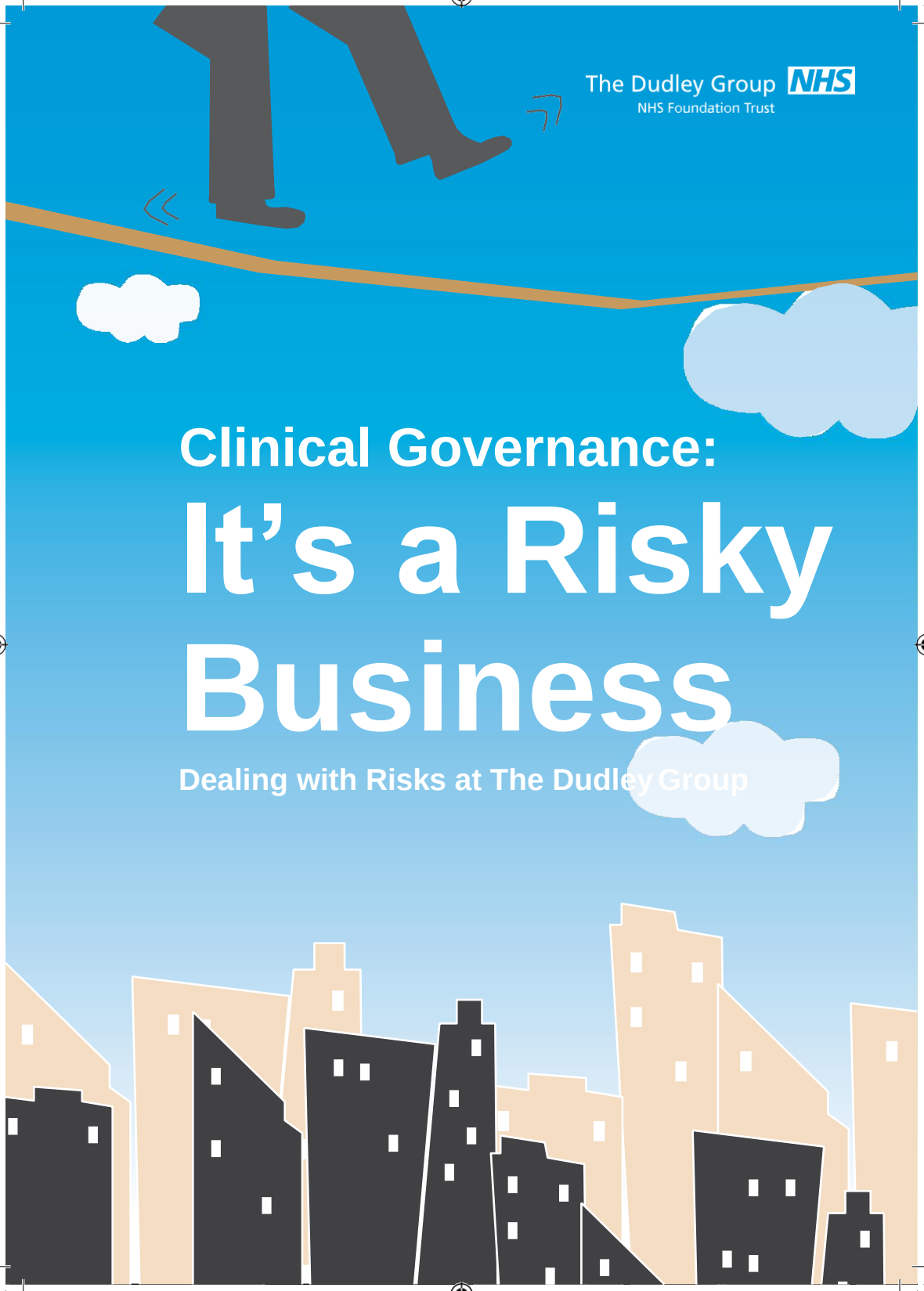
The Dudley Group NHS
NHS Foundation Trust



Clinical Governance:
It's a Risky Business

Dealing with Risks at The Dudley Group

INTRODUCTION

The NHS treats thousands of people every day. There are risks involved in the treatment of patients, the management of staff and the running of hospitals and clinics. Human error, poor organisation and lack of clarity on management arrangements are all risks. Errors and accidents can cause discomfort, cost money, jobs and in the most extreme cases, lives.

What is risk management?

A good risk management system incorporates identification, recording and reporting of risks, proactive strategies for managing and monitoring risks, staff awareness of risks and evidence of learning from incidents within an overall management and monitoring framework.

Recent high profile clinical errors and incidents have raised the awareness of patient safety as a key feature of risk management. Health service staff rarely deliberately set out to harm patients or colleagues. Often they will feel terrible when an incident occurs. Suspension and/or blaming of staff may lead to a climate of fear and covering up of the extent of a problem.

An effective risk management system recognises that mistakes will happen and encourages staff to identify, report and take action to prevent and minimise risks as part of the work they do every day.

What is the risk register?

A risk register is part of the process of recording and managing the risks in your work area.

All risks should be recorded in a register that summarises:

- A description of the risk, its cause and impact
- The existing controls for the risk
- The consequences and likelihood of the risk happening
- The risk rating or score: low, medium, high or very high (1 – 5)
- The overall priority of the risk

Keeping a record of risks will help you review and check whether risks have changed or new risks need to be added.

This is what the Risk Management Process looks like overall:

Risk Identification

- Complaints
- Incidents
- Accidents
- Staff/Patient Concerns

What arrangements do you have in place?

Do your staff know what to do if they identify a risk

Risk Assessment

Complete a risk assessment form identifying hazards, controls in places, the risk score and the action you are going to take.

Development of Action Plans

- Validate controls
- Assign a lead
- Set implementation dates
- Set review dates
- Confirm review process and forum
- Confirm escalation process

Risk Register

- Submit Risk Assessment for addition to risk register
- Risk acknowledged by Manager
- Level of Risk accepted by Manager

Reporting and Communication

- Quarterly Risk Register report to Patient Safety Group and Risk and Assurance Commitee
- Quarterly Corporate Risk and Assurance Report to Risk Committee and Board

Review of Actions

- Confirm progress
- Re-assess risk - have completed actions mitigated the risk (in part/ in full/not all)?
- Escalate uncontrolled risks
- Accept/sign off residual risk

Risk Management Arrangements Monitoring of Risks

- Local risk management arrangements
- Staff awareness/training
- Maintenance of local risk registers
- Directorate arrangements for communicating risks/ sharing learning

Why is it important?

Managing risk effectively also involves identifying and minimising the opportunity for risks to occur and identifying and learning from risks. This can involve co-ordinating and communicating information from different sources including:

- Incident reporting of errors and near misses (clinical and non clinical)
- Clinical effectiveness and audit projects that may impact or influence risk
- Work undertaken by Trust or Directorate committees or groups and detailed in minutes and reports
- Complaints and claims management
- Local and national policies and initiatives i.e. waiting time initiatives,
- Changes in process or legislation
- Joint working arrangements and service level agreements
- Clinical outcome indicators that tell you whether you have achieved what you want from an intervention

What difference does it make?

- Clinical errors and incidents that are reported can be assessed and used as a basis for improving the quality of treatments, services and premises.
- Actions taken can improve patient and staff safety, security and clinical outcomes and may prevent future incidents and accidents.
- Reporting of incidents provides an opportunity for other teams and departments to learn and make changes to their practice.
- Risks that impact on patient care can be monitored, managed and reported via the risk management process and linked to professional and organisational learning through the governance structure.
- Patients choose to come to The Dudley Group.

What does it mean for you?

Risk management is everyone's responsibility. You should:

- Know where to find and read the Risk Management Strategy and Policy and have a working knowledge of all related risk policies.
- Comply with the Trust policies, procedures and guidelines to protect the health, safety and welfare of any individuals affected by Trust activity.

- Acknowledge that risk management is integral to your working practice within the Trust.
- Report all incidents in accordance with the Incident Reporting Policy and take action to reduce or prevent further incidents.
- Report any issues to your line manager and when required, undertake risk assessments with the support of your manager.
- Participate in the investigation of any incidents if requested.
- Attend mandatory training appropriate to your role.
- Seek assistance when you are unsure about the action required.

Don’t ignore it!

How we can help?
The Risk Management Strategy & Policy is available on the Trust intranet.

Training is available and can be booked on the Hub.

ADVERSE INCIDENTS

In a service as large and complex as the NHS, the potential for error presents a constant challenge. Things will sometimes go wrong. When they do, the response is not one of blame, but of learning from these and having a framework to reduce risk for future patients, visitors and staff.

What is an adverse incident?

An unintended or unexpected event that happened as a result of an event or omission, which caused physical or psychological injury to a patient, visitor or staff member or any event or circumstances arising during NHS care that could have, or did lead to, unintended or unexpected harm, loss or damage.

Incident – An event or circumstance that did or could have resulted, in damage, loss or harm to person or property.

Clinical Incident – A clinical event or circumstance which could have or did lead to harm of one or more patients.

Health and Safety Incident – An incident which arises when a person did or could have sustained harm or injury due to an unexpected hazard (not during the course of treatment or care).

Assault Incident – Can be physical i.e. the intentional application of force to the person without lawful justification resulting in injury or discomfort. This may also be non physical abuse i.e. the use of inappropriate words or behaviours causing distress and/or constituting harassment.

Security Incident – An incident of actual or potential theft, criminal intent or damage.

Accident – An incident not covered by any of the categories above e.g. a staff member slip/trip without explanation and no obvious hazard.

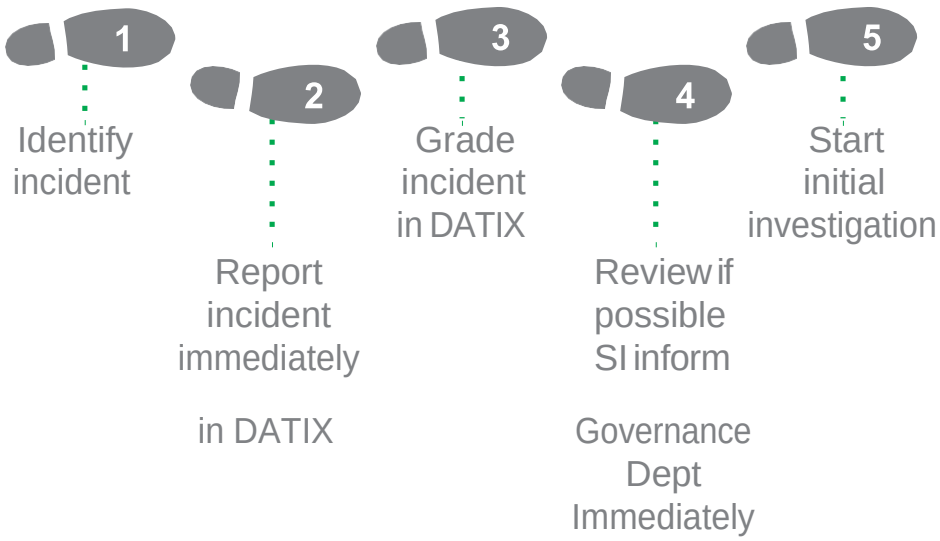
Near-miss – Any situation that could have resulted in an incident, but did not due to either chance or intervention.

Serious Incident (SI) – An incident which has resulted in death, serious injury or major public harm and is likely to lead to public concern.

Never Event – A serious, largely preventable patient safety incident that should not occur if the available preventative measures have been implemented.

Confidential Information Leak – Any incident involving the leak/loss or possible leak/loss of person identifiable information, e.g. a letter being sent to the wrong person, computers with patient records being stolen, records not being disposed of correctly and being found by members of the public.

How do we report an incident?



What does this mean for you?

Identify incident – You will have:

- Read the Trust policy for Incident reporting
- The knowledge of what constitutes a reportable incident
- Ensured no person is in danger

Report incident immediately in DATIX – You will have:

- Completed training on DATIX to report an incident (Dif 1)
- If a line manager (if role requires) completed training for Incident Investigation (Dif 2) in DATIX
- Actively reported all incidents in DATIX as soon as possible after the event (same day).

Grade incident in DATIX – You will have:

- Made an initial assessment of severity (grading 0-5) in DATIX and given consideration if the incident is an SI
- Escalated any areas of concern immediately to your line manager

Review if possible SI – You will have:

- The knowledge of what constitutes a serious incident or never event
- If the incident is a potential SI informed your line manager and Governance Department
- Assessed the need to implement the Being Open policy (refer to senior manager)

Start the initial investigation – You will have:

- Got any witness statements and secured any documentation/equipment
- Ensured any material evidence is labelled and kept secure

How do we learn from incidents?

Identification of incident

Investigation of incident

Identification of what did/may have gone wrong

The Trust has mechanisms in place to investigate, analyse and learn from incidents, to learn how to change practice to improve safety and quality within the organisation.

What does this mean for you? – You will have:

- Read the Trust policy for the investigation, analysis, learning and improvement from incidents, complaints and claims.

All incidents are graded as to their severity (0-5). The level of investigation required is based on this grading. However, the identification of trends in lower grade events or occurrences may prompt a higher level investigation.

Serious incidents (grade 4 & 5) are subject to formal investigation in the form of a full root cause analysis.

What does this mean for you? – You will:

- Support investigations into all incidents, identifying root cause, gaps in practice, areas of concern or good practice
- If you are a line manager (if role requires) complete training for Root Cause Analysis Investigation
- Support the development of robust action plans in response to investigation findings

How to change practice?

In response to all incident investigations a robust action plan is developed to enable the organisation to learn from the incident. This will facilitate a framework to reduce the risk of recurrence and enable a change in practice. It is the responsibility of managers to ensure that information on safety lessons is shared.

What does this mean for you? – You will:

- Implement changes to undertake development or adopt different ways of working in response to actions identified on the action plan.
- If you are a line manager you will share lessons on safety.

For more information

The Trust policy for incident reporting is available on the Hub.

BEING OPEN

Being open means apologising and explaining what happened to the patients, family and/or carers who have been involved in a complaint or patient safety incident as soon as possible following an adverse event (i.e. incident/ complaint/claim).

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 after effects.

It is important to ensure that patients/carers receive the information they need to enable them to understand what happened and the reassurance that everything possible will be done to ensure that a similar type of incident does not recur. This helps create an environment where patients/ carers/ healthcare professionals and managers feel supported when things go wrong.

Principles of being open

Acknowledgement – All patient safety incidents should be acknowledged as soon as they are identified, all concerns must be taken seriously. Denial of a person's concerns will make future open and honest communication more difficult.

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 not an admission of liability and it **is the right thing to do**. A sincere expression of sorrow or regret should be given verbally as this allows face to face contact. This should be followed up with a written apology.

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 – Investigations (e.g. Root Cause Analysis) following a patient safety incident 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:

- Being Open

You will:

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

Further reading

Being Open - **www.nrls.npsa.nhs.uk**

CONSENT

Valid consent must be gained before starting any treatment, physical investigation or provision of personal care. This is a legal and ethical requirement with the potential for legal action by the patient or professional bodies if this is not adhered to. **Patients have the right to determine what happens to their bodies.**

What can happen if consent is not gained?

English case law ('common law') has established that touching a patient without valid consent may constitute a civil or criminal offence of battery.

If healthcare professionals fail to obtain proper consent and the patient subsequently suffers harm as a result of treatment, this may be a factor in a claim of negligence against the healthcare professional involved.

Poor handling of the consent process may also result in complaints from patients through the NHS complaints procedure or to professional bodies.

Is the consent valid?

Consent is a patient's agreement for a health professional to provide care. Patients may indicate consent non-verbally (e.g. presenting their arm for their pulse to be taken), orally or in writing. For the consent to be valid, the individual must:

- Give it voluntarily / not acting under duress
- Have been appropriately informed
- Have the capacity to make an informed decision.

Voluntary/ not acting under duress – Consent must be given voluntarily and freely. There must be no pressure or undue influence to either accept or refuse treatment (e.g. from partners, family or healthcare professionals). Individuals should be given time to consider if they want to consent and be made aware they can retract this at any time.

Capacity – A person lacks capacity if they have an impairment/ disturbance (disability, condition or trauma or the effect of drugs or alcohol) that affects the way their mind or brain works (this may be long or short term).

An assessment of a person's capacity must be based on their ability to make a decision at the time it needs to be made, and not their ability to

make decisions in general. A person is unable to make a decision if they cannot do one or more of the following things:

- Understand the information given to them that is relevant to the decision
- Retain that information long enough to be able to make the decision
- Use or weigh up the information as part of the decision-making process
- Communicate their decision – this could be by talking or using sign language and includes simple muscle movements such as blinking an eye or squeezing a hand.

Informed decision – To give valid consent, the person needs to understand the nature and purpose of the procedure. Any misrepresentation of these elements will invalidate consent.

Do I have to get consent for photos and audio recordings?

Consent should be obtained for any visual or audio recording, including photographs or other visual images. The purpose and possible future use of the recording must be clearly explained to the person before their consent is sought for the recording to be made.

Do I need to get consent for the treatment of young children?

In law the parents' consent is required for treatment, physical investigation or provision of personal care. This is not always practicable therefore you should discuss with the patient what routine procedures will be necessary and gain their consent for these interventions in advance. Only people with parental responsibility are able to give consent on behalf of their child.

What does this mean to you?

You must read Trust policies:

- Advanced Decisions – Assessing Mental Capacity and complying with the Mental Capacity Act (MCA) 2005.
- Consent for Post Mortem Examination and Retention and Use of Organs
- Consent to Examination or Treatment
- Patient Centred Care Approach

Department of Health – Reference guide to consent for examination or treatment is available on www.dh.gov.uk

CLINICAL EFFECTIVENESS

What is Clinincal 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 health gain)

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.

What Quality Improvement Activities are available to you?

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

- Evidence, guidelines and standards to identify and implement best practice
- Quality improvement tools, (such as clinical audit, evaluation, benchmarking) to review and improve treatments and services based on:
    - The views of patients, service users and staff
    - Evidence from incidents, near-misses, clinical risks and risk analysis
- 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 Clinical 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:

Further reading

www.evidence.nhs.uk
www.nice.org.uk
www.nrls.npsa.uk

CLINICAL AUDIT

What is Clinincal 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.

So you want to carry out a Clinincal Audit?

Contact your Specialist Clinical Audit Lead

- Rate priority of audit
- Agree criteria/standards
- Complete proposal form

Submit to Clinical Audit team

- Objectives & standards checked
- Reviewed by Trust clinical audit lead
- Approved audits logged on audit plan

Gain advice & support from audit team on:

- Methodology
- Data collection tools
- Analysis

What to do next?

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 2368 / 1196 / 2316.

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 PALS service). If the verbal complaint is unable to be resolved within 1 working day this must be forwarded to the Complaints and Claims Manager to register and acknowledge.

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?

Complaints may be made by:

- 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

Where someone other than the patient or their authorised agent wishes to make a complaint, they must be able to demonstrate that they have obtained the patient's (normally written) consent.

Who responds to complaints, concerns or issues?

All staff – any member of staff who is approached by a patient or their representative should try to resolve the concern/complaint/issue quickly and on the spot, wherever possible. This may be through an immediate informal response by a front-line member of staff or practitioner, or through subsequent investigation. Staff must inform service users of the Patient Advice and Liaison Service (PALS) or the Complaints Department if it cannot be resolved locally.

Steps to complaints resolution?

Step 1: Local resolution – by department/ specialty to the initial issue concern/ complaint /issue raised
Step 2: PALS service – verbal expressions or following referral after local resolution has failed
Step 3: Written complaint requiring a complaint to be registered and acknowledged within 3 working days
Step 4: The Ombudsman – local resolution has not been possible within the organisation.

What will the organisation do?

The organisation (staff), for all steps in the complaints process, will:

- Listen to concerns expressed.
- Be open, fair, flexible and conciliatory.
- Be courteous and sympathetic.
- Be apologetic where appropriate; an apology is not an admission of liability.
- Be prompt and follow agreed time limits.
- Patients' care will not be adversely affected because of the complaint.

What will the organisation do?

The organisation will not file any documentation related to the concern/ complaint in the patient's health records nor refer to a complaint during treatment or review.

What does this mean to you?

You must read the Trust's policies:

- Concerns and Complaints Policy
- Being Open Policy

POLICIES AND PROCEDURAL DOCUMENTS

All Trust employees are responsible for keeping up to date and complying with all Trust documents that affect their work.

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. Strategies will always be organisation-wide and not local documents.

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.

Local Policy

- The same principles apply as organisation-wide policies but local policies deal with issues that relate to individual teams/depts/ directorates.

Organisation-wide Procedure

- 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.

Local Procedure

- The same principles as an organisation-wide procedure apply but local procedures impact on a specific part of the Trust.

Clinical 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.

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 Clinical 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
- Follow the agreed template.
- Ensure full consultation with all relevant stakeholders.
- Complete an Equality Impact Assessment.
- Submit to Trust Policy Group for discussion and recommendation for approval
- For advice contact the Clinical Effectiveness Manager extension 3727.

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Dealing with Risks at The Dudley Group

You may 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 .....