be able to eat or drink independently. The order for such appliances was delayed by five weeks, as it was misplaced in the system.

- This has a **medium** impact on people using the service, because a person's choice to eat independently has not been supported.
- The likelihood of it recurring is **unlikely**, because the equipment was ordered.
- This means it is a **minor concern**.

Outcome 5**Moderate concern**

Where moderate concerns are identified, people who use the service are generally safe, but there are risks to their outcome, health and wellbeing. Provision of care is inconsistent and may not always meet this safety and quality regulation.

People's nutritional and hydration needs and medical dietary requirements are not always reviewed and accounted for in their plans, and/or are not regularly monitored. People are occasionally asked for their input in their dietary plan but staff do not encourage this. Diverse dietary needs are accommodated if specifically requested, but the range of food offered is limited and is not available 24 hours a day, seven days a week.

Food is not always presented in an appetising manner or people's dignity respected at mealtimes. Support for people when eating and drinking is limited and people have to wait for help. Independence is not promoted and limited facilities are available to enable people to independently feed themselves.

People regularly endure delays, have insufficient time to finish eating or are frequently interrupted during mealtimes.

There is concern that people may be at risk of malnutrition or dehydration.

Case study 5

The carer of a patient at a specialist hospital for people with cancer told us that their relative had a particularly difficult time after chemotherapy, and had requested food that did not need cutting up or chewing as the patient felt tired and weak. When the food arrived, it was a roast chicken dinner and did not meet the needs of the patient.

The carer spoke to the nurse who provided some soup as a replacement; this was kept on the ward for situations like this. The patient was able to eat the soup, but the need to replace meals was a regular occurrence as the kitchen frequently sent inappropriate meals.

- This has a **low** impact on people using the service, because people do not get food that meets their needs.
- The likelihood of it recurring is **almost certain**, because the kitchen does not understand the importance of supplying food that has been requested.
- This means it is a **moderate concern**.

Case study 6

An intermediate care centre provides rehabilitation services for people who have had a stroke. They provide nutritious meals and drinks for all the patients, and there is a good choice of food for all types of needs. However, staff are not able to tell patients what the ingredients of the dishes are, as the catering is contracted out and is served by catering assistants who do not speak English as their first language. This prevents people who use the service from being able to make an informed choice and, because people are recovering from a stroke, most are unable to communicate easily or understand what is being said.

- This has a **medium** impact on people using the service, because they do not have enough information to make choices and the situation has made them more vulnerable.
- The likelihood of it recurring is **possible**, because staff cannot communicate with the catering assistants.
- This means it is a **moderate concern**.

Case study 7

A local supplier to a nursing home started baking its own products and the nursing home started to use this supplier for some baked goods. However, the products came without labelling. The nursing home's manager and the residents were unaware that these goods contained nuts. As some residents had nut allergies, they suffered side effects and needed medical attention. The home stopped using this supplier and ensured that all products bought in future were clearly labelled including any nut content.

- This has a **high** impact on people using the service, because they are unaware of the food's content.
- The likelihood of it recurring is **unlikely**, because staff took action quickly to address the issue and all goods are now labelled.
- This means it is a **moderate concern**.

Outcome 5**Major concern**

Where major concerns are identified, people who use the service are not protected from unsafe or inappropriate care. The provision of care does not meet this safety and quality regulation.

Food is unappetising and people's dignity is not respected at mealtimes. Support for people when eating and drinking is limited and people frequently have to wait for help from staff. Independence is not promoted and facilities are not available to enable people to independently feed themselves.

Mealtimes are frequently unpleasant with regular interruptions and long delays resulting in people not eating.

There is evidence that people are suffering from unattended malnutrition or dehydration. Food is only offered or available during routine or normal working hours.

Case study 8

All residents in a care home have their meals in the dining area at set times in the day. A number of residents say they are very unhappy about meal arrangements, and would like to be able to eat their meals in their own rooms and for the mealtimes to be longer and more flexible. In particular, the evening mealtime was particularly early and short, meaning some residents did not have time to finish their food and often felt hungry later in the evening. Staff said that meal arrangements cannot change because of the shift patterns of catering staff and the additional cleaning requirements if people ate in their rooms.

- This has a **medium** impact on people using the service, because they are not able to finish eating and their choices are not being accommodated.
- The likelihood of it recurring is **almost certain**, because the service is not willing to be flexible.
- This means it is a **major concern**.

Case study 9

We received a notification of the death of a person with learning disabilities living in a residential home, following an allergic food reaction. In response to our enquiries, the staff said that they did not know that the person had a food allergy, as they had only just moved to the home. However, they confirmed that they didn't ask about allergies, as these are usually recorded in care plans that come with the person when they move into the home.

- This has a **high** impact on people using the service, because they are not protected from the risk of allergic reactions.
- The likelihood of it recurring is **possible, because** staff rely on information contained in care plans written by others that may not be up to date.
- This means it is a **major concern**.

Case study 10

A care home provides care for people with dementia. All the residents have a nutritional assessment and a care plan, which includes their nutritional and hydration needs. It was noted by the local authority that the care home had called for an ambulance many times in the past year for people suffering severe urinary tract infections and dehydration. On further investigation, it was found there were inadequate arrangements to ensure that people were drinking enough, as staff found the behaviour of some residents difficult to cope with and so did not provide the support needed.

- This has a **high** impact on people using the service, because they are not protected from dehydration and subsequent illnesses.
- The likelihood of it recurring is **almost certain**, because the home does not have the appropriate staff to deliver the care needed by the residents.
- This means it is a **major concern**.

Outcome 6 (Regulation 24) Cooperating with other providers

Outcome 6 Compliance

The provider has met all aspects of this safety and quality regulation as the outcome described in the guidance about compliance is fully met (refer to the guidance about compliance for detail).

Case study 1

A local voluntary group for people with arthritis has been closely involved in the development of care pathways for people admitted to hospital during acute episodes of illness. Staff explained the processes that are used to ensure that information is shared with everyone involved in people's care. People told us that their specialist needs are met, regardless of where the care is delivered. They always take their care plans with them into hospital and know that staff will follow them to arrange their discharge.

Outcome 6

Minor concern

Where minor concerns are identified, people who use the service are safe, but the provision of care may not always meet this safety and quality regulation.

There are clear processes in place about how a person's needs should be assessed, and their care should be planned and delivered when more than one provider is involved in a person's care, but these are not reviewed regularly and some staff are not fully aware of them.

The service works with other providers to make sure that there is a joint care assessment and plan for all to contribute to, but these assessments may not be fully up-to-date. The service is aware of the care they are responsible for but is not clear about the roles of each of the other providers.

The plan of care is documented but may be inaccessible to some of those involved. The service discusses the person's plan of care with the person and the other providers, but this does not happen routinely.

There are clear processes in place about what should happen when a person moves from one service to another to ensure that the person's needs continue to be met and their rights protected, including admission, transfer, referral and discharge. These are not reviewed regularly and some staff are not fully aware of them.

When needed, information about a person's care, treatment and support is passed to other service(s) to enable assessment, planning or delivery of care by the other provider. There are clear protocols in place that meet the legal requirements of the Data Protection Act 1998, but these are not regularly reviewed and some staff are not aware of them.

Where it is required by either the Health Emergency Planning Officer or the Local Government Emergency Planning Officer, a service has an effective major incident plan in place, which clearly states how the service will cooperate with other providers if the plan is implemented. Not all relevant staff are aware of the plan.

Case study 2

A patient was transferred from an elderly care ward to a cardiac care ward. During transfer, the patient had all their medications with them. However, their medical records were not available and arrived the day after the transfer was completed. This was due to a lack of staff on the elderly care ward, which caused a delay in transferring the records. The staff were aware of what the process should have involved.

- This has a **low** impact on people using the service, because there was no risk to health outcomes.
- The likelihood of it recurring is **unlikely**, because the correct process is in place.
- This means it is a **minor concern**.

Case study 3

A manager from a local authority review team reports that they have had recent difficulty in obtaining up-to-date information from a home for 10 people who have a learning disability. He states that the manager at the home is usually unavailable when they visit and staff members are uncooperative when asked for further information. A review has recently been cancelled by the home at short notice and requested information not supplied.

- This has a **low** impact on people using the service, because information is not being shared.
- The likelihood of it recurring is **possible**, because staff are uncooperative.
- This means it is a **minor concern**.

Case study 4

People living in a care home told us they have been unable to attend their weekly physiotherapy sessions, because it has coincided with their weekly art class. Staff said that they don't routinely share with physiotherapy information about people's social activities, and the physiotherapist said that she was unaware that people would not be available during this time. The manager explained that training had commenced for all staff about how and when to cooperate with other providers and share information, and the availability for the physiotherapy sessions should be confirmed with the person receiving the care.

- This has a **medium** impact on people using the service, because treatment is not being received.
- The likelihood of it recurring is **unlikely**, because training has been put in place.
- This means it is a **minor concern**.

Outcome 6**Moderate concern**

Where moderate concerns are identified, people who use the service are generally safe, but there are risks to their outcome, health and wellbeing. Provision of care is inconsistent and may not always meet this safety and quality regulation.

Processes about how a person's needs should be assessed, and their care should be planned and delivered when more than one provider is involved in a person's care are incomplete and not monitored. The service does not work well with other providers and does not systematically contribute to joint assessment and delivery of care.

Processes relating to when a person moves from one care service to another, including admission, transfer, referral and discharge, are inconsistent and not monitored.

When needed, information about a person's care, treatment and support is passed to other services to enable assessment, planning or delivery of care by the other provider, but this transfer of information is inconsistent and often delayed. Protocols about transferring information are poorly implemented and not understood by staff.

Processes about how information relating to a safeguarding allegation, or another matter of wider public interest, should be transferred between more than one service are poorly implemented and not understood by staff.

Where it is required by either the Health Emergency Planning Officer or the Local Government Emergency Planning Officer a service has a major incident plan in place, but the plan is not reviewed or communicated to staff.

Case study 5

A continuing care health needs assessment is completed for Mr F by hospital staff, and this information is shared with other agencies to identify a suitable nursing home placement. However, Mr F is not discharged for another three weeks and develops a grade one pressure sore. The assessment is not updated and the change in needs are only identified to the nursing home on discharge. The home is still able to meet Mr F's needs, but they had not been given up-to-date information prior to transfer. The hospital report that ward staff do not have an approach for updating assessments if a delay occurs on discharge.

- This has a **low** impact on people using the service, because an assessment is carried out and shared.
- The likelihood of it recurring is **almost certain**, because staff do not routinely update the needs assessment following delays.
- This means it is a **moderate concern**.

Case study 6

A person was discharged home from hospital and information about the care they had received was not communicated to the domiciliary care agency. The care plan, therefore, was not updated to reflect newly assessed needs. The person said that, as a result of this, only one care worker arrived at their home and they could not be moved until a second care worker arrived two hours later. The manager of the hospital said that agency staff were responsible for the poor communication, as they had not yet been trained in the discharge procedure.

- This has a **medium** impact on people using the service, because care plans are not being updated.
- The likelihood of it recurring is **possible**, because training has not yet been provided to all relevant staff.
- This means it is a **moderate concern**.

Case study 7

A young man with challenging behaviour attends a special school and is in receipt of CAMHS services within the school setting. His annual multidisciplinary review is approaching: a time to explore how his needs and independence can be developed and re-assessed in the transition from children to adult services. Although CAMHS staff are present at the meeting, adult mental health services have not been invited.

The parents raise concerns about access to adult services, as it is acknowledged that the young man will have continuing health needs. Following the meeting, CAMHS staff refer the family to adult services for a transitional assessment and incorporate the need for routine involvement with adult services in their process.

- This has a **high impact** on people using the service, because not all those who need to be involved in a person's treatment and support have contributed to the review of needs.
- The likelihood of it recurring is **unlikely**, because once the omission was recognised the provider put processes in place to prevent a similar incident.
- This means it is a **moderate concern**.

Outcome 6

Major concern

Where major concerns are identified, people who use the service are not protected from unsafe or inappropriate care. The provision of care does not meet this safety and quality regulation.

The service rarely contributes to joint assessments of a person's care and can be obstructive when working with other providers.

Processes relating to when a person moves from one care service to another, including admission, transfer, referral and discharge, are incomplete and poorly implemented.

The transfer of information about a person's care, treatment and support to other services is often incomplete, delayed or incorrect, and has an adverse impact on the ongoing care of the person.

There are no specific protocols about transfer of information relating to safeguarding allegations or any other matters of wider public interest.

Where it is required by either the Health Emergency Planning Officer or the Local Government Emergency Planning Officer a service has a major incident plan but the documentation is incomplete and it is not available to staff.

Case study 8

An Asian man is admitted to a care home from hospital and English is not his first language. The discharge notes give good information about his healthcare needs, medical history, mobility and diverse needs. The notes clearly state that he has special dietary preferences and needs help to walk. However, this information is disregarded and is not recorded in his care plan.

The man's appetite is poor, he is losing weight and he has suffered a fall as he was not offered help to walk. A relative visits him at the home five days after admission and gives the home important information about the man's cultural background and needs. The care home amends his care plan in line with this, even though it had been given the same information in his discharge notes.

- This has a **medium** impact on people using the service, because individual needs are not being met.
- The likelihood of it recurring is **almost certain**, because staff do not use the information provided in the discharge notes.
- This means it is a **major concern**.

Case study 9

Mrs T has dementia and is admitted to the hospital emergency department in some distress at 11.30pm, after a fall at her care home. The member of staff accompanying her is from an agency and does not know Mrs T well. The notes supplied from the home are incomplete and do not include the medication record. The hospital staff are unable to treat Mrs T immediately because of these omissions. A further enquiry tells us that the care home has no formal procedures for staff to follow concerning transfer of information.

- This has a **high** impact on people using the service, because medical records are not known so care is delayed.
- The likelihood of it recurring is **possible**, because there is a lack of a process to support the sharing of information.
- This means it is a **major concern**.

Case study 10

Collaborative end-of-life plans have been drawn up for people transferring to a hospice, but the ambulance service were not involved in this. An emergency ambulance recently resuscitated someone, during the journey to the hospice, who had a documented advanced decision. This was against their documented wishes. Ambulance staff had not been given access to the plans of people transferring to the hospice.

- This has a **high** impact on people using the service, because their documented advanced decisions are not respected.
- The likelihood of it recurring is **almost certain**, because providers have not been working together.
- This means it is a **major concern**.

Outcome 7 (Regulation 11) Safeguarding people who use services from abuse

Outcome 7 Compliance

The provider has met all aspects of this safety and quality regulation as the outcome described in the guidance about compliance is fully met (refer to the guidance about compliance for detail).

Case study 1

Staff in a hospital were all able to explain what they understand by the term abuse and were able to correctly describe the procedure they take when abuse is suspected. The policy for staff is clear and includes the latest guidance and legislation. One person explained how a staff member acted when she reported that she felt unsafe; this reflected the hospital policy.

Outcome 7**Minor concern**

Where minor concerns are identified, people who use the service are safe, but the provision of care may not always meet this safety and quality regulation.

There are clear processes and actions in place to minimise and prevent abuse from occurring in a service. The requirements of national and local guidance are communicated, implemented and reviewed regularly.

Most staff are informed and trained to the appropriate level. Training records are maintained and up to date, but not routinely reviewed to identify where staff need further training. Staff understand and recognise the signs of abuse, and know how to respond and raise concerns appropriately if there is suspicion of abuse in a service.

There are clear procedures and actions in place to manage, investigate and stop alleged abuse if it has occurred. These are not always routinely reviewed, and learning from incidents may not be communicated effectively to all staff or people who use services.

Case study 2

Care workers from a domiciliary care agency have all had training relating to safeguarding people and were able to explain how to report an allegation of abuse. The policy has been updated to include the new telephone number of social services, but a new version has not been circulated to all staff. Staff said that this could have stopped them making an immediate report. The manager has said that she will circulate the latest policy straightaway. She will also implement a regular review process.

- This has a **low** impact on people using the service, because abuse will be reported but this may not be immediate.
- The likelihood of it recurring is **unlikely**, because the manager is circulating the phone list and implementing a review process.
- This means it is a **minor concern**.

Case study 3

A newly admitted patient in a mental health hospital suffers from self-harming and is known to become aggressive when he feels emotional or stressed. He has been involved in his care planning and has discussed and agreed preferred de-escalation and restraint techniques. However, an evening shift consisted of temporary staff that were not familiar with the patient's preferred techniques. When an incident occurred, even though they used an appropriate level of restraint, it was not the preferred technique for the patient.

- This has a **low** impact on people using the service, because a preferred method of restraint was not used.
- The likelihood of it recurring is **possible**, because temporary staff will be used again.
- This means it is a **minor concern**.

Case study 4

A staff member from the community nursing service recently reported an allegation of abuse to the appropriate bodies. The current staff understand what action to take when abuse is suspected, although they feel that the policy is quite complicated and doesn't have all of the up-to-date contact numbers for the police and social services. Staff said that it may be difficult for new staff members to understand. The manager said that she is in the process of updating the policy and providing training for staff.

- This has a **medium** impact on people using the service, because abuse may not be reported.
- The likelihood of it recurring is **unlikely**, because the manager is taking the necessary actions.
- This means it is a **minor concern**.

Outcome 7**Moderate concern**

Where moderate concerns are identified, people who use the service are generally safe, but there are risks to their outcome, health and wellbeing. Provision of care is inconsistent and may not always meet this safety and quality regulation.

The processes and actions in place to minimise and prevent abuse from occurring in a service are not clear or communicated effectively to all staff. The requirements of national and local guidance are not always communicated, implemented or regularly reviewed.

Most staff feel informed and are trained, although training may not be adequate, at the right level or up to date. Training records are maintained, but may not cover all staff groups and may not be up to date. They may not be routinely reviewed to identify where staff need further training. Some staff understand and recognise the signs of abuse, and know how to respond and raise concerns appropriately if there is suspicion of abuse in a service.

There maybe clear procedures and actions in place to manage, investigate and stop alleged abuse if it has occurred, but these are not communicated to all staff and not all staff groups have a knowledge or understanding of the procedures.

Safeguarding processes are not always routinely reviewed, and learning from incidents may not be communicated effectively to all staff or people who use services or influence change.

Case study 5

Staff in the training department of a primary care trust were unable to demonstrate how many of their staff had been trained or were up to date with the requirements for safeguarding. Although clinical staff told us they had accessed training as part of their continuing professional development, the trust did not have a system for recording, monitoring and maintaining training records.

- This has a **low** impact on people using the service, because clinical staff were able to tell us how to recognise the signs of abuse and how to report their concerns appropriately.
- The likelihood of it recurring is **almost certain**, because the provider does not have a system for recording and monitoring staff training requirements and cannot be assured that all staff are competent.
- This means it is a **moderate** concern.

Case study 6

A woman went to a walk-in centre with a young child. She alleged that the child had been subject to abuse by another adult. The staff member involved advised her that she should report the incident to the police. A physical assessment was conducted, but staff did not report the incident until they could speak to the manager to confirm it was a safeguarding issue and was appropriate, which was after the woman and child had left the centre.

- This has a **medium** impact on people using the service, because a delay in reporting a serious allegation means they may not be protected.
- The likelihood of it recurring is **possible, because** not all staff are aware of their duty to respond immediately.
- This means it is a **moderate concern**.

Case study 7

We were notified during an information-sharing meeting of an incident that occurred when a person with learning disabilities was transferred to a care home in an ambulance. The paramedic had repeatedly shouted at the person to “shut up and be quiet” and, at one point, had put his hands over the person’s mouth to stop him from shouting in pain.

The ambulance trust notified us that the staff member admitted that he had abused the person during the investigation. The staff records included a reference from a previous employer that “he was prone to violent tempers”. The manager has reviewed the process for staff recruitment to ensure people are recruited safely.

- This has a **high** impact for people who use services, because they are put in a situation where they maybe abused.
- The likelihood of it recurring is **unlikely**, because the manager has taken the necessary actions.
- This means it is a **moderate concern**.

Outcome 7**Major concern**

Where major concerns are identified, people who use the service are not protected from unsafe or inappropriate care. The provision of care does not meet this safety and quality regulation.

The processes and actions in place to minimise and prevent abuse from occurring in a service are absent, not robust or not embedded within the organisation. Staff are unaware of the requirements of national and local guidance.

Staff training is ad hoc and records are not maintained. Staff are not trained or do not maintain their training relevant to their case mix or area of working. There is no capacity to identify staff training needs, and staff are unaware of their duty of care and responsibilities in relation to safeguarding adults and children.

Procedures and actions to manage, investigate and stop alleged abuse are absent or poor. Most staff groups have little or no knowledge or understanding of the procedures. Processes are not reviewed and there is no learning from incidents. Outcomes from incidents are not monitored or influence change.

Case study 8

Young adults in a specialist college told us that several members of staff, including the manager, regularly borrow money from them and don't return it until they have been paid. They said that the manager has told them the people using the service don't need the cash, so it doesn't matter to them. The money is usually returned on 'pay day'.

- This has a **medium** impact on people using the service, because their rights are not being respected.
- The likelihood of it recurring is **almost certain**, because the manager is supporting the behaviour.
- This means it is a **major concern**.

Case study 9

Nursing staff do not know what to do if they are in a situation that requires the use of restraint, and the policies relating to restraint are not up to date. There has been a recent case where excessive restraint was used to manage an episode of challenging behaviour. The staff in question said that they had no option but to restrain the person. However, they were unaware of the legislation relating to restraint.

- This has a **high** impact on people using the service, because inappropriate restraint is likely to be used.
- The likelihood of it recurring is **possible**, because staff are not trained in restraint.
- This means it is a **major concern**.

Case study 10

A young child was brought into the emergency department with a broken leg in the early hours of the morning. Staff did not recognise the potential signs of abuse, even though the child's records showed that he had been seen in the department several times recently and the 'story' of how the injury was acquired could have been suspicious. The incident was recorded but not reported. Although the staff concerned had received child protection training, this was not up to date and they were unaware of local reporting procedures.

- This has a **high** impact on people using the service, because their safety is not protected as staff were unable to recognise possible signs of abuse.
- The likelihood of it recurring is **almost certain**, because staff are not up to date with child protection training and local reporting procedures.
- This means it is a **major concern**.

Outcome 8 (Regulation 12) Cleanliness and infection control

Outcome 8 Compliance

The provider has met all aspects of this safety and quality regulation as the outcome described in the guidance about compliance is fully met (refer to the guidance about compliance for detail).

Case study 1

A patient was admitted to hospital for treatment. On arrival, they observed an information display with the latest infection rates and details of what the trust was doing to prevent the spread of infection, and they were also provided with a wealth of information during their consultation. They felt well informed about the service's infection controls and comfortable to ask staff to wash their hands before treating them. Their visitors had fed back comments about the information provided to them about healthcare associated infections, which had been acknowledged and was seen in the amended information leaflet during future visits.

Outcome 8

Minor concern

Where minor concerns are identified, people who use the service are safe, but the provision of care may not always meet this safety and quality regulation.

There are sufficient resources available to prevent and control infections, although there is a need for clarity around the roles and responsibilities of some staff. Training and supervision on infection control is available for staff. However, update training can be delayed, and staff who do not attend mandatory training may not be followed up. The physical environment used for the provision of care is generally clean and fit for purpose, with a member of staff that is accountable. However, cleaning schedules are not publicly available and hand-washing facilities are inadequate for the purposes of the service. There are effective processes for the decontamination of instruments and other equipment, which is recorded and audited. However, the staff's clothing is not in line with the provider's clothing policy, so is not fit for purpose. People who use the service do not always feel fully informed about how the service is preventing and controlling infections or how they can reduce their risks. However, information is available and accessible in a range of formats. There are sufficient isolation facilities available for patients, but this does not always involve single-bedded rooms.

Case study 2

During a visit, a phlebotomist assistant was observed taking blood samples while wearing long sleeves. Medical teams undertaking physical examinations were also wearing long sleeves and watches while treating patients. The trust has a dress code in place, but a recent audit carried out identified poor compliance with the policy. This has resulted in the trust taking action to manage staff who do not comply with the policy and to repeat audits to monitor the implementation of the dress code.

- This has a **low** impact on people using the service because there is a risk of cross contamination.
- The likelihood of it recurring is **unlikely** because the trust has implemented actions and audits to monitor improvements.
- This means it is a **minor concern**.

Case study 3

A patient who had acquired seasonal flu was being transferred by ambulance. Assessors asked the ambulance technician what the practice was to manage this patient. The technician was unsure as he had not received any training about what to do. It was identified that staff were updated through leaflets and a staff magazine. However, staff were not always aware of updated infection control practices such as managing seasonal flu. Also, they had not received their annual update training on infection control in the last 12 months. Managers immediately reinstated the training programme and rolled it out across the service.

- This has a **low** impact on people using the service because staff were unaware of how to manage people with seasonal flu.
- The likelihood of it recurring is **possible** because staff have not received update training, although the training programme has been reinstated.
- This means it is a **minor concern**.

Case study 4

During treatment, a patient observed a nurse move from one patient to another without using hand gel. Inspectors followed this up with staff, and asked them about recent audits, especially relating to hand washing. Staff were unable to demonstrate any recent audit activity by the trust in relation to infection control or gathering information for monitoring the prevention and control of infection. The management team confirmed that there had previously been no infection control audit programme. However, the trust had recently devised an audit tool specifically for infection control and had initiated a programme of audit looking at hand washing practice, as well as rolling out an annual training programme on hand washing and infection control.

- This has a **medium** impact on people using the service because they were treated by a nurse that had not washed his hands.
- The likelihood of it recurring is **unlikely** because the trust has initiated training, introduced an audit programme specifically targeting hand washing, and has developed a tool to help implement the programme.
- This means it is a **minor concern**.

Outcome 8

Moderate concern

Where moderate concerns are identified, people who use the service are generally safe, but there are risks to their outcome, health and wellbeing. Provision of care is inconsistent and may not always meet this safety and quality regulation.

Resources are available to manage the prevention and control of HCAs. However, this is not always sufficient if staff are ill or on annual leave, as cover may not be available. Also, roles and responsibilities need to be clarified. Training and supervision for infection control is inconsistent and update training does not always happen. Training records do not identify when staff need to be updated. The audit programme to review policies and practice involving infection control is inconsistent, resulting in limited learning across the service. The physical environment used for the provision of care is not entirely fit for purpose, as some areas are unclean. There are processes for the decontamination of instruments and other equipment, but recording and auditing of decontamination of equipment can be limited. People who use the service have limited access to information about how the service is preventing and controlling infections and how they can reduce the risks of HCAs. Isolation facilities are available for patients, but few single-bedded rooms are available.

Case study 5

A patient was transferred for an outpatient appointment. During the journey, the patient noticed the poor condition of the ambulance and reported this. The complaint was followed up; stains and visible dirt covered the interior walls and floor, as well as the storage cupboards. The technician responsible for the ambulance said it was not included in the routine cleaning rota because it was used primarily for low priority ambulance jobs such as patient transfers and urgent admissions from GPs.

- This has a **low** impact on people using the service because they experience an unclean environment while being transferred between services. Because the patients are generally fit and well, the impact has been adjusted to take account of the situation.
- The likelihood of it recurring is **almost certain** because the ambulance is not part of the cleaning rota.
- This means it is a **moderate concern**.

Case study 6

During a visit, a service was asked about their antibiotic prescribing. It was found that the guidance was not within the regional joint formulary. The guidance should have been updated every six months, but no monitoring or updates had occurred. Auditing of antibiotic prescribing was infrequent and the last audit showed a trend of high prescribing of antibiotics.

- This has a **medium** impact on people using the service because they could be prescribed antibiotics inappropriately.
- The likelihood of it recurring is **possible** because there is no process to review prescribing or update policies relating to prescribing.
- This means it is a **moderate concern**.

Case study 7

A patient commented on the condition of an air mask during a visit. When followed up with staff, it was identified that agency staff had recently been used who had not received induction training, and they appeared to have poor knowledge about infection control processes as they re-used single use equipment. However, there was a policy for single-use equipment that was reviewed and updated when necessary. The issue involving agency staff had been identified, and resulted in checks on induction training for agency staff. Also awareness around policies relating to infection control were raised with all staff, especially relating to single-use equipment.

- This has a **high** impact on people using the service because single use equipment was re-used.
- The likelihood of it recurring is **unlikely** because induction training has been re-introduced, as has a programme to raise awareness of relevant policies for all staff.
- This means it is a **moderate concern**.

Outcome 8

Major concern

Where major concerns are identified, people who use the service are not protected from unsafe or inappropriate care. The provision of care does not meet this safety and quality regulation.

Resource to manage the prevention and control of HCAs is insufficient, and the roles and responsibilities are not clear or understood by the people carrying out these roles or by senior managers. Training and supervision for infection control is infrequent. The majority of staff have not received training and update training does not happen. There is a lack of audit to review policies and practice involving infection control, and lessons are not learned. The physical environment used for the provision of care is not fit for purpose, single-use equipment is frequently used again and the processes for decontamination of instruments or other equipment are limited or do not exist. People who use the service are ill-informed about how the service is preventing and controlling infections and how they can reduce the risks of HCAs, and isolation facilities are limited or not available.

Case study 8

During a visit, patients expressed concerns about the cleanliness of the hospital and identified unclean areas and equipment. It was observed that commodes marked as 'clean and ready to use' were still soiled. Bed frames, interior walls, curtains, wall-mounted equipment and equipment trolleys were covered in dust and dirt. Cleaning records and procedures were missing when followed up with the service manager.

- This has a **medium** impact on people using the service because the environment is unclean and not fit for purpose.
- The likelihood of it recurring is **almost certain** because of poor procedures for maintaining cleanliness.
- This means it is a **major concern**.

Case study 9

During a visit, bench top sterilisers were observed to be used in theatres and day surgery units. When asked, staff were unable to describe the process for tracing the origin, history and use of any instruments that were decontaminated using this equipment. This was followed up with the manager who was able to describe what the process should be, but could not provide any policies or documentation involving the use of the bench top steriliser.

- This has a **high** impact on people using the service because people may be exposed to equipment that is not decontaminated.
- The likelihood of it recurring is **possible** because processes are not in place to ensure the equipment is used appropriately.
- This means it is a **major concern**.

Case study 10

An acute trust experienced an increase in *C. difficile* infection rates. When followed up with the trust, issues with the decontamination of mattresses were identified. The facilities were not fit for purpose due to the lack of space, drainage facilities, disposal facilities for clean and dirty water, and storage for protective clothing. No policy for the decontamination of mattresses existed, and cleaning schedules for the facility were lacking. There had been no consultation with the infection control team about the process for managing the decontamination of mattresses.

- This has a **high** impact on people using the service because of the risk of cross-contamination
- The likelihood of it recurring is **almost certain** because the process for decontaminating mattresses is poor.
- This means it is a **major concern**.

Outcome 9 (Regulation 13) Management of medicines

Outcome 9 Compliance

The provider has met all aspects of this safety and quality regulation as the outcome described in the guidance about compliance is fully met (refer to the guidance about compliance for detail).

Case study 1

The chief pharmacist at a mental health trust provided a range of policies and standard operating procedures for the handling of medicines. They take into account the recommendations set out in the Duthie Report and guidance on standard operating procedures for controlled drugs. Records showed that pharmacists (or a clinician) routinely checked a patient's medicines on admission to the inpatient unit. Patients also told us that they were able to store their medicines in a lockable bedside cabinet and were supported in self-administering their medicines.

Outcome 9**Minor concern**

Where minor concerns are identified, people who use the service are safe, but the provision of care may not always meet this safety and quality regulation.

Medicines prescribed to people are appropriate and safe, and staff generally take into account people's needs and lifestyle, as far as reasonably possible.

Generally, people's medication is monitored and amendments made, but this does not always happen routinely. Information is provided but is not easily accessible in a range of formats, and people's understanding is not proactively sought by staff. People are supported to manage their own medication.

There are processes for all aspects of medicines management including obtaining, purchasing, storing, prescribing, dispensing, preparing, administering and monitoring. These are safe and in line with the latest legislation and follow published evidence-based guidance. But they are not all up to date and some policies need reviewing. Audits occur, but these do not always result in learning.

There is a good record of compliance with the receipt, administration, safekeeping and disposal of controlled drugs.

Staff handling medicines are qualified for their role, but competencies are not checked regularly.

There are clear processes for the safe and appropriate use of medical devices. Staff are aware of which devices are single use and practice supports this, but this is not audited frequently.

Training is provided to staff and monitored, although some staff may not have attended the training. Qualified staff use medical devices. All medical devices are used in accordance with the manufacturer's requirements and other appropriate published guidance, but regular audits are not carried out to review practices.

A process for reporting and managing adverse events, near misses or errors relating to medicines and medical devices is in place and is understood by all staff, but lessons are not always learned from the process. Action is taken on national safety alerts and medical device bulletins, but the effectiveness of implementation is not always audited.

Case study 2

A care home was found to have poor temperature control of the medicine storage areas. A dedicated medicines fridge had been provided and a monitoring chart was present, but it had not been used. The temperature at the time was found to be within the temperature range specified by the manufacturers of the medicines stored. There was no monitoring of the other medicine storage areas.

We found that the temperature of these were above the 25°C as specified by the medicine manufacturers. The care home had a policy and procedure that specified that these temperatures were to be monitored and recorded daily. The home said that they only stored medicine for 28 days. However, they have reissued the policy and will be auditing the temperature control to ensure the problem is addressed.

- This has a **low** impact on people using the service, because the medicines are only stored for 28 days, but if stored for longer periods this could have a significant impact on the effectiveness of the products.
- The likelihood of it recurring is **unlikely**, because the problem has been identified, addressed and will be monitored.
- This means it is a **minor concern**.

Case study 3

The chief pharmacist of a primary care trust provided examples of an audit for a number of aspects of medicines management. An audit of repeat prescribing for the drug Clopidogrel showed that a number of GPs were continuing to prescribe beyond the recommended treatment period set out by the National Institute for Health and Clinical Excellence. The trust had developed an action plan in response, but no steps had been taken to re-audit or to assess whether these actions had been implemented.

- This has a **low** impact on people using the service, because patients have not had their medication reviewed and are taking the medicine for longer than necessary.
- The likelihood of it recurring is **possible, because** actions to implement change have not been followed up.
- This means it is a **minor concern**.

Case study 4

During inspection, no evidence was presented to indicate that the prescribing policy for a mental health trust had been reviewed at the scheduled review date. Consequently, the policy did not reflect updated guidance on rapid tranquillisation. However, our assessors were informed that an updated policy was due to be ratified at the next meeting of the trust's board.

- This has a **medium** impact on people using the service, because patients are currently receiving sub-optimal treatment.
- The likelihood of it recurring is **unlikely**, because the trust is in the process of updating the policy.
- This means it is a **minor concern**.

Outcome 9**Moderate concern**

Where moderate concerns are identified, people who use the service are generally safe, but there are risks to their outcome, health and wellbeing. Provision of care is inconsistent and may not always meet this safety and quality regulation.

Medicines prescribed to people are appropriate, but may not always take into account their needs and lifestyle. People are not supported to manage their own medication.

Reviews of medication occur infrequently and the results are not always acted on.

Some processes are lacking across aspects of medicines management including obtaining, purchasing, storing, prescribing, dispensing, preparing, administering and monitoring. Not all processes are safe or in line with the latest legislation, nor do they follow published evidence-based guidance and auditing is limited with very few examples of change.

There is a poor record of compliance with the receipt, administration, safekeeping and disposal of controlled drugs.

Not all staff are appropriately qualified for their role in handling medicine, and limited competency checks are carried out.

Some processes for the safe and appropriate use of medical devices are lacking, and some single use devices are occasionally re-used.

Limited training is provided to staff. This is not monitored and records demonstrating attendance are limited or do not exist. Some unqualified staff use medical devices, and not all medical devices are used in accordance with the manufacturer's requirements or other appropriate published guidance. Limited auditing occurs with few lessons learned.

The process for reporting and managing adverse events, near misses or errors relating to medicines or medical devices is not clear, and few lessons are learned. Some action is taken on national safety alerts and medical device bulletins, but the effectiveness of implementation is not audited.

Case study 5

A number of inpatients at an acute hospital told us that they were anxious about keeping up with their prescribed medicines regime following their discharge from hospital. Several wanted the opportunity to self-administer for a few days prior to their discharge, in order to build up their confidence. Although we were informed by the trust that they were keen to encourage this, there was no policy for self-administration. Furthermore, there were no bedside lockers for patients to securely store their medicines.

- This has a **low** impact on people using the service, because patients are still receiving their medicines, with nursing staff administering medication during regular drug rounds.
- The likelihood of it recurring is **almost certain, because** there is no policy or facilities to support self-administration.
- This means it is a **moderate concern**.

Case study 6

A small number of people from a residential care home told us that they did not fully understand the purpose or side effects of the medicines they were taking. Furthermore, records show that the majority of residents taking repeat medication have not recently seen a GP for a review of their medication. For those residents who did have a review, we were told that concerns about the medicine's impact on their lifestyle were seldom listened to by the GP. Only a small number of cases resulted in a change to medication.

- This has a **medium** impact on people using the service, because they are uninformed and the medication affects their lifestyle.
- The likelihood of it recurring is **possible**, because medication is not reviewed or resident's needs taken account of.
- This means it is a **moderate concern**.

Case study 7

Medicines are seen to be placed in pots for administration at a later time in a care home. We have been informed of an incident where the pots were placed on the breakfast table before the people sat down for breakfast. Person A took the contents of a pot to their left. The care worker then asked Person A to take the contents of their medicine pot, which was to their right.

Only after Person A had consumed both pots of medication did the care worker realise what had happened. This resulted in Person A being admitted to hospital for observation. During an inspection following this incident, these practices were not observed to be continuing and the staff said that they had put measures in place to ensure it didn't happen again.

- This has a **high** impact on people using the service, because of the consumption of inappropriate medication.
- The likelihood of it recurring is **unlikely**, because processes have been reviewed and updated.
- This means it is a **moderate concern**.

Outcome 9**Major concern**

Where major concerns are identified, people who use the service are not protected from unsafe or inappropriate care. The provision of care does not meet this safety and quality regulation.

Medicines prescribed are not specific to people's needs and are not person-centred. People using the service are prevented from managing their own medication.

No monitoring or changes to people's medication is made in response to a review.

Processes are lacking across all aspects of medicines management including the safe obtaining, purchasing, storing, prescribing, dispensing, preparing, administering and monitoring. Processes are not in line with the latest legislation, or follow published evidence-based guidance. Auditing is not undertaken, nor improvements made.

There is no record of compliance with the receipt, administration, safekeeping and disposal of controlled drugs.

Staff are not appropriately qualified to handle medicine, and no competency checks are carried out.

Processes for the safe and appropriate use of medical devices are lacking, and some devices are unsafe or used inappropriately. Single use devices are frequently re-used.

Training is not provided to staff or monitored and unqualified staff use medical devices. Medical devices are not always used in accordance with the manufacturer's requirements or other appropriate published guidance, and no auditing occurs.

The process for reporting adverse events, errors and near misses relating to medicines or medical devices is unclear and staff are not aware of it. Lessons are not learned and there is poor recording of the process. There is little evidence of action being taken on national safety alerts and medical device bulletins.

Case study 8

An NHS acute trust reported that it actions any alerts received from the National Patient Safety Agency (NPSA), including an alert for injectable medicines. However, supporting evidence showed an incomplete action plan and no audit check of the actions marked as completed. Furthermore, there was no systematic approach for auditing the implementation of NPSA alerts for safer medicines.

- This has a **medium** impact on people using the service, because people maybe treated using out of date guidance.
- The likelihood of it recurring is **almost certain**, because the trust has no means of auditing changes implemented to ensure practice is up to date.
- This means it is a **major concern**.

Case study 9

A number of people in a care home had not received their medicines in accordance with the directions of the prescriber, because stock was not available. The home had an audit system in place to monitor the levels of stock and, while this was being used, staff were taking no action on the findings of the audit. This resulted in some people not getting their medicines.

- This has a **high** impact on people using the service, because they are not receiving their medicines as prescribed.
- The likelihood of it recurring is **possible**, because members of staff administering medicines are not following procedures.
- This means that it is a **major** concern.

Case study 10

No standard operating procedures exist for controlled drugs at a specialist hospital. Furthermore, we were informed of an incident involving the theft of a controlled drug at the hospital, which resulted in a member of staff resigning. However, no evidence was provided to indicate that this had been followed up or reported to the local intelligence network.

- This has a **high** impact on people using the service, because controlled drugs could be open to abuse.
- The likelihood of it recurring is **almost certain**, because no standard operating procedures or protocols exist for reporting and handling concerns.
- This means it is a **major concern**.

Outcome 10 (Regulation 15)

Safety and suitability of premises

Outcome 10 Compliance

The provider has met all aspects of this safety and quality regulation as the outcome described in the guidance about compliance is fully met (refer to the guidance about compliance for detail).

Case study 1

A care home for people with dementia has been designed with safety, independence, wellbeing and dignity in mind, with a clear layout suited to people's needs and appropriate adaptations for people with physical and sensory disabilities. There is a regular schedule of maintenance and risk assessment, and all risks are prioritised and acted on accordingly.

All staff are aware of the procedures to undertake in an emergency, and announced and unannounced evacuations are practiced on a regular basis. Residents are often taken out on trips, and a full risk assessment is undertaken before the visit of all premises and arrangements to be used. There is a monthly staff meeting where any problems relating to the environment are shared and discussed.

Outcome 10

Minor concern

Where minor concerns are identified, people who use the service are safe, but the provision of care may not always meet this safety and quality regulation.

The physical environment is generally safe and fit for purpose to meet the requirements or specialist needs of the people using the service, including people with a disability, and all relevant legislation. There are ongoing risk management, maintenance and waste management programmes, and the environment is safe and in reasonable condition.

All waste is appropriately identified, stored, handled, treated and disposed of in accordance with legislation. However, repairs are not always carried out immediately and tend to be reactive rather than proactive.

The design and layout is safe and appropriate for the provision of care being offered and space is adequate and meets the legal requirements.

The environment takes account of people's privacy and dignity, including access to toilet, bathroom and bathing facilities. More could be done to encourage the independence of the people using the service and to protect people's rights to a family life, by providing more appropriate and accessible facilities for visitors.

Adjustments to the environment have occurred in line with relevant safety alerts, and design, technical and operational standards. Audits on the Disability and Discrimination Act requirements and safety of the environment, including waste management, are carried out, but this tends to be reactive rather than proactive.

Essential back-up systems and emergency procedures are in place, in accordance with current legislation, but they are not routinely tested.

The environment is person-centred and people using the service influence the environment, but harder to reach groups or people that have limited communication do not have the same influence.

Case study 2

The family visiting room at a specialist college is temporarily out of use due to a refurbishment programme. Families have been contacted and asked to notify the college in advance if they want to visit, as an alternative facility is available but only for specific times during the day. So far, most visits have been organised around the availability of the facilities, but some have been postponed due to the lack of facilities. However, the refurbishment is due to be complete in two weeks' time.

- This has a **low** impact on people using the service, because peoples' access to facilities to enable them to have privacy with their family is restricted.
- The likelihood of it recurring is **unlikely, because** an alternative process has been put in place and it is a temporary situation.
- This means it is a **minor concern**.

Case study 3

A consultant outpatient clinic is held in an old part of the building, which has not been refurbished for a number of years. The decorations and furnishings are outdated and dreary, but a full risk assessment has been undertaken. Action has been taken to ensure that all potential hazards have been addressed, and any essential adaptations to meet the needs of people with disabilities have been made.

However, it is very cold in the clinic, which is unpleasant when patients have to get undressed, and there have been comments and complaints about the environment. The trust has plans to relocate the clinic in the next financial year.

- This has a **low** impact on people using the service, because the environment is unpleasant.
- The likelihood of it recurring is **possible**, because the service will not be relocated until the next financial year.
- This means it is a **minor concern**.

Case study 4

An assessor visiting the local hospice notices that some of the floor tiles are damaged and present a hazard. The hospice staff take immediate remedial action to tape down the damaged tiles and make arrangements for a more permanent repair to be undertaken the following week.

- This has a **medium** impact on people using the service, because the tiles are a hazard.
- The likelihood of it recurring is **unlikely**, because action was put in place to resolve the problem and the tiles will be repaired.
- This means it is a **minor concern**.

Outcome 10 **Moderate concern**

Where moderate concerns are identified, people who use the service are generally safe, but there are risks to their outcome, health and wellbeing. Provision of care is inconsistent and may not always meet this safety and quality regulation.

The physical environment is not entirely safe or fit for purpose, and has not taken account of all the needs of people using the service, for example, the needs of people with limited ability to communicate, such as a person with a physical disability or a child, have not been considered.

The risk management and maintenance programmes are dependent on other factors and can slip due to priorities elsewhere. However, essential repairs will occur in a timely manner. Waste management practices are not routinely followed in line with current legislation or are not well understood.

The design and layout is not appropriate for the provision of care being offered to all people using the service, and the space is inadequate for some people. The design, including toilets, bathrooms and bathing facilities, does not directly support privacy and dignity. Where amenities are available to assist privacy and dignity, such as screens, these are not proactively offered or always available. People's rights to a family life are not always protected, as appropriate or accessible facilities for visitors are not provided.

Relevant safety alerts and design, technical and operational standards are considered, but other priorities can impact on whether these are taken account of. Audits checking the safety and effectiveness of risk and waste management procedures are limited and do not regularly result in improvements.

Essential back-up systems and emergency procedures are in place, in accordance with current legislation, but have not been tested.

The environment is not person-centred and there is limited resource and effort allocated to ensuring the environment takes account of people using the service. The ease of staff offering care is a major influence on the environment and its design.

Case study 5

There are no single sex bathrooms available in a six-bedded coronary care unit. However, patients are normally accompanied to the bathroom and all steps are taken to respect privacy and dignity. There have been no complaints.

- This has a **low** impact on people using the service, because actions have been put in place to take account of people's dignity and respect.
- The likelihood of it recurring is **almost certain**, because the premises do not offer single sex accommodation.
- This means it is a **moderate concern**.

Case study 6

An inpatient mental health unit has separate day rooms for male and female residents. However, the layout of the building means that female residents can only access their day room via an external route or passing through the male-only day room, which regularly occurs when the weather is poor. The unit has plans in place to rearrange the layout of the facilities to connect the female ward and day room areas. However, these will take some time. so in the meantime they try to ensure that staff are able to accompany female residents when passing through the men-only day room.

- This has a **medium** impact on people using the service, because their rights to privacy and dignity are not protected.
- The likelihood of it recurring is **possible, because** of the layout of the facilities.
- This means it is a **moderate concern**.

Case study 7

The only wheelchair-friendly access to a temporary facility being used by the rehabilitation service is down a narrow corridor. This could become blocked in the event of a fire or other emergency. However, the rehabilitation team hold regular fire drills, including the evacuation of people with disabilities via alternative exits, and evacuation procedures are explained at the start of each session.

- This has a **high** impact on people using the service, because there is a potential risk to the safety of wheelchair users during an emergency.
- The likelihood of it recurring is **unlikely**, because processes have been put in place to manage the risk.
- This means it is a **moderate concern**.

Outcome 10

Major concern

Where major concerns are identified, people who use the service are not protected from unsafe or inappropriate care. The provision of care does not meet this safety and quality regulation.

The physical environment is not fit for purpose, as it does not meet the requirements or specialist needs of the people using the service, including people with disabilities. There are no ongoing risk management, maintenance or waste management programmes, and the environment needs upgrading to meet essential standards. The only maintenance is for essential repairs when a problem arises.

The design and layout is not safe or appropriate for the provision of care being offered, does not meet legal requirements and the space is inadequate. Insufficient amenities are available that do not allow privacy for people using the service. Facilities are inaccessible for visitors.

There have been no adjustments to the environment in line with relevant safety alerts and design, technical and operational standards, or following audits considering the Disability and Discrimination Act requirements, compliance with waste management legislation or checking the safety of the environment.

Essential back-up systems and emergency procedures do not comply with current legislation.

The environment is not person-centred and the focus is on the requirements of the staff, rather than providing as welcoming an environment as possible while ensuring care can still be provided.

Case study 8

A large care home only has one telephone for residents' use in a public area. This is heavily used, resulting in the phone breaking regularly and making it very difficult for residents to make calls, especially in private. There is a public telephone about a mile from the home that many residents prefer to use. However, some residents need help to reach the public phone, which makes them dependent on staff. Residents are not allowed to use the phones in the staff offices.

- This has a **medium** impact on people using the service, because their rights to privacy are not protected.
- The likelihood of it recurring is **almost certain**, because the design of the premises means private calls are not possible.
- This means it is a **major concern**.

Case study 9

A review of a disused ward in a mental health unit has identified a number of unprotected ligature points. While this ward is not actively being used for service delivery, access to the ward is not secure and patients pass through it to reach the garden.

- This has a **high** impact on people using the service, because of the safety risks of the ligature points.
- The likelihood of it recurring is **possible**, because access is not secure.
- This means it is a **major concern**.

Case study 10

The approach to a drug treatment centre is secluded and poorly lit. There is no CCTV coverage. During winter, there were a number of attacks and muggings of people using services and staff, some of whom suffered serious injury. The service provider has no plans to improve the lighting or enhance the security of the premises.

- This has a **high** impact on people using the service, because of the attacks on people accessing the service.
- The likelihood of it recurring is **almost certain**, because no actions have been taken to improve the situation.
- This means it is a **major concern**.

Outcome 11 (Regulation 16)

Safety, availability and suitability of equipment

Outcome 11 Compliance

The provider has met all aspects of this safety and quality regulation as the outcome described in the guidance about compliance is fully met (refer to the guidance about compliance for detail).

Case study 1

A hospital's joint equipment store is well stocked and an asset register is maintained for all items of equipment. This identifies when and where equipment was purchased, its maintenance and servicing requirements and its history, and it logs the use of the equipment. Staff are required to provide evidence of their competence before being issued with any equipment, and all items are issued with copies of the manufacturer's instructions.

The equipment store is adequately staffed and managed, with restricted access to the storage areas. All items are signed in and out, and there are frequent audits of stock and status. The store runs an incident reporting system, and staff or people who use services are encouraged to report any problems they experience with the equipment by phone or email or in writing.

The store manager routinely checks the central alerts system for any concerns relating to equipment, and there are clear procedures in place for recalling equipment where necessary.

Outcome 11**Minor concern**

Where minor concerns are identified, people who use the service are safe, but the provision of care may not always meet this safety and quality regulation.

Equipment is available when needed, installed and used in a safe and correct manner, and generally fit for purpose. Equipment meets legislation and specifications, but is not regularly checked by an appropriately trained person. There is an ongoing renewal programme that is documented, but slippage can occur. Equipment levels are generally sufficient and equipment is stored safely and securely.

Staff are informative and explain the safe use and purpose of the equipment to users. Carers may be involved, but this practice is not consistent. Information is available in different formats but is not easily accessible. People's comments are accommodated, but not proactively sought, about the use of equipment, ensuring that comfort (where possible) and privacy and dignity are accommodated if easily achieved.

Equipment is used safely by appropriately qualified staff. Occasionally, this practice is not followed. Training occurs, but attendance varies and training records are not kept up to date. Equipment is installed and used in accordance with manufacturer's instructions and other appropriate national guidance.

A process for reporting and managing adverse events, near misses or errors is in place, but not understood by all staff. Lessons are not always learned from the process. Action is taken on national safety alerts, but the effectiveness of implementation is not always audited.

Case study 2

A private hospital, specialising in orthopaedics, has been using a particular brand of knee replacement joint. This has been shown to be linked to high revision (repeat operation) rates and subject to a medical device alert. The hospital has stopped using the device, and has identified all patients who have been fitted with the specific brand and model in the last five years. These patients have all been invited for a review and will be recalled every 12 months to be monitored.

- This has a **low** impact on people using the service, **because** the trust has responded to the alert immediately.
- The likelihood of it recurring is **unlikely**, because there is a process to respond to alerts and the required actions have been implemented.
- This means it is a **minor concern**.

Case study 3

An appliance clinic in a hospital issues basic equipment to people using services and provides them with verbal instructions on how to use it. However, written instructions are not always provided and people are not given the details of someone who they can contact if they have any questions or concerns about the use of the equipment.

- This has a **low** impact on people using the service, because the equipment and verbal information is provided.
- The likelihood of it recurring is **possible**, because written instructions are not always available.
- This means it is a **minor concern**.

Case study 4

A care home is experiencing failures in their electronic beds after they have been in use for a number of years. This has resulted in people that need to sleep upright being unable to sleep properly. Arrangements are in place to manually lift the beds for people that need the help, until the electronic motors can be replaced.

- This has a **medium** impact on people using the service, **because** it impacts on their independence and ability to sleep.
- The likelihood of it recurring is **unlikely**, because staff are manually moving the beds until the motors can be replaced so the required action has been taken.
- This means it is a **minor concern**.

Outcome 11**Moderate concern**

Where moderate concerns are identified, people who use the service are generally safe, but there are risks to their outcome, health and wellbeing. Provision of care is inconsistent and may not always meet this safety and quality regulation.

Equipment is not always available when needed, nor fit for purpose. Generally legislation and specification requirements are met, but there are infrequent checks and modifications, resulting in some equipment not being fit for purpose. There is an ongoing renewal programme, but this is poorly documented and other priorities frequently impact on the delivery of the programme, resulting in long delays. Equipment levels are below acceptable, and equipment can be in poor condition and may not be stored safely or securely.

Staff do not always explain the safe use and purpose of the equipment to users and carers, resulting in inconsistency in practice. Information is available in limited formats and is not easily accessible. The use of equipment is predominantly concerned with the ease of staff, although comments and people's privacy and dignity are occasionally accommodated.

Unsafe use of equipment occurs occasionally by unqualified staff. Training occurs but is provided infrequently. Attendance is low and training records are of poor quality. Equipment is not always installed and used in accordance with manufacturer's instructions and other appropriate national guidance.

The process for reporting and managing adverse events, near misses or errors is not very clear, resulting in few lessons being learned. Action is taken on national safety alerts, but the effectiveness of their implementation is not audited.

Case study 5

A care home replaces the TV in the reception room with new TVs for all the residents in their own rooms. However, many of the residents are partially sighted. The TVs have small screens and come with a standard remote control that is difficult to operate by someone who is partially sighted. Residents have to rely on staff to help them operate the remote controls. A request for a large replacement TV in the reception room has not been acted on.

- This has a **low** impact on people using the service, **because** they have access to a TV although it does not sufficiently meet their needs.
- The likelihood of it recurring is **almost certain**, because the required action to resolve the issue has not been taken.
- This means it is a **moderate concern**.

Case study 6

A poor stock control and returns policy in a rehabilitation service means there are frequent shortages in supply of equipment to help people when walking. This has resulted in people being given inappropriate equipment, such as elbow crutches for people with hip and elbow problems.

- This has a **medium** impact on people using the service, because there is a risk of further injury.
- The likelihood of it recurring is **possible**, because of the poor stock control.
- This means it is a **moderate concern**.

Case study 7

A particular brand of patient hoist, used in a nursing home, is prone to collapsing if not assembled correctly. This could result in severe harm or injury. However, the nursing home has fitted safety notices to all hoists of this type, ensured that there are laminated assembly instructions kept with the hoists and has provided additional training to its entire staff to emphasise the correct assembly process and consequences of not doing it correctly.

- This has a **high** impact on people using the service, **because** of the potential harm that can be caused.
- The likelihood of it recurring is **unlikely**, because action has been taken to reduce the likelihood that the equipment will be assembled incorrectly.
- This means it is a **moderate concern**.

Outcome 11**Major concern**

Where major concerns are identified, people who use the service are not protected from unsafe or inappropriate care. The provision of care does not meet this safety and quality regulation.

Appropriate equipment is limited and frequently unavailable, resulting in alternative options having to be sought regularly or delays in care.

Equipment does not meet all legislation and specifications, and no checks are carried out. The renewal programme does not exist or is not followed, and equipment levels are insufficient and in poor condition.

The safe use and purpose of the equipment is seldom discussed, and people generally do not have a clear understanding of the purpose of the equipment. Information is limited and in very few formats, and is usually unavailable. People's comments are not sought about the comfort or ease of the use of equipment, and the ease of the equipment for staff is the priority rather than the appropriateness or comfort of the person.

Equipment is frequently used or installed unsafely by staff who are unqualified. Update training does not occur, or happens sporadically with very low attendance. Training records are of poor quality or do not exist. Equipment is often not installed or used in accordance with manufacturer's instructions and other appropriate national guidance.

The process for reporting adverse events, errors and near misses is unclear and staff are not aware of it. Lessons are not learned and there is poor recording of the process. Action is not always taken on national safety alerts.

Case study 8

Medical devices intended for single use only are shared between patients, because staff have not been trained about their use and there are limited supplies.

- This has a **medium** impact on people using the service, because there is a risk of cross infection.
- The likelihood of it recurring is **almost certain**, because staff do not know how to use the equipment appropriately.
- This is a **major concern**.

Case study 9

The accident and emergency department of an acute hospital does not stock face masks for children. During the day, they can be requested via the paediatric department. However, during the evening, there is no one available to provide this equipment. Children suffering respiratory problems do not receive the correct dose of nebulised medicines, because the adult face masks do not fit properly.

- This has a **high** impact on people using the service, because children may not receive the required dose of medication.
- The likelihood of it recurring is **possible**, because of the lack of stock.
- This means it is a **major concern**.

Case study 10

An acute hospital's diagnostic imaging service has been found to be using a particular brand of disposable endoscopy equipment. This has a tendency for part of it to detach and fall into the patient's stomach or alimentary canal, requiring an additional procedure to remove it. There have been a few incidents where this has occurred. However, the hospital has failed to take any action to quarantine the affected stock, or to report the defect via its local incident reporting system.

- This has a **high** impact on people using the service, because of the potential harm that can be caused.
- The likelihood of it recurring is **almost certain**, because no action has been taken to resolve the matter.
- This means it is a **major concern**.

Outcome 12 (Regulation 21) Requirements relating to workers

Outcome 12 Compliance

The provider has met all aspects of this safety and quality regulation as the outcome described in the guidance about compliance is fully met (refer to the guidance about compliance for detail).

Case study 1

A primary care trust provides a broad range of community health services and employs a variety of professional staff including nurses, midwives, social workers and physiotherapists. To ensure that all professional registrations are up to date, the details are recorded for all staff in their central records. The trust has an automatic alert system, which sends staff a reminder email six weeks before their registration is due for renewal. Staff are asked to confirm their re-registration details, and a further system of escalation is used where necessary.

Outcome 12

Minor concern

Where minor concerns are identified, people who use the service are safe, but the provision of care may not always meet this safety and quality regulation.

The organisation has effective and fair recruitment procedures that meet all legal requirements, but they are not always consistently applied. All relevant employment, criminal record and barring, qualification and professional registration checks are undertaken, but all records are not fully up to date.

People providing additional support to staff, such as agency staff or volunteers are subject to the same checks, although the records of these checks are not consistent. When staff are experiencing problems, the necessary actions are taken to support them and to ensure their practice does not impact on people using the service, although delays can occur.

Disciplinary and grievance procedures that take account of professional bodies are available and communicated, and most staff understand them. There are procedures for investigating incidents involving staff that are implemented well, but action taken can be inconsistent.

Case study 2

A domiciliary care agency was increasing the number of people it provided a service for. As a result, more staff were needed. Due to last minute delays in new staff starting, because a number of employment checks were missed in the volume of recruitment activity, the provider had to use agency cover to ensure enough staff were on duty until the new employees were able to start.

- This has a **low** impact on people using the service, because of the large number of agency staff being used.
- The likelihood of it recurring is **unlikely**, because this was a one-off event following the increase in capacity.
- This means it is a **minor concern**.

Case study 3

A care home for older people uses volunteers to help at mealtimes a few afternoons each week. The skills of these volunteers have not been checked and they have not been given any specific training. However, they are always supervised in their duties by a trained member of staff. The care home says that it is about to implement a new policy for using volunteers.

- This has a **low** impact on people using the service, because volunteers may not have the necessary skills to support people.
- The likelihood of it recurring is **possible**, because the new policy is not yet implemented.
- This means it is a **minor concern**.

Case study 4

A private clinic employs 10 staff. Their recruitment process does not include an occupational health assessment or declaration. The consultant who owns the clinic says that this is covered in discussions during staff induction, but that none of his current staff need any specific support. There is no record of these induction discussions, but staff members say they are confident that they could raise such issues with their managers.

- This has a **medium** impact on people using the service, because if the health needs of staff are not supported the quality of the service will be affected.
- The likelihood of it recurring is **unlikely**, because despite the lack of process staff are confident any needs would be met.
- This means it is a **minor concern**.

Outcome 12

Moderate concern

Where moderate concerns are identified, people who use the service are generally safe, but there are risks to their outcome, health and wellbeing. Provision of care is inconsistent and may not always meet this safety and quality regulation.

Some recruitment procedures are unclear or inconsistently applied. Recording of checks of employment, criminal record and barring, qualification and professional registration are inconsistent and not kept up to date.

People providing additional support to staff, such as agency staff or volunteers, are not routinely checked and records are inconsistent. When staff are experiencing problems they can access support, but this is not routinely available.

Disciplinary and grievance procedures are available, but they are not routinely updated, communicated or understood by many staff and they do not always take account of professional bodies. Procedures for investigating incidents involving staff are delayed or not implemented well, and action taken is inconsistent.

Case study 5

A diagnostics clinic has no photographic record of any of its staff members (as required in Schedule 1). However, all recruitment records show that identity checks have been done. The clinic only employs 15 staff, all of which are known to the managers.

- This has a **low** impact on people using the service, because there is no evidence that staff are inappropriate.
- The likelihood of it recurring is **almost certain**, because the process does not require records to be kept.
- This means it is a **moderate concern**.

Case study 6

A care home provides care for 23 people, a number of whom have dementia. When recruiting staff, Criminal Records Bureau and Independent Safeguarding Authority checks are routinely done, but references are not always taken up and record keeping is not consistent, as this depends on the person recruiting to record the information rather than a systematic approach.

- This has a **medium** impact on people using the service, because checks are not always completed.
- The likelihood of it recurring is **possible**, because there is no central record.
- This means it is a **moderate concern**.

Case study 7

A long-term well regarded employee has just returned from a long period of sickness. An occupational health assessment recommended that they do not return to work yet, but the management allowed the member of staff to return to their original job because they felt they had a duty to protect the employee's job. Evidence for other employees shows that there are correct processes in place and they appear to have been followed.

- This has a **high** impact on people using the service, because the staff member may not be fit to work and no specific support has been put in place.
- The likelihood of it recurring is **unlikely**, because it seems that an exception has been made for this one staff member.
- This means it is a **moderate concern**.

Outcome 12

Major concern

Where major concerns are identified, people who use the service are not protected from unsafe or inappropriate care. The provision of care does not meet this safety and quality regulation.

The organisation does not have clear or consistent recruitment procedures. It is not clear that all relevant employment, criminal record and barring, qualification and professional registration checks are undertaken, as records are poor or absent or there are significant delays.

People providing additional support to staff, such as agency staff or volunteers are not checked. Staff are not given the support they need to do their job, and risks to staff are not consistently identified or managed

Disciplinary and grievance procedures are not routinely updated and not understood by all staff. Incidents are not properly investigated and any action taken can be inappropriate and disproportionate, including referrals to professional bodies.

Case study 8

A doctor was recruited from abroad to work as an interim measure in a private doctors' clinic. Although his original medical qualifications had been provided, the clinic did not include verification of the doctor's qualifications or competencies to address the needs of the patients attending the clinic. No other pre-employment checks had been completed prior to the doctor starting work.

- This has a **medium** impact on people using the service, because there is a risk the member of staff is not fully qualified.
- The likelihood of it recurring is **almost certain**, because there is no review of qualifications in the recruitment process.
- This means it is a **major concern**.

Case study 9

A care home has a documented recruitment process that is used in most cases. However, there is evidence that, on a number of occasions, it has recruited care staff based only on recommendations of current staff members. This has included recruiting family members and friends without going through the appropriate due process or vetting and barring.

- This has a **high** impact on people using the service, because there are no checks to ensure that people being employed are appropriate.
- The likelihood of it recurring is **possible**, because there is a process that is normally used but there are no checks to ensure this is always done.
- This means it is a **major concern**.

Case study 10

A safeguarding concern has been raised about a community nursing service. An investigation shows that there have been recent changes in its recruitment procedures. It has become clear that these changes have meant that some staff have been employed without Criminal Records Bureau and Independent Safeguarding Authority checks being undertaken. Also, the recruitment process does not include checking that nurses are on the appropriate part of the nursing register that enables them to deliver care to children.

- This has a **high** impact on people using the service, because there are no checks to ensure that people being employed are safe to work with children.
- The likelihood of it recurring is **almost certain**, because the new recruitment process allows staff to be recruited without the necessary checks being completed.
- This means it is a **major concern**.

Outcome 13 (Regulation 22) Staffing

Outcome 13 Compliance

The provider has met all aspects of this safety and quality regulation as the outcome described in the guidance about compliance is fully met (refer to the guidance about compliance for detail).

Case study 1

A domiciliary care service provides care to a range of clients. The registered manager ensures that the staffing mix is suitable to meet the range of assessed needs of the people who use the service. When there are changes to a person's care plan, this is always reviewed to ensure that the allocated staff are able to continue to meet their needs. Whenever new staff members start or any new agency staff used, there is always an induction to ensure they are competent for the role they need to do and that they know how to seek advice and report concerns.

Outcome 13**Minor concern**

Where minor concerns are identified, people who use the service are safe, but the provision of care may not always meet this safety and quality regulation.

There is an assessment of the needs of people who use services and the skills, qualifications and experience that are needed in order for staff to provide care that is safe and effective, and which meets those needs, protects people's rights and promotes independence. Generally, there is sufficient staffing levels with an appropriate skill mix, such as at weekends or outside regular working hours. Although there is insufficient cover for staff rotas, periods of annual leave, sick leave, maternity leave, parental and carer leave.

Case study 2

On the day of visiting a care home for 10 people, we find that there are two fewer staff on duty than on the rota. The manager says that there has been a stomach bug going around and three staff have called in sick. They have found cover for one member, but not the others yet. Otherwise, they have clear procedures for accessing agency staff and their staff record shows they are very rarely down in staff numbers. On the day in question, some of the activities had been rearranged so that all residents had adequate staff support.

- This has a **low** impact on people using the service, because activities have been changed to ensure people have the support needed.
- The likelihood of it recurring is **unlikely**, because there are clear procedures in place that show this is an infrequent occurrence.
- This means it is a **minor** concern.

Case study 3

At night time, the five acute medical wards in a hospital often have a high proportion of newly qualified junior nursing staff on duty. There are some senior nursing staff on duty, but they are not available on all wards and have to be called if needed, so there can be a delay in people receiving the right care.

- This has a **low** impact on people using the service, because there can be a delay in care.
- The likelihood of it recurring is **possible**, because of the skill mix of staff during the night.
- This means it is a **minor concern**.

Case study 4

A residential home for four people with learning disabilities has recently employed a registered learning disabilities nurse. The owner of the home felt this would be a positive move for the care of the residents.

While the owner followed the appropriate recruitment procedures, he allowed the nurse to visit and spend a couple of hours at the home prior to all appropriate employment checks being confirmed. During the visit, the nurse was asked by a member of staff to help them with a resident who had fallen in the bath. No other staff were available as they had taken a resident to the shop while the 'new manager' was there.

The nurse reported this incident to the owner and explained that she felt that she should not have been put in that position. The owner admitted that he had told staff that the new manager was coming in to help. A few days later, all employment checks were completed satisfactorily. On commencement of her employment, the new manager reviewed the home's safeguarding policies and implemented training sessions for staff.

- This has a **medium** impact on people using the service, because of the potential safeguarding issue due to checks not being confirmed.
- The likelihood of it recurring is **unlikely**, because the new manager amended the policy and provided training to prevent it happening again.
- This means it is a **minor concern**.

Outcome 13**Moderate concern**

Where moderate concerns are identified, people who use the service are generally safe, but there are risks to their outcome, health and wellbeing. Provision of care is inconsistent and may not always meet this safety and quality regulation.

There is some assessment of the needs of people who use services and the skills, qualifications and experience that are needed in order for staff to provide care that is safe and effective, and which meets those needs. But the need to protect rights and promote independence are not considered. At different times, such as at weekends or outside regular working hours, there are insufficient numbers of staff or an inappropriate mix of competence, skills and qualifications. Changes to staff numbers and mix can be difficult and slow to make.

Case study 5

A hospice’s staffing plan shows that they need two qualified nurses on duty at night time. However, it is clear from their records that they frequently only have one on duty. The hospice say this is due to shift patterns and overall staff numbers and that, because of resources, there is usually an extra healthcare assistant on duty rather than a registered nurse. The main problems are the lack of appropriate support and the administration of medications that are often late during the night time.

- This has a **low** impact on people using the service, because there maybe a delay in people’s care.
- The likelihood of it recurring is **almost certain**, because the service is understaffed.
- This means it is a **moderate concern**.

Case study 6

A care home provides care for 23 people, a number of whom have dementia. When speaking to staff, it is clear that some are not sure who their manager is or who to go to if there is a problem, referring instead to colleagues who are on duty at the same time. While staff have a range of skills and competencies, the mix varies depending on the time of day, and is more limited overnight.

- This has a **medium** impact on people using the service, because they may be put at risk if the right care cannot be provided.
- The likelihood it recurring is **possible**, because the problems with staff mix continue.
- This means it is a **moderate concern**.

Case study 7

During an audit of recruitment procedures, the provider became aware that several staff had recently started work, even though the results of Criminal Records Bureau checks had not been confirmed and the rationale for ‘gaps’ in their employment history had not been explored and verified. Once recognised, the recruitment manager amended the process to ensure that no staff were offered employment or started working until all pre-employment checks had been finalised.

- This has a **high** impact on people using the service, because staff may have started work who did not have the right skills or competencies to meet patient needs.
- The likelihood of it recurring is **unlikely**, because once recognised the provider modified the procedure to ensure robust control processes at all stages of the recruitment process.
- This means it is a **moderate concern**.

Outcome 13**Major concern**

Where major concerns are identified, people who use the service are not protected from unsafe or inappropriate care. The provision of care does not meet this safety and quality regulation.

The organisation does not assess how the care and welfare needs of people who use services link to the skills, qualifications and experience that are needed in order for staff to provide care that is safe, effective and meets those needs. The number and mix of staff is often inappropriate or insufficient, and it is difficult to get more staff quickly.

Case study 8

During a visit to a supported living service for people with learning disabilities, we speak to residents as well as family members. Their feedback suggests that the staffing levels are too low, as residents are often not able to undertake the activities they would like or have to wait a few hours for someone to come and help them. The managers say they have a good system for ensuring they have enough staff to meet the needs of their residents. They do not think there are any problems.

- This has a **medium** impact on people using the service, because support is not available when people need it.
- The likelihood of it recurring is **almost certain, because** there is a lack of recognition within the service that the problem exists.
- This means it is a **major concern**.

Case study 9

A care home providing nursing care to 40 residents, some of whom need a considerable amount of nursing care to meet their needs, has been open for six months. While the home has excellent facilities, staff feel that the home does not have enough staff with the appropriate qualifications, skills and experience to deliver the care needed by residents, as some have never undertaken care work before. They are also being asked to work long hours to cover staff shortages.

There have been problems recruiting to posts, particularly registered nursing posts, but the home does not appear to have plans in place to address this. Some attempts have been made to secure agency staff to cover shortages, but this happens on an ad hoc basis. The registered manager does not appear to think staffing levels pose a risk to residents.

The home undertook a risk assessment three months after opening and set staffing levels accordingly. However, staffing levels are not currently at those set following the risk assessment. The home has an induction and training programme for staff, but it does not have records of attendance.

- This has a **high** impact on people using the service, because staffing levels and skill mix are not appropriate for the needs of the service.
- The likelihood of it recurring is **possible, because** there is a lack of recognition within the service about what staffing levels are needed.
- This means it is a **major concern**.

Case study 10

An inpatient mental health unit has an ongoing problem of staff shortages due to long-term sickness and unfilled permanent vacancies. The unit is heavily reliant on agency staff, but they often are not able to get the type of staff they need. During a number of recent visits with people who are detained under the Mental Health Act, concerns have been raised that they have had very little time outside. It seems that this is because there are not enough staff to provide appropriate observation.

- This has a **high** impact on people using the service, because agency staff do not have the skills needed.
- The likelihood of it recurring is **almost certain, because** the staffing problems are ongoing.
- This means it is a **major concern**.

Outcome 14 (Regulation 23)

Supporting workers

Outcome 14 Compliance

The provider has met all aspects of this safety and quality regulation as the outcome described in the guidance about compliance is fully met (refer to the guidance about compliance for detail).

Case study 1

An NHS trust has a good appraisal system. They have a recorded appraisal rate for all clinical staff of 97% and higher than 90% for every group of staff. They have demonstrated examples of appraisal being used to identify learning and development needs, and it is clear that the results have been fed into an overall learning and development plan for the trust.

Results from the NHS staff survey show that the majority of staff in the trust feel that the appraisal system is effective, that they are happy with their line management arrangements and that they have received the training outlined in their personal development plans.

Outcome 14 Minor concern

Where minor concerns are identified, people who use the service are safe, but the provision of care may not always meet this safety and quality regulation.

Management structures and lines of accountability and supervision are not clear to all staff. Most staff have a regular appraisal and access to supervision, including clinical supervision where appropriate, but some groups have poor coverage. Where necessary, these meet relevant professional requirements.

Most staff (including students, agency and temporary workers) working within the organisation have appropriate corporate and workplace induction and undertake mandatory training as required. This may be inconsistent among trainee, temporary or agency staff. Attendance at mandatory training is monitored, but not always followed up. The learning and development plan is not implemented across all of the organisation and is ineffective for some staff groups. There are links between the learning and development plan and the needs of people who use services, but they are not always clear. The service provides some support for learning and development opportunities, but resources can be difficult to access. Most staff have a personal development plan.

Case study 2

Six months ago, a new system of incident reporting was introduced in a social care service, with the intention that all staff would have received formal training within four months. Training records show that so far only 40% of staff have received the formal training. However, it is clear that this includes all managers and there is record of a communication asking managers to provide some informal training to their team members that have not yet attended the formal training session.

The number of incidents being reported has increased slightly since the new system was introduced. Speaking to staff who have not had training, most say that they either know how to use the new system or know who to ask.

- This has a **low** impact on people using the service, because not all staff have been trained in the incident reporting system.
- The likelihood of it recurring is **unlikely**, because managers are disseminating learning and staff are aware of the new system.
- This means it is a **minor** concern.

Case study 3

Part-time therapy staff working in a community location do not have regular access to their manager to discuss personal development needs, because she is based in the main department of the hospital 20 miles away. In addition, most training is delivered from the main hospital site. This does not affect other therapy staff as they are located in bases around the main hospital site.

Due to the location of the community based therapy staff and the hours they work, staff told us that it was difficult to arrange meetings with their manager and not “good use of their time” to travel to internal training events, because of the distance and the fact that relevant training didn’t coincide with the days they work.

The manager was informed and immediately took measures to address the issues. She arranged to travel to the community base to discuss and explore how the personal development needs of part-time staff could be addressed.

- This has a **low impact** on people using the service, because it was an isolated issue.
- The likelihood of it recurring is **possible**, because a process to visit part-time staff and re-arrange training to suit their work schedule needs to be arranged.
- This means it is a **minor** concern.

Case study 4

A community midwifery service has an insufficient number of registered midwife supervisors available locally, so some of their staff are not currently receiving clinical supervision that is in line with the statutory requirements for midwives. The service has recognised this problem and has an action plan in place to address this issue. The plan sets out the time by which all midwives will have access to the required supervision.

- This has a **medium** impact on people using the service, because midwives competency is affected by a lack of supervision.
- The likelihood of it recurring is **unlikely**, because an action plan is in place to address the shortage.
- This means this is a **minor concern**.

Outcome 14

Moderate concern

Where moderate concerns are identified, people who use the service are generally safe, but there are risks to their outcome, health and wellbeing. Provision of care is inconsistent and may not always meet this safety and quality regulation.

Management structures and lines of accountability and supervision are not clear. Only some staff have a regular appraisal and access to supervision, including clinical supervision where appropriate, but some groups are excluded or have poor coverage. Professional requirements are not clearly identified.

Some staff working within a service have an appropriate induction and undertake mandatory training as required, but this is poor for temporary or agency staff. Arrangements for monitoring attendance at mandatory training are not systematic, and there is little follow up. The learning and development plan makes few links between the needs of people who use services and skills and training required, and is poorly implemented in many parts of the service. Support for learning and development opportunities is not equal and records are not up to date.

Case study 5

Staff survey results from an acute hospital indicate that few employed healthcare professionals have participated in a clinical audit during the last year. Further investigation shows that it is primarily only junior doctors that have been involved in audits, and the programme they are following is very broad.

The hospital says that, although it recognises the importance of audit for professional development, it does not have enough resources to adequately support other staff members to participate in clinical audit. Results and recommendations of audits are always shared across teams and action plans are developed.

- This has a **low** impact on people using the service, because limited monitoring of quality through audit is taking place.
- The likelihood of it recurring is **almost certain, because** there is no intention to change the system at present due to a lack of resources.
- This means it is a **moderate concern**.

Case study 6

A small domiciliary care service employs 10 care workers. Any training provided is always done on Friday afternoons and they run a programme of training over a six-month period. When questioned about the lack of flexibility, whether part-time staff are able to attend training and what happens if someone misses a session, the managers say that staff have to wait for the next training period to make up any missed sessions and all their current part-time staff work on Fridays.

- This has a **medium** impact on people using the service, as their care may be affected, because staff do not have up-to-date training if they have to wait for six months.
- The likelihood of it recurring is **possible, because** there is no flexibility in the training system.
- This means it is a **moderate concern**.

Case study 7

Staff in a community rehabilitation service told us that they could not remember when they last had any formal supervision and that, at that time, there was little learning and development activity due to constrained resources. However, the majority of staff did say that they felt they did not have any particular outstanding development needs. They are confident in going to their managers with problems and, if they raised particular issues, these would be taken seriously and addressed.

- This has a **high** impact on people using the service, because staff may not be keeping up to date with skills needed to do their job due to a lack of training and supervision.
- The likelihood of it recurring is **unlikely, because** there is a supportive culture that is flexible to accommodate immediate needs.
- This means it is a **moderate concern**.

Outcome 14 Major concern

Where major concerns are identified, people who use the service are not protected from unsafe or inappropriate care. The provision of care does not meet this safety and quality regulation.

Management structures and lines of accountability are not made clear to all staff. Appraisal and access to supervision, including clinical supervision, are ineffective or not available to all staff.

Not all staff receive an induction or inductions are poor. Provision and monitoring of mandatory training are not up to date and there is no monitoring of attendance or follow up. Learning and development needs are not consistently evaluated or linked to the needs of people who use services or, where appropriate, professional requirements about qualifications, updating skills and skill gaps. It is very difficult for staff to access resources for learning and development meaning their skills and competencies are not kept up to date. Few staff have an up-to-date personal development plan.

Case study 8

A number of complaints from residents of a care home and their family members indicate that there are some problems with staff morale, and that this is spilling over to affect the way in which some staff deal with residents, particularly in terms of being rude and unapproachable.

A visit to the home at which residents, care workers and managers were all spoken to indicated the problem stems from friction between members of staff, which is not being addressed as the service is lacking a clear process to act on and resolve such issues. No member of management is actively taking a lead to tackle these issues which risk escalating. Managers are adamant that it is just a clash of personalities that they have no control over.

- This has a **medium** impact on people using the service, because they are being treated inappropriately, due to staff's personal problems.
- The likelihood of it recurring is **almost certain, because** there is no accountability among managers for resolving the issue.
- This means it is a **major concern**.

Case study 9

A nursing home provides nursing care to 13 residents with a range of nursing care needs. Staff training has been sporadic and infrequent over the last year and records show that professionally registered staff are not meeting training requirements. Continued budget pressures mean that resources for training – including induction training – have been cut and that, as a result, practice is not as good as it should be.

- This has a **high** impact on people using the service, because staff are not up to date with skills needed to do their job due to a lack of training.
- The likelihood of it recurring is **possible, because** there is no identified budget to address the issue.
- This means it is a **major concern**.

Case study 10

A story is reported in a local newspaper involving a staff member from the local ambulance service exposing significant problems with the safety of vehicles and equipment being used, which the staff member says are being completely ignored by the service.

When we discuss this with the service, we are informed that the member of staff was immediately suspended until further notice following the article. While the service says that they look into all concerns, record keeping is very limited. When speaking to other staff in confidence, many say they share the concerns, but it is no longer worth mentioning it to anyone as they are never taken seriously by management. Others say they do not know who they would raise this with, or they are told it is not in their best interest to mention it.

- This has a **high** impact on people using the service, because staff are not able to raise concerns about the service, are not taken seriously, or are punished if they do.
- The likelihood of it recurring is **almost certain, because** the problem is systematic.
- This means it is a **major concern**.

Outcome 16 (Regulation 10)

Assessing and monitoring the quality of service provision

Outcome 16 Compliance

The provider has met all aspects of this safety and quality regulation as the outcome described in the guidance about compliance is fully met (refer to the guidance about compliance for detail).

Case study 1

A large maternity unit has established good clinical governance mechanisms that mean mothers and their babies are protected from risks of harm. Following a recent serious incident during a caesarean section, a case review meeting was held involving all members of the multidisciplinary team and a representative from the local maternity services liaison committee. It was chaired by the board level lead. An action plan was developed as a result of the meeting, which was communicated to the whole of the department. The mother was involved throughout the process.

Outcome 16**Minor concern**

Where minor concerns are identified, people who use the service are safe, but the provision of care may not always meet this safety and quality regulation.

There is a culture of risk management and quality improvement, but there are some inconsistencies in parts of the organisation. Information about quality and safety, including information about outcomes and experiences of people who use services, is gathered and monitored to identify risks and areas for improvement.

The organisation makes use of a more limited range of internal and external information sources, for example they may not evaluate the impact of recommendations and findings from national reports for their services.

There is a good record of identified risks and issues, but action plans may not be monitored to ensure that improvements are made to people's safety and welfare. There are effective decision-making procedures and lines of accountability, but these are not fully communicated or understood by all staff. Staff are aware of how to raise concerns.

There are inconsistencies in how the organisation provides information about quality monitoring and service improvement, and how feedback is provided to staff and people who use services about the impact of actions taken to improve services.

Case study 2

A GP has recently taken over a private practice in partnership with her husband, who is a registered nurse providing support in clinical practice and acting as the practice manager. Prior to the commencement of the new partnership, the practice had no mechanisms in place for taking account of complaints by patients and there are several outstanding issues that have been brought to our attention.

The new partnership have started developing new policies and procedures, and intend to write to all the outstanding complainants outlining the changes in policies and procedures in an attempt to address and resolve any outstanding clinical governance issues.

- This has a **low** impact on people using the service, because the views of people are being recognised and accommodated.
- The likelihood of it recurring is **unlikely**, because procedures are being developed.
- This means it is a **minor concern**.

Case study 3

A care home actively seeks the views from people who use services, their carers and staff on how the service is run. These views are discussed and acted on individually, and improvements are made, although these are not always fed into how the service is delivered and run as a whole. Also, feedback is not centrally recorded.

- This has a **low** impact on people using the service, because views are not fed into the delivery of the service.
- The likelihood of it recurring is **possible**, because of the lack of learning from feedback.
- This means it is a **minor concern**.

Case study 4

When visiting a large domiciliary care service, we discuss their system for dealing with and learning from complaints. During the discussion, it is apparent that the person responsible for coordinating trend analysis of complaints is on maternity leave and this role has not been reallocated in her absence. Therefore, a number of recent complaints about the performance of one particular staff member have been overlooked. The provider is embarrassed by this apparent failure and says that both issues will be addressed immediately.

- This has a **medium** impact on people using the service, as potential risks relating to the poorly performing staff member have not been picked up.
- The likelihood of it recurring is **unlikely**, because it will be addressed immediately.
- This means it is a **minor concern**.

Outcome 16**Moderate concern**

Where moderate concerns are identified, people who use the service are generally safe, but there are risks to their outcome, health and wellbeing. Provision of care is inconsistent and may not always meet this safety and quality regulation.

Information about quality and safety is gathered, but does not often include feedback from people who use services or information about people's experiences. It is not clear how information is consistently monitored to identify risks and areas for improvement.

There is limited evidence of learning from incidents and the organisation does not make use of the full range of information sources.

Risk management is reactive, and actions are not evaluated to see whether risks are addressed and improvements are made. Decision-making procedures and lines of accountability across the organisation are not clear and reporting structures are not communicated effectively or understood by all staff. Staff are unsure how to raise concerns, or are nervous about speaking out and are not encouraged to report concerns.

Information about quality and safety are not openly displayed or provided, and feedback to staff about actions and improvements is limited.

Case study 5

A mobile diagnostic screening provider has six different teams, each covering a large area and working independently of the other teams. Each team has clear and effective monitoring and risk assessment arrangements, but there is no central system to report issues and communicate improvements between teams or across the whole provider.

- This has a **low** impact on people using the service, because risks are dealt with effectively at a team level but not at provider level.
- The likelihood of it recurring is **almost certain**, because of the lack of a central system.
- This means it is a **moderate concern**.

Case study 6

A medical directorate does not have a mechanism to receive and consider national reports and communicate the findings to each of their wards. People admitted to Nightingale wards are at risk of developing kidney failure. This is because the ward team have not taken into account the recommendations of this year's NCEPOD (National Confidential Enquiry into Patient Outcomes and Deaths) report to carry out risk assessments to check for kidney damage.

- This has a **medium** impact on people using the service, because they are placed at risk by outdated practice.
- The likelihood of it recurring is **possible, because** there is no system to receive and communicate recommended changes from national reports.
- This means it is a **moderate concern**.

Case study 7

Over a six-month period, we have received a number of notifications of serious untoward incidents involving slips trips and falls of both staff and residents in a care home, including one resident being admitted to hospital with a broken hip. After following this up with the home, they say that there have been some problems with recording and addressing maintenance issues. They assure us that a new system has been put in place so these risks are identified and dealt with quickly.

- This has a **high** impact on people using the service, because they are placed at risk by an unsafe environment.
- The likelihood of it recurring is **unlikely**, because a new system has already been put in place.
- This means it is a **moderate concern**.

Outcome 16**Major concern**

Where major concerns are identified, people who use the service are not protected from unsafe or inappropriate care. The provision of care does not meet this safety and quality regulation.

There is evidence that reporting systems are poor or missing, or there is a limited use or awareness of them among staff. Some information about quality and safety is collected, but links to risk management and quality improvement are weak.

A limited range of information sources are used, for example very few external sources are used or incidents are inconsistently evaluated to identify risks or common issues.

Action plans are poor or absent and there is no monitoring of implementation. Decision-making and accountability structures are complex and ineffective. Staff are not engaged in quality improvement and feedback about risks is not circulated. Staff do not know how to raise concerns and feel concerns are not welcome and would not be listened to or acted on.

Case study 8

A mental health service provides a broad range of services in a number of different settings. Through analysis of notifications, we identify a high number of serious untoward incidents being reported, which is discussed with the service. There is an overall system for managing major risks. The governance lead takes responsibility for these. All other risks, however, are dealt with by each individual department within the service.

The different systems for recording and managing risks vary widely. Most of the risk registers are incomplete and not up to date. When comparing different departments, it is clear there are some common risks that have not been identified and managed in a consistent way, including poor medicines management practices. The provider was not aware of the high number of notifications or of these inconsistencies.

- This has a **medium** impact on people using the service, because risks are dealt with inconsistently and trends are not identified.
- The likelihood of it recurring is **almost certain**, because there is a system wide failure.
- This means it is a **major concern**.

Case study 9

An NHS trust has recently received notification that its emergency department has a higher than expected mortality rate for emergency admissions. The trust and its emergency department was unaware of this situation, although it did undertake a review and put this down to coding errors.

The emergency department team did not have a department-wide process for monitoring the quality of care given to patients, although some individual clinicians reviewed their own practice as part of clinical supervision. The outcomes of these were not shared. The department did not participate in any national audits and the only local audits undertaken were by junior medical staff as part of their rotation. Generally, little notice was taken of the outcomes of these. The trust board received little clinical information about the quality of service in its emergency department.

- This has a **high** impact on people using the service, because outcomes are not monitored or reviewed.
- The likelihood of it recurring is **possible, because** there is no system to identify poor outcomes.
- This means it is a **major concern**.

Case study 10

Mr J runs a small home care agency. He says that he runs a quality service and his staff use “common sense” in dealing with any incidents or problems. He has no formal system for this, and there are no records of any type of quality assurance or risk management.

When speaking with staff, it is clear that they do not know how to report incidents and are unsure of actions that they should take. One staff member said that she had no way of raising a concern about a hoist that wasn't working and she had been manually lifting the person using the service for the past month. She didn't realise she should report this.

- This has a **high** impact on people using the service, because staff are not working in line with any policy or process.
- The likelihood of it recurring is **almost certain, because** there is no risk management structure in place.
- This means it is a **major concern**.

Outcome 17 (Regulation 19) Complaints

Outcome 17 Compliance

The provider has met all aspects of this safety and quality regulation as the outcome described in the guidance about compliance is fully met (refer to the guidance about compliance for detail).

Case study 1

In a care home, one resident told us that she made a complaint about her clothes going missing in the laundry. She was pleased to have a meeting with the manager who told her how this had been dealt with and also what would be done as a result of her complaining. Staff explained how they welcome comments and complaints from people as this helps them to improve the service.

Outcome 17

Minor concern

Where minor concerns are identified, people who use the service are safe, but the provision of care may not always meet this safety and quality regulation.

The complaints process is publicly available and offered in a range of formats, but it is not promoted or proactively distributed. However, people using the service and staff are generally aware of the complaints process and an advocate is available if needed. There is a record of all complaints made. Not all are acted on resulting in learning and improvements.

People who make a complaint generally receive an appropriate response that includes an explanation of any actions implemented to address the concerns, but these responses are not always received in a timely manner.

Case study 2

A person in a supported living service said that she had made comments to staff because she was unhappy about the time she had to be back from the pub at night. The staff didn't take her comments seriously, as they thought she was joking. On reflection, the staff recognised that there was a serious nature to this concern and reviewed the care plan with the person resulting in a change.

- This has a **low** impact on people using the service, because staff needed to be prompted to acknowledge the comments as a person's choice.
- The likelihood of it recurring is **unlikely**, because staff understand the importance of following the procedure.
- This means it is a **minor concern**.

Case study 3

The manager of a care home for people with learning disabilities explained how she has developed a complaints procedure that is understood by all. The policy states that people should always get a response to complaints they make. People said that staff always listen to their complaints and the manager looks into them, but sometimes there is a delay to their response as it needs to be produced in an easy-read format.

- This has a **low** impact for people who use services, because there is a delay in receiving a response.
- The likelihood of it recurring is **possible**, because the policy has not been fully adhered to.
- This means it is a **minor concern**.

Case study 4

A person told us they had made a complaint to an independent doctor about the environment he had to wait in. The doctor investigated the complaint in accordance with the procedure, but the complainant wasn't made aware of the outcome, as this was usually the responsibility of the receptionist who was on leave at the time of the complaint. The doctor told us he has implemented a system to prevent this recurring.

- This has a **medium** impact on people who use services, because they did not receive a response about the outcome of the investigation.
- The likelihood of it recurring is **unlikely**, because a process has been put in place.
- This means it is a **minor concern**.

Outcome 17

Moderate concern

Where moderate concerns are identified, people who use the service are generally safe, but there are risks to their outcome, health and wellbeing. Provision of care is inconsistent and may not always meet this safety and quality regulation.

A complaints procedure is available, but not easily accessible or available in a range of formats. People who use services are aware of the complaints process but do not have a full understanding of the process. Staff have an understanding of the complaints process, but they are not aware of the importance of listening to and acting on people's concerns raised ad hoc. Most people who make a complaint receive a response in a timely manner, but the service does not fully address the concerns that were raised or is delayed. An advocate is not always available if needed.

Case study 5

A person with visual impairment in a hospital wanted to complain about the lack of dignity and care experienced during his admission. No complaints information was available in any other form except written English. The request to meet someone in person to discuss his complaint was agreed although, when staff were asked what the process would be to enable anyone visually impaired to make a complaint, they were not aware of any process.

- This has a **low** impact on people using the service, because certain peoples' complaints are not being captured.
- The likelihood of it recurring is **almost certain**, because there is no system in place.
- This means it is a **moderate concern**.

Case study 6

People in a long-term conditions unit said that they had repeatedly made complaints to the staff about the meals being served late, resulting in them often being cold. Previously the manager has resolved issues raised, but the manager told them that she can't do anything about it as the kitchens are managed under a different department.

- This has a **medium** impact on people who use services, because they are having to eat cold food.
- The likelihood of it recurring is **possible**, because the manager is unwilling to follow up the complaint as it involves a different department.
- This means it is a **moderate concern**.

Case study 7

People who use a nursing agency said that they had complained to the manager about how some staff don't respond to concerns they raise and do not seem to take things seriously or respond appropriately. The manager investigated this and concluded that staff were not following procedures. In response, a full training programme has been planned for all staff.

- This has a **high** impact on people using the service, because complaints are not listened to.
- The likelihood of it recurring is **unlikely**, because the manager has implemented a training programme.
- This means it is a **moderate concern**.

Outcome 17

Major concern

Where major concerns are identified, people who use the service are not protected from unsafe or inappropriate care. The provision of care does not meet this safety and quality regulation.

Complaints are not welcomed. People are discouraged from making complaints or making suggestions to improve services. The complaints procedure is not accessible and if supplied is unclear. No records of complaints exist, or where they do they are poor. No learning or improvements have occurred as a result of complaints. Many people who make a complaint do not receive a response. Responses that are sent are poor and do not address the concerns.

Case study 8

People who use a domiciliary care agency do not have access to the complaints procedure. They say they do not know how to make a complaint. When they ask staff to help them, they are told they are too busy. There were limited records of complaints resulting in actions held by the agency, and many staff said that they were unfamiliar with the complaints process and would not know what to do if someone wanted to make a complaint.

- This has a **medium** impact on people using the service, as they are not supported to make complaints.
- The likelihood of it recurring is **almost certain**, because the procedure is not shared with people who use the service or staff.
- This means it is a **major concern**.

Case study 9

A person on the elderly ward was complaining that they had tripped on the flooring in the ward again and this was the third time they had made a complaint. However, they had not received a response to any of their complaints and nothing had changed. When discussing it with the ward staff, the staff commented that they helped patients to put complaints in, but generally they would not receive a response and nothing tended to change as a result of the complaints.

The flooring had been in a hazardous condition for six months, and nothing had changed following a number of complaints made by patients and incidents that had occurred because of the hazard.

- This has a **high** impact on people using the service, as their safety is at risk through the lack of improvement and learning.
- The likelihood of it recurring is **possible**, because the process is not effective.
- This means it is a **major concern**.

Case study 10

The window in an elderly resident's room in a care home does not shut properly and the radiator does not work. The resident tried to raise the issue with staff in the care home telling them that he is constantly cold. They told him to stop complaining and put another jumper on.

After becoming ill and being admitted to hospital with a chest infection, his family raised the issue with staff. They did not offer to help them to make a formal complaint. The complaint was only taken seriously once an advocacy agency became involved, resulting in the necessary changes being made.

- This has a **high** impact on people who use services as their safety is at risk through staff not responding to complaints.
- The likelihood of it recurring is **almost certain**, because the process for managing complaints is not in place.
- This means it is a **major concern**.

Outcome 21 (Regulation 20) Records

Outcome 21 Compliance

The provider has met all aspects of this safety and quality regulation as the outcome described in the guidance about compliance is fully met (refer to the guidance about compliance for detail).

Case study 1

Staff at an outpatient clinic are aware of the process for requesting and retrieving patient records at hospital, and all patients attending had their records available during their appointment. The process had been audited regularly and 95% of patients in the previous month had their records available during their appointment. The problem resulting in 5% of patients not having their records available was identified, and changes were being made to prevent a recurrence.

Outcome 21**Minor concern**

Where minor concerns are identified, people who use the service are safe, but the provision of care may not always meet this safety and quality regulation.

A personalised record is kept for each person who uses the service. Some records are not clear, complete, accurate or updated at the time the service is provided or as soon as is practical. Records about people who use services are used to plan appropriate care treatment and support, but it is not always clear what relevant information needs to be recorded.

Records, whether they are paper or electronic, are stored and used in a way that protects confidentiality but are accessible in a way that allows them to be located quickly. People who use services and their nominated representatives are not consistently able to access and contribute to the information in their record when necessary.

Processes are in place to store, share and destroy records properly and securely. These processes are reviewed and updated, but this is not regular, so there may be some inconsistencies with the Data Protection Act 1998, the Department of Health's Code of Practice for Records Management and other relevant guidance about information security and governance. There are clear protocols detailing the circumstances, timeliness, sharing and transfer of records to other organisations, but these may not have been reviewed or updated. Staff who have access to personal records have appropriate knowledge and understanding of the protocols and comply with the legal requirements about records management and confidentiality, although this may be out of date for some staff.

Wherever they are relevant to the service, records required by the Care Quality Commission under outcome 21 (records) are kept. Most of these records are accurate and up to date.

Case study 2

An ambulance service has appointed a Caldicott guardian who is able to access the latest information governance documents and who could explain the process for accessing and storing records. Paramedics described, when asked, what they do with their records after each shift that was in line with the policy. However, no audits had been carried out to check the consistency of the process and its compliance with the Data Protection Act 1998. This was immediately resolved and audits planned.

- This has a **low** impact on people using the service, because the management of patient records is not being checked.
- The likelihood of it recurring is **unlikely**, because the information governance system is in place and an action to audit.
- This means it is a **minor concern**.

Case study 3

A patient in a mental health hospital is repeatedly asked a question that does not relate to them or any historical care they have received. The patient asks for a copy of their records and, when they review them, they find that incorrect information is documented.

The issue is raised with records, who explained that information had been attached to two sets of records because it was unclear which patient it related to. A note had been included on both patients' records to explain the issue and to clarify whether the information had been correctly attached for them, but this had not been followed up.

- This has a **low** impact on people using the service, as the issue had been identified.
- The likelihood of it recurring is **possible**, because the process to attach a note rather than clarify which patient the information relates to is ineffective.
- This means it is a **minor concern**.

Case study 4

Mr R has dementia and was admitted to a care home after a stay in hospital. His care plan was case tracked and refers to him as single with the section around 'expressing sexuality' left blank. A male visitor of Mr R's speaks to our expert by experience during the site visit and raises concerns about not being acknowledged by the care home as Mr R's partner.

This is raised immediately with the home and the manager takes immediate steps to change the care plan and ensure that Mr R's partner is fully acknowledged. Staff training around sexuality is booked and the need to enquire about partners recording this information on the care plan is introduced to the planning process.

- This has a **medium** impact on people using the service, because diversity is not being respected.
- The likelihood of it recurring is **unlikely**, because training has been recognised to educate staff about the need to recognise people's sexuality.
- This means it is a **minor concern**.

Outcome 21**Moderate concern**

Where moderate concerns are identified, people who use the service are generally safe, but there are risks to their outcome, health and wellbeing. Provision of care is inconsistent and may not always meet this safety and quality regulation.

A personalised record is kept for most people who use the service. Some records are not clear, complete, accurate or up to date. Records about people who use services are used to plan appropriate care treatment and support. Some of the information needed for this is not systematically recorded.

Records are stored and used in a way that protects confidentiality, but records are often not accessible or able to be located quickly. People who use services and their nominated representatives are not consistently able to access and contribute to the information in their record when necessary.

Processes are in place to store, share and destroy records properly and securely. These processes are not reviewed, so records management may not be in accordance with the Data Protection Act 1998, the Department of Health's Code of Practice for Records Management and other relevant guidance about information security and governance. There are some protocols detailing the circumstances, timeliness, sharing and transfer of records to other organisations, but these are not comprehensive or implemented throughout the service. Staff who have access to personal records do not consistently understand the protocols and the legal requirements about records management and confidentiality.

Wherever they are relevant to the service, records required by the Care Quality Commission under outcome 21 (records) are kept. Some of these records are not consistently held, up to date or accurate.

Case study 5

When checking the records storage for a Shared Lives service, care plans and personal details for people who no longer use the service were identified. When discussing this with staff, it became apparent that there was no retention policy or process for disposal. Records remained in storage and files for people who previously used the service were only removed and destroyed when there was no space to add new records.

- This has a **low** impact on people using the service, because this does not directly affect their care, treatment or support.
- The likelihood of it recurring is **almost certain**, because there is no process identifying when documents should be disposed of or how.
- This means it is a **moderate concern**.

Case study 6

Records relating to people living at a care home were found in the lounge that was accessible to anyone visiting the home. Staff said that they had not had any training about the importance of storing records securely and didn't realise they were doing anything wrong by leaving records in a communal area, as they felt the care home was a secure place if staff were around and using the records.

- This has a **medium** impact on people using the service, because their privacy is not being maintained.
- The likelihood of it recurring is **possible**, because staff are not competent in this area.
- This means it is a **moderate concern**.

Case study 7

A local authority safeguarding investigation has highlighted a consistent shortfall in record-keeping by care staff working for a community nursing agency. Their investigation shows the majority of daily note entries state "all care given" or "care given as planned", with little or no further detail recorded. The new registered manager for the service tells us that training around record-keeping has been booked for all care staff and full audits of notes will now be taking place each month.

- This has a **high** impact on people using the service, because the lack of records can impact on any review of care or future decisions.
- The likelihood of it recurring is **unlikely**, because staff are booked in to be trained and audits have been initiated.
- This means it is a **moderate concern**.

Outcome 21**Major concern**

Where major concerns are identified, people who use the service are not protected from unsafe or inappropriate care. The provision of care does not meet this safety and quality regulation.

A personalised record is kept for some people who use the service, but not all. Records management is not systematic and many records are not clear, complete, accurate or up to date. There is no consistent protocol about what relevant information needs to be recorded.

Records cannot be accessed quickly and people who use services, and their nominated representatives are not able to access their record.

The processes to store, share and destroy records are poor or absent. There are significant inconsistencies with the requirements of the Data Protection Act 1998, the Department of Health's Code of Practice for Records Management or other relevant guidance about information security and governance. There are no systematic protocols about sharing or transferring records to other organisations, or protocols are often ignored. Many staff that have access to personal records are not aware, or trained in the records management processes and do not comply with legal requirements.

The records required by the Care Quality Commission under outcome 21 (records), that are relevant to the service, are not identified as needing to be systematically held.

Case study 8

Computerised records are being kept by a community hospital. Staff report they have limited access to a computer and find it difficult to use the system. Care plans seen are of varying quality and some have not been updated for over three weeks. The manager says that the system has been in place for over a year but that some staff are still struggling to use it. All staff have had two days training in how to use the system, but there are no current plans for further ICT training.

- This has a **medium** impact on people using the service, because inconsistencies in records can impact on decisions made.
- The likelihood of it recurring is **almost certain**, because staff do not understand how to use the computerised system.
- This means it is a **major concern**.

Case study 9

A resident of a care home had a strained relationship with her daughter and had stipulated she did not want her daughter involved in her care. The daughter phoned the care home to find out how her mother was doing and, as her mother would not communicate with her, the daughter demanded that the staff share a copy of her mother's care plan with her. As she was unable to visit the care home, she asked for the documents to be posted to her.

Staff did not understand that the daughter had no rights to see her mother's care plan if she did not want them to be shared with her. They sent copies by first class post, which included all the details about her mother's condition and care.

- This has a **high** impact on people using the service, as it breaches their confidentiality.
- The likelihood of it recurring is **possible**, because staff do not understand their responsibilities under the Data Protection Act.
- This means it is a **major concern**.

Case study 10

An assessor was leaving an acute hospital following a visit, and noticed some paperwork in bins that were not secure at the back of the building by the car park. The paperwork turned out to be records of deceased patients that were being disposed of using regular rubbish bins. The acute hospital did not have a process for disposing records.

- This has a **high** impact on people using the service, because patients' records are not being disposed of securely.
- The likelihood of it recurring is **almost certain**, because management systems are not in place.
- This means it is a **major concern**.

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