

An Introduction to Clinical Governance



INTRODUCTION

Clinical Governance is an overarching term for the framework of activities we utilise for ensuring we are continuously improving the quality of our services and safeguarding high standards of care. It involves monitoring systems and processes to provide assurance of patient safety and quality of care across the organisation.

Organisational culture is a major factor that influences the effectiveness in which clinical governance activities are implemented and how they facilitate improvement. Good governance requires a culture in which organisations consider quality improvement as part of core business. Where staff feel valued and psychologically safe and work collectively to recognise and rectify problems whilst appreciating the importance of patient experience of care and utilise patient feedback in a meaningful way to improve services.

This training booklet provides an overview of some of the key activities of the Trust's governance framework.

ADVERSE INCIDENTS

The Trust recognises that incidents will at times occur; it is important that incidents are reported and managed to minimise the risk of them happening again. The incident reporting and management process is intended to provide the Trust with insight into the opportunities for safety improvement. The key focus being learning and supporting those who have been involved in an incident, using a restorative just culture approach and reducing health inequalities where they are identified. It is not about apportioning blame to individuals involved.

What is an adverse incident?

An incident is an unintended or unexpected event that has occurred, which could have or did cause physical or psychological harm to a patient, visitor, or staff member.

Patient Safety Event – Any event that could have or did impact the safety of one or more patients during the provision of health care, including risks to patient safety in the future, and positive events that could be learned from to improve safety.

Patient Safety Incident – Something unexpected or unintended has happened, or failed to happen, that could have or did lead to patient harm.

Learn from Patient Safety Events (LFPSE) – the NHS system for the recording and analysis of patient safety events that occur in healthcare.

Why report?

Reporting helps to raise awareness of things when they go wrong, it helps us to understand existing risks and identify any new risks to safety; both at a local and national level, so actions can be put in place to reduce or eliminate them in future. It also ensures those involved in an incident receive timely support.

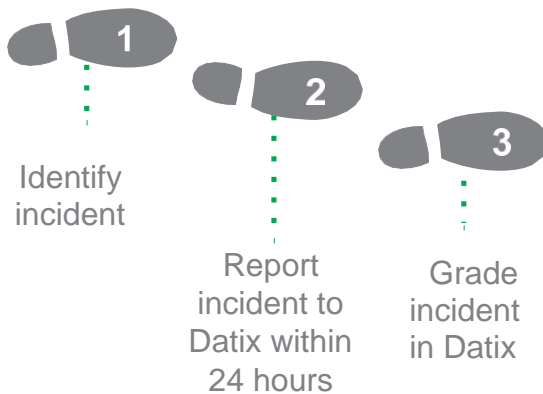
How do we report an incident?

You can report incidents by accessing the Datix system through the Trust Hub page. It is found under “Essential links” on the right hand side

Essential links



- [Clinical Guidelines](#)
- [Datix – Incidents, Risks and Complaints](#)



How can you help with these stages?

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Identify incident: Please ensure you have:

- Read the Trust Incident Reporting and Management Policy
- The knowledge of what constitutes a reportable incident
- Ensure immediate actions have been taken to manage the incident and where possible risks have been managed

Report incident within 24 hrs in Datix – Please ensure you have:

- Completed incident reporter training
- Completed incident management training (if your role requires)
- Actively reported all incidents on Datix as soon as possible after the event

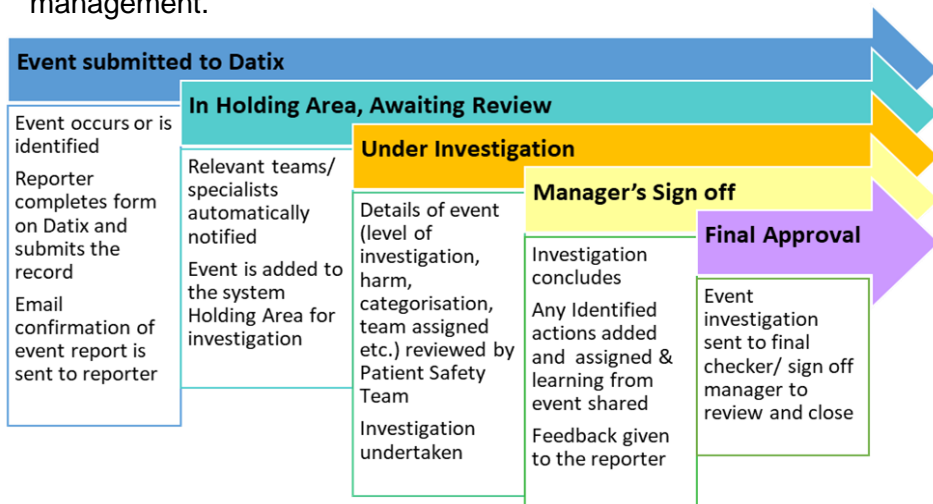
Grade incident in Datix – Please ensure you:

- Make an initial assessment of assigning physical and psychological harm(s) associated with each patient involved in the incident (for patient safety events)
- Make an initial assessment of assigning an overall incident impact grade according to the perception of the incident and its consequences at the time (consider actual harm to all individuals, the organisation and its reputation. The overall impact will never be less than the harm to an individual but may be a higher grading)
- Escalate any areas of concern immediately to line manager



What happens next?

An incident manager will be assigned on Datix by the Patient Safety Team. Every incident reported will be subject to investigation however the type and extent of review will be different. The level of response required for an incident is detailed in the Trust's Patient Safety Incident Response Plan (PSIRP). If the incident does not meet the criteria for a planned response, the incident manager will undertake the response process for local incident management.



What is the Patient Safety Incident Response Framework (PSIRF)?

PSIRF is the way in which the NHS responds and learns from incidents; this framework replaces the Serious Incident Framework. There are 4 framework standards that we need to demonstrate:

- Compassionate involvement of those affected by incidents; ensuring staff, patients and families are supported and provided with opportunities to contribute meaningfully to responses.
- Application of a range of system-based approaches to learning; a suite of investigative tools replaces Root Cause Analysis.
- A more proportionate approach to investigating incidents by balancing the resources allocated to investigation with those needed to deliver improvement. With the exception of a small number of mandated national priority incident investigations, PSIRF removes the mandated requirement to investigate when a threshold of harm is reported and avoids repeatedly conducting similar investigations which yield similar recommendations.





- Supportive oversight focused on strengthening responses and improvement.

What is the Patient Safety Incident Response Plan (PSIRP)?

It is our local plan that sets out how we intend to respond to national and local priority patient safety incidents at the Dudley Group. Our plan is not permanent. We will work flexibly and consider the specific circumstances of incidents and the needs of those affected. Responses are conducted for the purpose of systems-based learning and improvement. There is no remit to apportion blame, determine liability, preventability or cause of death.

Which system-based approaches to learning are the Trust using?

After Action Review (AAR) – An incident response which is a structured, facilitated discussion of an event, the outcome of which gives individuals involved in the event understanding of why the outcome differed from that expected and the learning to assist improvement.

Multidisciplinary Team (MDT) Review – An incident response that supports the care team to learn from patient safety incidents that occurred in the significant past and/or where it is more difficult to collect staff recollections of events either because of the passage of time or staff availability. Through open discussion (and other approaches such as observations and walk throughs undertaken in advance of the review meeting(s)), the key contributory factors and system gaps that impact on safe patient care will be agreed.

Patient Safety Incident Investigation (PSII) – An in-depth review of a single patient safety incident or cluster of incidents to understand what happened and how. Undertaken when an incident or near-miss indicates significant patient safety risks and potential for new learning.

SWARM (huddle) – An incident response whereby, immediately after an incident, staff ‘swarm’ to the site to quickly analyse what happened and how it happened and decide what needs to be done to reduce risk.

Thematic Review – An incident response used for understanding common links, themes or issues within a cluster of investigations, incidents, or patient safety data. Themed reviews seek to understand key barriers or facilitators to safety.





What can you do to get involved?

The most important things you can do to support PSIRF:

- If you are invited to an incident response meeting (AAR, PSII, Swarm etc) make every effort to attend; this is your opportunity to be part of shaping improvements and getting the support you need. Staff delivering care understand the challenges and barriers to daily work better than anyone else and your insight and experience is key to making PSIRF a success.
- Keep reporting incidents and let the patient safety team know if you have any queries or training needs.
- Support the development of and completion of robust action plans in response to investigation findings.

For more information

- Access the Patient Safety Incident Management Hub page: [Governance - Incidents](#)
- Incident Reporting and Management Policy [Incident Reporting and Management Policy.pdf](#)
- Patient Safety Incident Response Policy and Plan [Governance - PSIRF](#)



ENGAGING AND INVOLVING PATIENTS, FAMILIES AND STAFF (BEING OPEN)

Open and effective communication with patients should begin at the start of their care with the Trust and this should continue throughout. This should be no different when a patient safety incident occurs.

When things do go wrong in care being open means providing a prompt, compassionate, honest disclosure and apology about what happened.

What is the purpose?

Being open about what happened and discussing incidents promptly, fully and compassionately can help patients and staff cope better with the aftereffects. It is also an opportunity to identify areas of improvement opportunity by understanding the patient's/family's perspective about what happened.

It is important to ensure that patients/carers receive the information they need to understand what happened and the reassurance that everything possible will be done to prevent a similar type of incident occurring. This helps create an environment where patients, carers and staff feels supported when things go wrong.

Principles of being open

Acknowledgement – All patient safety incidents should be acknowledged and reported as soon as they are identified. Where a patient, their family or carers inform staff that something has gone wrong, they must be taken seriously from the outset, and treated with compassion and understanding by all staff.

Truthfulness, Timeliness and Clarity of Communication – Patients families and/or carers should be given timely, clear and truthful information about the incident and should be kept informed of any new information as it emerges.

Apology – Saying sorry **is the right thing to do**. It is not an admission of liability. A sincere expression of sorrow or regret should be given for the harm resulting from an incident.

Recognising Patient and Carer Expectations – It is important to know what patients, families and/or carers expect from the investigation of the incident. Support should also be given where needed, this may be in the form of an independent advocate, interpreter or the Patient Advice and Liaison Service (PALS).

Professional Support – Staff should feel supported throughout the incident investigation process because they too may have been traumatised by being involved.

Multi-Disciplinary Responsibility – Incident responses (e.g. SWARMS, After Action Review, Patient Safety Incident Investigation) should be multidisciplinary. This will ensure that the Being Open process is consistent with the philosophy that incidents usually result from system failures and rarely from actions of an individual.

Clinical Governance – Being open requires the support of patient safety and quality improvement through Clinical Governance frameworks and involves a system of accountability through the Chief Executive to the Board to ensure that these changes are implemented, their effectiveness reviewed and findings disseminated.

Confidentiality – Details of a patient adverse event should at all times be considered confidential. The consent of the individual concerned should be sought prior to disclosing information beyond the clinicians involved in treating the patient. It is good practice to inform the patient, family and/or carers about who will be involved in the investigation before it takes place and give them the opportunity to raise any objections.

Continuity of Care – Patients are entitled to expect that they will continue to receive all usual treatment and continue to be treated with respect and compassion. If a patient expresses a preference for their healthcare needs to be taken over by another team, the appropriate arrangements should be made for them to receive treatment elsewhere.

What does this mean for you?

You must read Trust policies:

- Duty of Candour (Including Being Open)

You will:

- Have knowledge of what Being Open is
- Ensure that Being Open is promoted across the organisation

Further reading

Engaging and involving patients, families and staff following a patient safety incident – www.england.nhs.uk

CLINICAL EFFECTIVENESS

What is Clinical Effectiveness?

It's the right person (YOU) doing:

- The right thing (evidence based practice)
- In the right way (skills & competence)
- At the right time (providing treatment/services when the patient needs them)
- In the right place (location of treatment/services)
- With the right result (clinical effectiveness/maximising healthgain)

We need our staff to deliver high quality care to patients in a vast range of circumstances, from our District Nurses visiting patients at home, to our Midwives delivering babies, and our Emergency Department staff treating extremely ill patients.

Clinical effectiveness is made up of a range of quality improvement activities and initiatives including:

- Review of guidelines and standards to identify and implement best practice.
- The use of quality improvement tools, (such as clinical audit, evaluation, benchmarking) to review and improve treatments and services.
- Reviews of outcomes from treatments or services.
- Measurement of performance to assess whether the team/ department organisation is achieving the desired goals.
- Information systems to assess current practice and provide evidence of improvement.
- Development and use of systems and structures that promote learning across the organisation.

We also need you to:

- Support the implementation of National Institute for Health and Care Excellence (NICE) Clinical Guidance.
- Ensure participation in all Trust mandatory audits.
- Support the implementation and audit of any other National guidance and recommendations.

- Participate in all other local and national audits and initiatives for innovation and improvement.

How can you get involved?

You can ensure that all our patients get the right result by getting evidence of what works into your everyday clinical practice and evaluating its effect on patient care.

Think about the treatment or service you provide:



How do you know it is effective?

What evidence do you have for this?

When was the last time you reviewed your practice?

Did this happen in discussion with colleagues?

Further reading

www.evidence.nhs.uk

www.nice.org.uk

www.nrls.npsa.uk

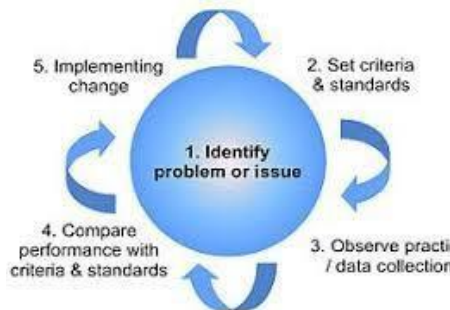
CLINICAL AUDIT

What is Clinical Audit?

Clinical Audit is the process you use to measure the effectiveness of your care and treatment.

Essentially, it's all about checking whether best practice is being followed and making improvements if there are shortfalls in the delivery of care. A good clinical audit will identify (or confirm) problems and lead to effective changes that result in improved patient care.

If areas for improvement are identified it's important to develop and carry out action plans, improve service provision and then re-audit to ensure the changes have had an effect.



What is the difference between Clinical Audit and Research?

Research is about obtaining new knowledge and finding out what treatments are the most effective, therefore telling us what we should be doing. Clinical Audit is about quality and finding out if best practice is being carried out. Clinical Audit tells us whether we are doing what we should be doing and how well we are doing it.



Who should be involved in Clinical Audit?

Everybody who is involved in the care a patient receives should be involved in Clinical Audit. From the start, if you are planning an audit, you should involve anyone who might later be affected by the result, i.e. people who might be asked to change practice.

If the audit has implications for professions or disciplines in other areas they should be consulted at the planning stage. It is important that your audit project is supported by those who have the authority and commitment to see changes put into practice.

If you want to carry out a Clinical Audit?

Please register via AMaT [Audit Management and Tracking - Welcome \(amat.co.uk\)](https://amat.co.uk)

Speak to your speciality audit lead and your clinical effectiveness facilitator. Complete your data collection, compare your findings with the set criteria and standards, write your report, present your findings, implement change and re-audit to measure improvements.

Why do we prioritise audits?

It's important to understand that our local mandatory and national audit participation provides our assurance of the quality of our services.

For more information?

Contact the Clinical Audit team on extension 3724 or via Teams for each member.



CONCERNS AND COMPLAINTS

As healthcare providers we strive to get things right and therefore we encourage the views, comments and suggestions of our patients, their families and carers. Competent handling of patient concerns and complaints can assist in improving the quality of the organisation's care delivery.

Types of concern and complaint?

A concern is a verbal expression of a problem that does not require a written response made to any member of staff (or the Patient Advice and Liaison Service (PALS)).

The PALS team

When a person contacts the PALS team, they will listen to the concerns and discuss the best way forward. The PALS team works in partnership with our patients and staff and are committed to providing impartial and confidential advice to support patients, their families, and carers.

The PALS team act confidentially when dealing with concerns. They will contact people involved, including doctors, nurses, managers, or support organisations, to seek answers to the questions and provide feedback. None of the information shared will be entered into patient records.

If a query is raised with the PALS team on behalf of someone else, the PALS team will need consent from the individual for their information to be shared with someone else.

The PALS team aim to resolve concerns as quickly as possible.

In cases where concerns, unfortunately, cannot be resolved by the end of the next working day, or need investigating further, the PALS team will refer concerns on to the complaints team.

A complaint is an expression, verbal or written, of dissatisfaction about any aspect of the Trust's services requiring a written response.

Who can make a complaint?

Anyone who is receiving or has received NHS treatment or services can complain:

- A patient, or former patient
- A person likely to be affected by a decision taken by our organisation
- Any appropriate person in respect of a patient who has died,



e.g. the next of kin or their agent

- Someone acting on behalf of an existing or former patient

Complaints should be raised as soon as possible and not more than 12 months after the incident. This time limit may sometimes be waived if there is a genuine reason why the complaint could not be made sooner.

Documents relating to a complaint investigation are securely stored and kept separately from medical records or other patient records. They are only accessible to staff involved in the consideration of the complaint.

Complaints that can be resolved quickly - early resolution

When we receive a complaint, we are committed to making sure it is addressed and resolved at the earliest opportunity (known as early resolution). If staff consider the issues cannot be resolved quickly, the complaint will continue under the formal complaints process in line with the Trust's timescale.

If we can answer or address the complaint early, we will ask relevant staff members to contact the complainant to discuss and resolve the concerns within three working days. This will often be done over the telephone. A summary of the complaint and how this was resolved will be shared with the complainant.

Formal complaints investigation

Not every complaint can be resolved quickly and sometimes we will require a longer period of time to carry out an investigation.

Staff who carry out investigations will give a clear and balanced explanation of what happened and what should have happened. They will reference relevant legislation, standards, policies, procedures, and guidance to clearly identify if something has gone wrong.

They will make sure the investigation clearly addresses all of the issues raised. As soon as practical after the investigation is finished, a written response will be sent to the complainant.

If the complainant is not happy with the response to their complaint, they can contact the Complaints Department who can arrange for the complaint to be reviewed.

Alternatively, the complainant can ask the Parliamentary and Health Service Ombudsman (PHSO) to review their complaint.





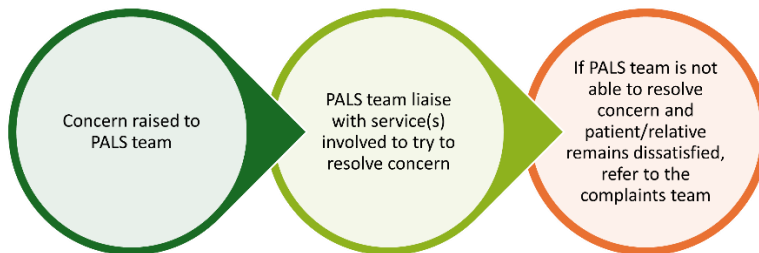
Summary of resolution of concerns/complaints

The below breaks down the process from the initial concern raised by the patient or relative through to the involvement of the PALS team and complaints team, and finally to the Parliamentary Health Service Ombudsman if necessary.

Step 1: Service approached with concern



Step 2: PALS team approached with concern



Step 3: Complaints team approached with complaint



What does this mean to you?

You must read the Trust's policies:

- Concerns and Complaints Policy
- Being Open Policy



POLICIES AND PROCEDURAL DOCUMENTS

What are Procedural Documents used for?

All staff are responsible for following all applicable policies, procedures and guidelines and reporting any adverse event to their line manager. Staff should know how to access all Trust procedural documents, which are held electronically on the Trust Hub.

Definitions

Strategy

A high-level plan designed to achieve a particular long term aim for the future success of the Trust e.g. the Risk Management Strategy.

Strategies are likely to apply for a number of years and must have an agreed review date.

Organisation-wide Policy

- A ratified corporate plan of action. These policies apply to all relevant staff as a 'must do' requirement.
- Is a formal document that is regarded as legally binding and therefore its purpose, definitions and the responsibilities outlined within its content must be upheld in order that it may be used to support an individual or the Trust during legal action.
- Policies provide a consistent logical framework for Trust action across different functions or directorates.
- Not all issues require a policy. Many routine matters can be dealt with by the formulation of procedures or guidelines.
- Policies must be reviewed at least every 3 years. Earlier review should be undertaken if there is a significant change impacting on the issue, such as changes to legislation.

Standard Operating Procedure (otherwise known as SOP)

- A procedure is a standardised series of actions taken to achieve a task so that everyone undertakes it in an agreed and consistent way to achieve a safe, effective outcome.
- The procedure is a formal document and must be complied with as it may be used to support an individual or the Trust during legal action.
- Organisation-wide procedures apply to all relevant staff as a 'must do' requirement.

Guidelines

- Clinical guidelines are systematically developed statements, which assist clinicians and patients in making decisions about appropriate and effective treatment for specific conditions.
- Local clinical guidelines need to be developed when no national guidelines exist, or national guidelines exist but need adapting for local use taking into account local resources. Guidelines should relate to an overarching policy but may stand alone.
- Where national guidelines are in place, these should be agreed locally to be used and this information shared with the Compliance Team so that the Guidelines can be placed on the Hub for easy access.

Protocol

- Local protocols are the descriptions of the steps taken to care for and treat a patient. They are sometimes called the 'integrated care pathway'.
- They are designed to implement national standards such as guidelines produced by the National Institute for Health and Care Excellence (NICE).



- Determine care provision by using the best available evidence if national standards are not available.
- Developed by multi-disciplinary teams, local protocols reflect local services and staffing arrangements.
- They identify who carries out key parts of the care or treatment and where they should be delivered.
- Examples of local protocols are patient group directions and referral advice.

For more information on developing a document:

Read the Trust Procedural Document Development and Management Policy or contact the Compliance/ Procedural Document Team on dgft.procedural.documents@nhs.net



COMPLIANCE

How is the quality of care delivered by the Trust monitored?

Care Quality Commission (CQC)

The CQC are the independent regulator of health and social care in England. They ensure health and social care services provide people with safe, effective, compassionate, high-quality care and encourage care services to improve. They inspect services and report on the quality of care provided.

How do we ensure we monitor the quality of care and prepare for CQC inspection?

- Self-assessment against CQC measures
- Internal Quality and Safety Reviews
- Internal focussed reviews
- Executive Walk rounds (ward to board)
- External partner visits (ICB)

Self-assessment against CQC measures

- Each clinical area undertakes a self-assessment of their area and compares against the CQC domains - Safe, Effective, Caring, Responsive and Well led.
- Evidence of good practice or assurance is noted and actions to address gaps in assurance are developed.

Internal Quality and Safety Reviews

- A multidisciplinary Trust team visits an area to review in a similar way to CQC inspection. The reviews are unannounced and use a suite of inspection tools that make an assessment against the CQC care domains of Safe, Effective, Caring, Responsive and Well led.
- A report is produced to help identify areas for improvement.



Internal focussed reviews

- Focussed reviews are completed by a small team who will have an identified focus on a few topics. This review usually follows concerns or risks that have been raised.
- Improvement plans are discussed with the teams following the review.

Board Walk rounds (ward to board)

- A small group of people, usually including a member of the Executive and a member of the non-executive team, visit areas and speak to staff. The Group can often include a Trust Governor or a Patient Safety Partner.
- The visits provide an opportunity for staff and patients to meet and speak with senior colleagues on a less formal basis and allows staff to show case good practice and raise any concerns/ feedback.
- The findings can be shared at Board meetings and actioned as

External partner visits – Integrated Care Board (ICB)

- A range of external partners conduct quality assurance visits, these can be planned as part of a wider schedule or can be conducted in response to concerns raised.
- The local authority commissioning body known as the integrated care board (ICB) routinely work with the Trust to support the Trust's programme of quality and safety reviews but that also conduct their own assurance visits.
- We work together to understand areas requiring improvement and develop improvement plans to help support continuous improvement of our services.





The Trust uses these sources of information to gain assurance on the quality of care we deliver and where needed develop and improve care for our patients. This area of work is known as compliance and is strongly linked to all other areas within governance to support patient safety, clinical effectiveness and risk and assurance processes.

For further Information please contact the Trust's Compliance team on dgft.complianceteam@nhs.net



RISK MANAGEMENT

Risk is an inherent part of the delivery of healthcare. Effective risk management processes are essential to the delivery of high quality and safe healthcare services. The Trust is committed to ensuring robust risk management systems are in place to reduce harm to patients and staff, to create safer environments for care delivery and to support the achievement of the organisation's corporate objectives.

Whilst our priority is to reduce those risks that impact on safety and patient experience, considered risk taking is encouraged. Not all risks are to be avoided, for example strategic and business related risk, where relevant, can be embraced and explored in order to grow our business and services.

Definition of risks in healthcare are:

- The threat that an event or action will adversely affect an organisation's ability to achieve its goals, objectives and execute its strategies"
- Risk is the exposure to the possibility of such things as economic or financial loss, physical and psychological harm, injury or delay of treatment as a consequence of pursuing a particular course of action"

What is risk management?

Risk Management is the assessment, analysis and management of risks. It is recognising which events (hazards) may lead to harm in the future and how to minimise the likelihood (how often) and consequence (level of impact) if the risk happens.

A good risk management system incorporates proactive strategies for the identification, recording, managing and monitoring of risks. The Trust utilises a framework that ensures that risks are identified, assessed, controlled, and when necessary, escalated.

These main stages are carried out through:

- Clarifying objectives (establish the context)
- Identifying risks to successfully achieve objectives
- Analysing risks
- Evaluating and Treating risk
- Monitoring and review of the risk

Not all risks can be dealt with in the same way. The 5T's provide a list of options available to anyone considering how to manage risk:

- **Tolerate** – the likelihood and consequence of a particular risk happening is accepted.
- **Treat** – work carried out to reduce the likelihood or consequence of the risk (this is the most common action).
- **Transfer** – moving the responsibility or risk to another party, e.g. the risk is insured against or subcontracted to another party.
- **Terminate** – an informed decision not to become involved in a risk situation, e.g., terminate the activity.
- **Take the opportunity** – actively taking advantage, regarding the uncertainty as an opportunity to benefit.

What is the risk register?

A risk register is a tool for recording and managing the risks in your work area. The register is recorded in the DATIX system. Every ward, department, specialty and Division have their own risk registers of which they are accountable to ensure these are live and up to date at all times.

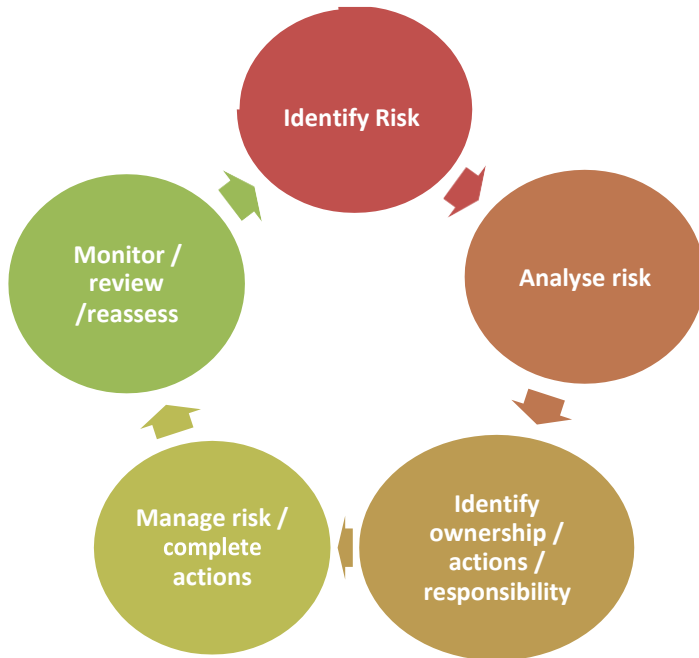
The register provides a central shared repository that includes:

- A description of the risk, its cause and impact (what could cause/ contribute to the risk happening/what will go wrong/consequences if risk happens)
- The consequences and likelihood of the risk happening
- The risk rating or score
- The existing controls for the risk and any gaps in the strength of those controls
- Action plans to mitigate any gaps

Why is risk management important?

In simple terms managing risk effectively minimises the likelihood of risks materialising along with reducing the impact of the consequences. It is essential that we understand and actively manage the risks that impact upon the Trust's ability to achieve its strategic objectives. Effective risk management improves patient safety and outcomes, staff wellbeing and morale.

This is what the Risk Management Process should look like:



What does it mean for you?

Risk management is everyone's responsibility. Please ensure that you:

- Are familiar with the Trust's Risk Management Strategy and Policy.
- If you identify an issue or a risk in your area, discuss this with your line manager.
- If you are responsible for the management of risks in your area that you have attended the Trust's risk management training and have a working knowledge of risk management procedures.

Further Information

For further information, training availability and reading materials, please visit the Risk Hub Page: [Governance - Risk Management](#)

If you have any queries relating to risks, please do not hesitate to contact the Risk Management Business Partners on ext 3802



An Introduction to Clinical Governance

Please confirm your receipt and understanding of the contents of this booklet through one of two methods:

- By e-mail confirmation to dgft.learning@nhs.net, stating your name, job role, and area of practice
- By post, by printing this single page and completing the details below before returning to:

**Statutory and Mandatory Training Department
 Learning and Development
 Room 2, Clinical Education Centre
 Russells Hall Hospital
 Dudley
 DY1 2HQ**

I confirm that I have read and understand the contents of the 'It's a risky business' booklet.

I understand that supporting policies will provide additional information and guidance that may be necessary for my role.

I confirm that I know how and where to access further guidance and support as needed.

Full Name (Capitals)

Signed Date

Job Role / Post

Department / Area

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