|  |
| --- |
| Document name: Clinical Governance Policy  Author:  Approved by: |

**[insert company name]:**

**Clinical Governance Policy**

1. **Policy Overview**

The Company recognises that that clinical governance is a framework which is integral to, and underpins, all aspects of our service. The Company is a rigorous upholder of best practice and has developed a suite of clinical governance policies, procedures and processes to underpin the delivery of a high quality and safe community eye care service.

1. **Policy Scope**

The Clinical Governance Policy is an overarching policy which has a broad scope and is comprised of the following areas [and/or sub-policies]:

* Professional & Regulatory Requirements
* Education, training and continuing professional development
* Premises and Equipment
* Evidence-Based Practice
* Clinical Audit
* Infection Control and HCAI Reduction
* Medicines Management
* Data and Records
* Risk & Issues Management
* Complaints
* Serious Incident Management
* Safeguarding
* Health and Safety.

1. **Clinical Governance Structure and Oversight**

The Company has overall responsibility for its clinical governance programme and for ensuring that all ‘agree actions’ to address actual issues or to drive improvements in the quality of services are implemented.

The Company’s lead for clinical governance is [insert name]. The lead will put into place procedures and processes which reflect the requirements of this policy [and sub-policies] and has responsibility for day to day monitoring of all clinical governance and quality assurance arrangements.

1. **Professional & Regulatory Requirements**
   1. **The Company**

# The Company has completed Quality in Optometry (QiO) Level 2, which is designed for community services. We have also completed Level 1 clinical governance as a requirement for the General Ophthalmic Services (GOS) Contract.

# The Quality in Optometry Toolkit ([www.qualityinoptometry.co.uk](http://www.qualityinoptometry.co.uk)) is a web based self-assessment toolkit to ensure practices meet robust information and clinical governance criteria. It is accompanied by a framework of audit and information to support achieving full compliance.

# The Company requires its practitioners participating in community services are registered annually with the General Optical Council.

# We also ensure that all practitioners participating in community services complete the practitioner checklist to show they are aware of all clinical governance requirements and policies within the Company and service.

* 1. **Ophthalmology Subcontractors**

# [To be completed if relevant.]

# 4.3 CPD Requirements

The Company’s Policy on Meeting the CPD Requirements of the Professional and Regulatory Bodies can be found at Appendix 1.

# Training and Accreditation

# All optometrists are required to be registered annually with the General Optical Council and to have completed the training and accreditation the particular service requires. This will be verified through uploading of certification where appropriate.

1. **Premises and Equipment**

* The Company complies with Level 1 and Level 2 QiO requirements.
* Consulting room equipment must be safe to use, properly maintained and fit for purpose.
* A log is kept detailing all maintenance checks.
* All members of staff who use equipment must be appropriately trained and have access to instruction and other manuals.
* Equipment needing maintenance or repair must be decontaminated beforehand.

1. **Evidence Based Guidelines and Protocols**

* The Company’s clinical lead is responsible for implementing evidence based guidelines and protocols for the community services.
* These guidelines and protocols, will be informed by national guidelines including those published by National Institute for Health and Care Excellence (NICE), Royal College of Optometrists and the Royal College of Ophthalmologist guidelines as applicable, and will relate to all aspects of patient care including:
* Patient Assessment
* Referral
* Patient management (including the use of medicines)
* Patient follow-up
* Discharge
* A formulary, setting out preferred medicine choices will be developed (see Appendix 2).
* All practitioners engaged to deliver the community services will be expected to work to Company guidelines.
* The Company will undertake clinical audit as required to demonstrate adherence with the local guidelines and protocols.

1. **Clinical audit**

* The Company’s clinical lead is responsible for establishing a programme of regular clinical audit which will include:
* Infection control arrangements
* Adherence with locally determined guidelines and protocols
* Adherence with the medicines formulary
* Adherence with medicines management arrangements
* Other audits which will be determined based on feedback from patients, clinicians, complaints and learning arising from the assessment and root cause analysis of issues and serious incidents.
* The clinical lead is responsible for reviewing the results of clinical audit.
* Where a clinical audit identifies a significant outlier, the Company’s clinical lead will:
* Undertake an independent review, based on a random selection of patient records in order to determine the appropriateness of the clinical decision making.
* Where there is evidence of inappropriate referral this will be followed up with the referrer(s).
* Where poor performance, is identified this will be addressed in accordance with the Company’s Managing Staff Performance document.

1. **Infection Control and Health Care Associated Infections (HCAI)**

The Company’s Infection Control and Health Care Associated Infections (HCAI) reduction plan can be found at Appendix 3.

1. **Medicines Management**

The Company’s Medicines Management Policy can be found at Appendix 4.

1. **Data and records**

The Company’s Information Governance and Data Management Policy can be found at Appendix 5.

1. **Risk and Issue Management**

The Company’s Risk and Issue Management Policy can be found at Appendix 6.

1. **Complaints**

The Company’s Complaints Policy and Procedures can be found at Appendix 7.   
  
The Policy and Procedures reflect the requirements of the standard NHS complaints procedure.

1. **Serious Incidents**

The Company’s Serious Incident Policy can be found at Appendix 8.

The Policy and Procedures reflect the requirements of the standard NHS complaints procedure.

1. **Health and Safety**

The Company’s Health and Safety Policy can be found at Appendix 9.

The Company’s Clinical Governance policy will be reviewed annually following commencement date [insert date].

**Appendix 1**

|  |
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| Document name: Meeting the CPD Requirements of the Professional and Regulatory Bodies  Author:  Approved by: |

**[insert company name]:**

**Meeting the CPD Requirements of Professional & Regulatory Bodies**

It is the Company’s responsibility to manage the general performance and conduct of its staff. The Company will ensure that its practitioners receive training appropriate to the level of duties they carry out and continually develop in the interests of patients.

The Company requires all optometrists and opticians engaged to deliver community services to register annually with the General Optical Council (GOC) and meet the requirements of the GOC’s mandatory Continuing Education and Training (CET) scheme. The GOC is the regulator for the optical professions in the UK and maintains a register of individuals who are qualified and fit to practise, train or carry on business as optometrists and dispensing opticians.

**Mandatory Continuing Education and Training (CET) Scheme for optometrists and opticians**

In order to ensure that eye care practitioners maintain the up to date skills and knowledge needed to practise safely and effectively throughout their career, the GOC oversees a mandatory CET scheme. The CET scheme is a points-based scheme that runs over a three-year cycle.

A total of 36 general points are required per cycle for all dispensing opticians and optometrists covering all competencies, with a minimum of six points being required in any one calendar year.

At least 18 of the 36 general points required must be achieved through interactive CET, and at least one point must be obtained for participation in a peer review.

The Company requires that all optometrists or opticians engaged to deliver community services have completed the training and accreditation the particular service requires. This may include attendance at peer discussion sessions, and will be verified through uploading of certification where appropriate.

Optometrists can also participate in the College of Optometrists’ voluntary CPD scheme.

The Company will maintain a register or practitioners accredited to provide the community services.

The Company will, if requested by the commissioner, as soon as possible and no more than twenty days following a written request, provide evidence demonstrating that its practitioners are suitably qualified to deliver the service.

The Company will hold an information pack including accreditation, guidelines and pathway details.

CPD for Ophthalmic Medical Practitioners and Ophthalmologists

[Information to be added if relevant to the service commissioned.]

The Company reserves the right to remove a practitioner from the register of accredited staff practitioners if he/she does not meet the accreditation criteria, including the mandatory CET or CPD requirements required for their profession.

The Company will work with Local Education and Training Boards and Health Education England to understand local workforce and healthcare requirements, local education and training needs and plan provision where applicable.

The Company’s Meeting Professional & Regulatory CPD Requirements Policy will be reviewed annually from commencement date [insert date].

**Appendix 2**

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| Document name: Optometrists Formulary  Author:  Approved by: |

**[insert company name]:**

**Optometrists’ Formulary – Community Optometry Service**

This is the Company’s optometrists*'* formulary for the service consisting of prescribing information for drugs relevant to this service:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Drug Name** | **Legal Classification** | **Available preparation** | **Drug type** | **Drug Classification** |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

Review date: annually from commencement date [insert date].

**Appendix 3**

|  |
| --- |
| Document name: Infection Control Policy and Health Care Associated Infection Reduction Plan  Author:  Approved by: |

**[insert company name]:**

**Infection Control Policy and Health Care Associated Infection Reduction Plan**

The Company is committed to reducing minimising the possibility of health care associated infection.

The use of appropriate hygiene procedures and precautions to prevent exposure to and reduce the risk of transmission of infectious diseases is essential. A culture of ‘zero tolerance’ of avoidable infections is required to achieve sustainable reductions in health care associated infections (HCAI). Strict hygiene must be observed when dealing with patients with particular attention being paid to any equipment with which they come into contact.

The Company will ensure the following infection control procedures are in place:

* Chin rests and headrests on slit lamps, field screeners, keratometers, tonometers, autorefractors, fundus cameras or any other equipment should be cleaned with a sterile wipe before use by each patient.
* Hand hygiene guidelines should be observed.
* Similarly, the bridge and sides of trial frames and forehead and cheek rests of refractor (phoropter) heads should be cleaned anew for each patient.
* Items coming into contact with a patient’s eye must not be reused.
* Disposable tonometer prisms must be used when performing contact tonometry using either a Perkins or Goldmann tonometer, and any permanent tonometer prisms must be removed from the consulting room.
* Alternatively, in accordance with College of Optometrist’s guidelines, permanent tonometer prisms may be soaked in 2% sodium hypochlorite (Milton) solution for 60 minutes between uses, although this does not guarantee protection against the transmission of vCJD. Disposable sleeves must be used with Tonopens.
* Liquid antibacterial soap and paper towels must be available at any sink used by staff and patients – fabric towels should not be provided.
* Alcohol hand rub should be available and used between patients.
* Diagnostic solutions such as sterile saline or contact lens soaking solutions must be clearly marked with the date first used. They must always be stored with caps on and not used beyond the recommended dates.
* Single-dose eye drops such as minims must only be used once and then discarded.

It is the Company’s responsibility to ensure that all staff comply with the above instructions.

This infection control policy will be reviewed annually with commencement date [insert date]. This policy also acts as the Company’s Health Care Associated Infection Reduction Plan.

**Appendix 4**

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| Document name: Medicines Management Policy  Author:  Approved by: |

**[insert company name]:**

**Medicines Management Policy**

The Company’s policy for medicines management is that its optometrists ensure that all medicines are ordered, stored, supplied, used and disposed of in accordance with all legal requirements, General Optical Council requirements and General Ophthalmic Services contract requirements.

The Company will ensure that:

* Prescription Only Medicines (POMs) are only ordered by, and administered or supplied under the supervision of a registered optometrist.
* Medicines are stored securely (i.e. in locked cupboards) in accordance with manufacturers’ recommendations.
* Where refrigeration is required, then the temperature of the refrigerator should be monitored regularly and a record of this kept.
* A medical history, including known allergies, before any eye drop is administered or before any medicinal product is supplied to the patient.
* Where possible, single dose eye drops, e.g. minims, are used for patient treatment.
* Patients are provided with advice and information concerning possible side effects and actions eye drops before they are administered.
* Patients are provided with advice and information (including the manufacturer’s patient information leaflet) on medication supplied as part of a management plan for their eye condition.
* All medications are used in accordance with the local evidence based guidelines and the local formulary. Where there is a clinical reason not to do so then this should be documented in the patient’s notes.
* All medicines are disposed of using an approved pharmaceutical disposal service.
* Signed orders for eye drops are written in the form recommended by the College of Optometrists.
* Records are kept for POMs, including documenting the batch number for each patient, expiry dates and date of disposal.
* Optometrists participate in the Medicines and Healthcare Products Regulatory Agency (MHRA) adverse drug reaction reporting scheme.

All optometrists working for the Company must keep their knowledge on the safe, secure use of medicines, licensed indications, side effects, drug interactions etc. up to date, as required by professional registration requirements.

The Company will undertake an audit to demonstrate compliance with the medicine management policy.

This Medicines Management Policy will be reviewed annually with commencement date [insert date].

**Appendix 5**

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| Document name: Information Governance and Data Management Policy  Author:  Approved by: |

**[insert company name]:**

**Information Governance and Data Management Policy**

**1. Purpose of Policy**

This policy sets out the procedures and management accountability and structures that have been put in place within the Optical practice to safeguard the movement of personal data in the Optical practice.

**2. Underpinning Procedures**

The following procedures have been put in place to support the confidential handling of information within the Optical practice and the sharing of this information with other organisations:

* **Staff Confidentiality Code of Conduct** (sets out the standards expected of staff in maintaining the confidentiality of patient information);
* **Staff Access Control and Password management SOP** (sets out procedures for the management of access to computer-based information systems);
* **Data Transfer SOP** (sets out procedures around the secure transfer of data, collecting consent and maintaining confidentiality within the Optical practice including the use of safe havens);
* **Incident management SOP** (sets out the procedures for responding to a security breach);
* **Business Continuity SOP** (sets out the procedures in the event of system failure);
* **Portable Device Staff Guidelines** (provides guidance for staff use on the use of portable devices).

**3. Staff Duties and Responsibilities**

All staff, whether permanent, temporary or contracted are responsible for ensuring that they remain aware of the requirements incumbent upon them for ensuring compliance on a day to day basis. These includes maintaining confidentiality of data, ensuring secure storage of data and being aware of situations where disclosure may be required or may not be required.

**4. Accountability and Responsibility for this Policy**

The designated Information Governance Lead in the Optical practice is responsible for overseeing day to day Information Governance issues; developing and maintaining policies, standards, procedures and guidance, coordinating Information Governance in the Optical practice, raising awareness of Information Governance and ensuring that there is ongoing compliance with the policy and its supporting standards and guidelines.

The Optical practice contractor (owner) is responsible for ensuring that sufficient resources are available to support the implementation of Information Governance procedures in order to ensure compliance with legal and professional requirements and the NHS Information Governance requirements.

**4. Monitoring this Policy**

This policy will be reviewed at least annually.

**5. Sanctions**

Breach of this policy could lead to disciplinary action. Depending on the circumstances this could range from remedial training to dismissal.

**Appendix 6**

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| Document name: Risk and Issue Management Policy  Author:  Approved by: |

**[insert company name]:**

**Risk and Issue Management Policy**

The Company recognises the importance of risk assessment in all aspects of our service. The Company is a rigorous upholder of best practice and has developed a procedure to support us with delivering a high quality and safe community eye care service.

The Company will implement an appropriate risk management policy and procedure. This policy describes how risk will be assessed by the Company.

The Company is responsible for:

* Overseeing and co-ordinating the approach to issue and risk management.
* Reviewing the risk and issue registers each month.
* Highlighting risks and issues which have arisen to the commissioner if necessary.

Once the Company is engaged by the commissioners to progress with implementation of the service, it will evaluate and ratify all risks with the commissioners. These risks and associated mitigation plans will then be reviewed regularly to ensure they are dealt with.

A 5-step process to risk and issue assessment will be used for systematic application to all risks and issues:

|  |  |  |
| --- | --- | --- |
|  | **Risk Assessment** | **Issue Management** |
| **Step 1** | * Risk identified | * Issue identified |
| **Step 2** | * Evaluate the potential risk to determine nature of risk considering who might be harmed and how * Score risk\* | * Evaluate the issue to determine who has been harmed and undertake ‘root cause analysis’ to determine how the issue occurred and the likelihood of it occurring again * Grade issue |
| **Step 3** | * Consider strategy to mitigate potential risk | * Consider strategy to mitigate the risk of the issue occurring again |
| **Step 4** | * Record risk, risk score\*, mitigating actions and timescales for implementation on risk register | * Record the issue, grade and action(s) taken on the issues register * Record risk(s) associated with the issue on the risk register, following the risk assessment procedure |
| **Step 5** | * Review risk register and all risk assessments every month to ensure actions have been implemented and update as required | * Implement Incident Response Plan procedure (if applicable) |

* *The risk scoring matrix adopted by the commissioner will be used for the purposes of our risk register (example below):*

|  |  |  |
| --- | --- | --- |
| **LEVEL** | **DESCRIPTOR** | **DESCRIPTION** |
| 0 | Negligible | No injuries. Little or no financial loss |
| 1 | Minor | First-Aid treatment. Low financial loss. |
| 2 | Moderate | Medical treatment required. Moderate environmental implications.  Moderate financial loss. Moderate loss of reputation. Moderate business interruption. |
| 3 | Serious | Serious injuries to one or more persons. Serious environmental implications. Serious financial loss. Serious loss of reputation. Serious business interruption. |
| 4 | Major | Excessive injuries. High environmental implications. Major financial loss. Major loss of reputation. Major business interruption. |
| 5 | Fatality/ies | Death or multiple deaths involving any persons. Potential closure of the business. |

Qualitative measures of likelihood:

|  |  |  |
| --- | --- | --- |
| **LEVEL** | **DESCRIPTOR** | **DESCRIPTION** |
| 0 | Impossible | The event cannot happen under any circumstances |
| 1 | Rare | The event may occur only in exceptional circumstances |
| 2 | Unlikely | The event could occur at some time |
| 3 | Moderate | The event should occur at some time |
| 4 | Likely | The event will probably occur in most circumstances |
| 5 | Almost Certain | The event is expected to occur |

Qualitative Risk Assessment Matrix – level of risk

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **CONSEQUENCES** | ***PROBABILITY*** | | | | | |
|  | Impossible  0 | Rare  1 | Unlikely  2 | Moderate  3 | Likely  4 | A/Certain  5 |
| Negligible – 0 | **0** | **0** | **0** | **0** | **0** | **0** |
| Minor – 1 | **0** | **1** | **2** | **3** | **4** | **5** |
| Moderate – 2 | **0** | **2** | **4** | **6** | **8** | **10** |
| Serious – 3 | **0** | **3** | **6** | **9** | **12** | **15** |
| Major – 4 | **0** | **4** | **8** | **12** | **16** | **20** |
| Fatality/ies – 5 | **0** | **5** | **10** | **15** | **20** | **25** |

**Key:**

No Risk (0)

Low Risk (1-3)

Moderate Risk (4-7)

Significant Risk (8-12)

High Risk (15-25)

Example Risk Assessment*Date:*

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Risk** | **Likelihood**  (1-5, with 1 least likely  and 5 most  likely) | **Impact**  (1-5) | **Total Risk**  (Likelihood  X Impact) | **Date Risk Identified** | **Nature of Risk**  (Clinical/ Non-Clinical) | **Management Strategy** | **Comments** | **Responsibility** | **Date Actioned** |
| 1. Equipment is incorrectly calibrated | 2 | 3 | 6 |  | Non-clinical | Ensure equipment is calibrated. |  |  |  |
| 1. Equipment failure | 2 | 2 | 4 |  | Non-clinical | Ensure patients are re-booked. Ensure support for equipment is in place for remediation. |  |  |  |
| 1. Patient contracts   infection in the consulting room | 2 | 3 | 6 |  | Clinical | Keep cross infection control procedures up to date. |  |  |  |
| 1. Referral letters not   received by GP | 2 | 3 | 6 |  | Non-clinical | Utilise secure fax to ensure delivery and receipt of patient details. |  |  |  |
| 1. IT System failure | 1 | 2 | 2 |  | Non-clinical | Alternative manual recording of patient records and all data collection. |  |  |  |

This Risk and Issues Management Policy will be reviewed annually from commencement date [insert date].

**Appendix 7**

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| Document name: Complaints Policy  Author:  Approved by: |

**[insert company name]:**

**Complaints Policy**

The Company will endeavour to deliver a service whereby the likelihood of complaints being made is very low. However, if complaints do occur, the Company is well placed to address these and implement lessons learned in order to improve the quality of our service provision, in the interests of patients.

This review/analysis mechanism allows the Company to identify areas for improvement. Central to the Company’s complaints policy is an emphasis on transparency for all parties.

The Company adheres to the Local Authority Social Services and National Health Service Complaints (England) Regulations 2009 and all local requirements on complaints management.

For the purpose of this policy, a complaint is not a complaint, if it is made orally and is resolved to the complainant’s satisfaction within 24 hours. A complaint may not refer to a failure to comply with the Freedom of Information Act. Nor may a complaint relate to a subject which has already been dealt with as a complaint and been resolved.

A complaint may be made orally, in writing or electronically. If it is made orally, a written record will be made of the complaint if 24 hours have elapsed since the complaint was made and if the complaint has not been resolved. A copy of the written record will be provided to the complainant.

The Company will make information available to the general public about their arrangements for dealing with complaints about NHS services.

Our named complaints manager with overall responsibility for complaints management is [insert name].

The complaints manager will ensure:

* Complaints are dealt with efficiently and are properly investigated.
* Complainants are treated courteously, fairly, expeditiously, appropriately and are informed of the outcome of the investigation of their complaint.
* Action is taken in the light of the outcome of the investigation if any is necessary.

Complaints are reported to the commissioner as required by the contract.

A service improvement plan is produced and implemented where appropriate, in accordance with the Company’s Quality and Continuous Improvement Policy.

**The Company’s Procedure for Managing Complaints**

1. All complaints will be acknowledged by the complaints manager within 3 working days.
2. When acknowledging receipt of a complaint, the complaints manager will offer to discuss with the complainant how and when he/she intends to investigate and resolve the complaint. If the complainant refuses this offer, the complaints manager will advise the complainant in writing how long it is likely to take him to respond concerning the substance of the complaint (the ‘response period’).
3. The complaints manager will endeavour to keep the complainant informed of the progress of the investigation. As soon as possible after completing the investigation, the complaints manager will advise the complainant in writing how he has considered the complaint and what he proposes to do to resolve the complaint and any consequent action. This will be done within 10 working days where possible. He will also inform the complainant of their right to pursue the complaint with the Health Service Commissioner (the ‘health ombudsman’).
4. The Company will endeavour to resolve the complaint within six months after receiving the complaint or, if it cannot be resolved, the complaints manager will tell the complainant why they have not managed to do so.
5. The Company will make information available to the general public about their arrangements for dealing with complaints about NHS services.
6. The Company will keep a record of each complaint received, the subject matter and outcome of each complaint, each response period where applicable, and, in the cases of a response period being applicable, whether the complainant was informed of the outcome of the investigation.

The Company will report complaints to the commissioner as per the terms of the contract for the service. This information will also be used within annual reports from the board.

In situations where a complaint develops into a serious incident - particularly when a patient becomes harmed or otherwise deemed at risk - the Company’s serious incident policy will be activated.

The Company’s Complaints Policy will be reviewed annually with commencement date [insert date].

**Appendix 8**

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| Document name: Serious Incidents Policy  Author:  Approved by: |

**[insert company name]:**

**Serious Incidents Policy**

The Company will respond to serious incidents in a timely, comprehensive and systematic manner in order to reassure concerned parties and improve future service. This Serious Incidents Policy has been developed in accordance with the NHS Serious Incident Framework March 2013.

The Company’s policy incorporates full support for its staff in ensuring they are part of the overall process, while seeking to avoid focus on particular individuals. The Company will ensure its staff are suitably trained and competent in emergency preparedness, resilience and response. The Company’s Incident Response Plan below demonstrates the process for responding to serious incidents.

The Company has incorporated transparency for all parties as a core theme in its Serious Incidents Policy as we consider this is the only way to understand how serious incidents occur and how they can be mitigated in the future. The Company fully subscribes to the ‘duty of candour’ requirement in order to promote openness and honesty in raising early warning signs and demonstrate evidence of learning from incidents. The Company will ensure that patients are informed when things go wrong, why they have gone wrong and what steps the Company is taking to mitigate any issues, both immediately and in the future.

A mechanism for apology as part of duty of candour will also be implemented. The Company will notify the person concerned (and their GP where appropriate) when areportable Patient Safety Incident occurs or is suspected to have occurred involving moderate to severe harm.

The Company recognises its accountability to the commissioning body.

The Company’s Serious Incident Policy becomes activated when its Complaints Policy is not adequate for managing a particular situation. A separate Safeguarding Policy exists for children and vulnerable adults.

Serious incidents may take the form of:

* Avoidable or unexpected death
* A never event
* A serious incident whereby the Company’s ability to deliver the service is compromised
* Data loss
* Allegations of physical misconduct or harm.

The response to these events will vary depending on the particular issue (e.g. the serious incident grading chart below for the appropriate response). If there is a suggestion that a criminal offence has been committed, the Company will contact the police as soon as made aware of the incident.

The Company’s accountable emergency officer is [insert name] who is responsible for patient safety, incident management and reporting to all appropriate bodies. The Company will work collaboratively with other bodies in managing serious incidents. It will:

* Publish data (excluding information affecting patient confidentiality).
* Support and train staff in communicating information to patients.
* Communicate with commissioners and all relevant bodies as appropriate.
* Implement actions as required.
* Close cases in a timely manner.
* Review and analyse incidents and responses in order to learn key lessons and embed systemic improvements, in accordance with the Company’s Quality and Continuous Improvement Policy.

The Company will implement a root cause analysis protocol as a methodical and systematic process to identify the specific factors that contributed to an incident. The Company’s root cause analysis protocol seeks to understand the underlying causes and environmental context which led to a serious incident occurring, strengthening systems in place for meeting the objective of fully securing patient safety.

The Company does not have access to Strategic Executive Information System (STEIS). We will therefore build in reporting via the appropriate commissioning body for incident logging.

The Company operates the following Incident Response Plan for driving an appropriate learning experience to improve patient outcomes. This will enable the Company to ensure quality issues are raised in order to make improvements as required:

Incident Response Plan

**Incident Occurs**

**↓**

**Company reports to local reporting systems**

**↓**

**Inform patient of serious incident management in process – ideally within three days**

**↓**

**Grade incident (grading chart below)**

**↓**

**Notify commissioning body within two working days**

**↓**

**Incident reported on Serious Incident Reporting and Learning Framework within two working days**

**↓**

**Consult commissioner as necessary over grading**

**↓**

**The Company to establish appropriate investigation**

**↓**

**Undertake investigation communicating with relevant local health bodies, patients and carers if applicable**

**↓**

**Develop action plan**

**↓**

**Submit incident investigation report to commissioner**

**↓ ↓**

**Implement action plan → Commissioner closes incident**

**↓**

**Share lessons learned if appropriate**

**↓**

**Review actions taken**

Incident grading chart

|  |  |  |  |
| --- | --- | --- | --- |
| **Incident**  **Grade** | **Example Incidents** | **Investigation**  **Grade and action** | **Timeframe** |
| 1 | Avoidable or unexpected death.  Healthcare associated infections.  Adult safeguarding incidents(see the Company’s Safeguarding Policy for more information).  Data loss and information security. | **Investigation Level 1:**  Concise root cause analysis (RCA) for both  No Harm and Low Harm and/or where the circumstances are very similar to other previous incidents.  A concise RCA will enable the Company to ascertain whether unique factors exist, thus focusing resources on implementing service improvement.  **Investigation Level 2:**  Comprehensive RCA for incidents causing moderate to severe harm or death. The Company’s policy is this will be the default investigation level for grade 1 incidents.  The Company may seek advice and services from specialist external sources as required. | The Company to submit initial report within two working days.  The Company will submit completed investigation within 45 working days. |
| 2 | Child protection incidents (see the Company’s safeguarding policy for more information).  ‘Never events’  Accusation of physical misconduct or harm.  Data loss and information security (DH Criteria level 3-5). | Comprehensive RCA. | Initial report within 2 working days. The Companywill submit a completed investigation within 60 working days. |
| Selected grade 2 incidents  These might include major systemic failure with multiple stakeholders. | **Investigation Level 3:**  Independent RCA. | Initial report within 2 working days. Independent investigators should be commissioned to complete an investigation  within 6 months |

Root cause analysis investigation model

The Company will ensure it has sufficient expertise in root cause analysis. The Company will manage this process and report to the commissioner on progress and with the outcome. A model we will use is below:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Action 1** | **Action 2** | **Action 3** | **Action 4** | **Action 5** |
| **Root CAUSE** |  |  |  |  |  |
| **EFFECT on Patient** |  |  |  |  |  |
| **Recommendation** |  |  |  |  |  |
| **Action to Address Root Cause** |  |  |  |  |  |
| **Level for Action**  (Org, Direct, Team) |  |  |  |  |  |
| **Implementation by:** |  |  |  |  |  |
| **Target Date for Implementation** |  |  |  |  |  |
| **Additional Resources Required**  (Time, money, other) |  |  |  |  |  |
| **Evidence of Progress and Completion** |  |  |  |  |  |
| **Monitoring & Evaluation Arrangements** |  |  |  |  |  |
| **Sign off - action completed date:** |  |  |  |  |  |
| **Sign off by:** |  |  |  |  |  |

This Serious Incidents Policy will be reviewed annually with commencement date [insert date].

**Appendix 9**

|  |
| --- |
| Document name: Health & Safety Policy  Author:  Approved by: |

**[insert company name]:**

**Health and Safety Policy**

The health and safety of our staff and patients is fundamental to the Company and we recognise our responsibilities in regards to this.

Our health and safety policy will be reviewed and possibly revised in the light of experience, or because of operational or organisational changes and/or annually.

Our named health and safety lead with overall responsibility for health and safety is [insert name].

A risk assessment is carried out to identify health and safety risks and action needed to remove/control any risks. The staff member responsible is noted as is the timetable for review.

The health and safety lead will:

* undertake consultation with employees on health and safety matters
* undertake supervision and training of new members of staff in health and safety matters
* identify when maintenance is needed, draw up maintenance procedures, reporting problems purchasing of new equipment
* ensure safe handling and use of substances (if applicable).

The Health and Safety Law Poster will be displayed or the equivalent leaflets will be issued.

Records of accidents will be kept by the health and safety lead and a member of staff will be trained in first aid.

Fire risk assessments and checks on escape routes, fire extinguishers, alarms and evacuation procedures will be carried out by the health and safety lead/fire officer.

NHS England maintains a Safety Alert Broadcast System (SABS). The Company will ensure that any appropriate action has been taken in response to a SAB. For effectiveness, we will send an acknowledgement that the alert has been received and any appropriate action has been taken.

Prevention, segregation, handling, transport and disposal of waste will be managed so as to minimise the risks to the health and safety of staff and patients (please see the Company’s Environmental Management System for more information).

The Company will use the following Incident Response Plan for driving an appropriate learning experience to improve patient outcomes and overall health and safety:

Incident Response Plan

**Incident Occurs**

**↓**

**Company reports to local reporting systems**

**↓**

**Inform patient of serious incident management in process – ideally within three days**

**↓**

**Grade incident (grading chart below)**

**↓**

**Notify commissioning body within two working days**

**↓**

**Incident reported on Serious Incident Reporting and Learning Framework within two working days**

**↓**

**Consult commissioner as necessary over grading**

**↓**

**The Company to establish appropriate investigation**

**↓**

**Undertake investigation communicating with relevant local health bodies, patients and carers if applicable**

**↓**

**Develop action plan**

**↓**

**Submit incident investigation report to commissioner**

**↓ ↓**

**Implement action plan → Commissioner closes incident**

**↓**

**Share lessons learned if appropriate**

**↓**

**Review actions taken**

Incident grading chart

|  |  |  |  |
| --- | --- | --- | --- |
| **Incident**  **Grade** | **Example Incidents** | **Investigation**  **Grade and action** | **Timeframe** |
| 1 | Avoidable or unexpected death.  Healthcare associated infections.  Adult safeguarding incidents(see the Company’s Safeguarding Policy for more information).  Data loss and information security. | **Investigation Level 1:**  Concise root cause analysis (RCA) for both  No Harm and Low Harm and/or where the circumstances are very similar to other previous incidents.  A concise RCA will enable the Company to ascertain whether unique factors exist, thus focusing resources on implementing service improvement.  **Investigation Level 2:**  Comprehensive RCA for incidents causing moderate to severe harm or death. The Company’s policy is this will be the default investigation level for grade 1 incidents.  The Company may seek advice and services from specialist external sources as required. | The Company to submit initial report within two working days.  The Company will submit completed investigation within 45 working days. |
| 2 | Child protection incidents (see the Company’s safeguarding policy for more information).  ‘Never events’  Accusation of physical misconduct or harm.  Data loss and information security (DH Criteria level 3-5). | Comprehensive RCA. | Initial report within 2 working days. The Companywill submit a completed investigation within 60 working days. |
| Selected grade 2 incidents  These might include major systemic failure with multiple stakeholders. | **Investigation Level 3:**  Independent RCA. | Initial report within 2 working days. Independent investigators should be commissioned to complete an investigation  within 6 months |

Root cause analysis investigation model

The Company will ensure it has sufficient expertise in root cause analysis. The Company will manage this process and report to the commissioner on progress and with the outcome. A model we will use is below:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Action 1** | **Action 2** | **Action 3** | **Action 4** | **Action 5** |
| **Root CAUSE** |  |  |  |  |  |
| **EFFECT on Patient** |  |  |  |  |  |
| **Recommendation** |  |  |  |  |  |
| **Action to Address Root Cause** |  |  |  |  |  |
| **Level for Action**  (Org, Direct, Team) |  |  |  |  |  |
| **Implementation by:** |  |  |  |  |  |
| **Target Date for Implementation** |  |  |  |  |  |
| **Additional Resources Required**  (Time, money, other) |  |  |  |  |  |
| **Evidence of Progress and Completion** |  |  |  |  |  |
| **Monitoring & Evaluation Arrangements** |  |  |  |  |  |
| **Sign off - action completed date:** |  |  |  |  |  |
| **Sign off by:** |  |  |  |  |  |

The Company will use the following risk assessment templates to remove/control risks:

|  |  |  |
| --- | --- | --- |
|  | **Risk Assessment** | **Issue Management** |
| **Step 1** | * Risk identified | * Issue identified |
| **Step 2** | * Evaluate the potential risk to determine nature of risk considering who might be harmed and how * Score risk\* | * Evaluate the issue to determine who has been harmed and undertake ‘root cause analysis’ to determine how the issue occurred and the likelihood of it occurring again * Grade issue |
| **Step 3** | * Consider strategy to mitigate potential risk | * Consider strategy to mitigate the risk of the issue occurring again |
| **Step 4** | * Record risk, risk score\*, mitigating actions and timescales for implementation on risk register | * Record the issue, grade and action(s) taken on the issues register * Record risk(s) associated with the issue on the risk register, following the risk assessment procedure |
| **Step 5** | * Review risk register and all risk assessments every month to ensure actions have been implemented and update as required | * Implement Serious Incident Response Plan procedure (if applicable - above) |

* *The risk scoring matrix adopted by the commissioner will be used for the purposes of our risk register (example below):*

|  |  |  |
| --- | --- | --- |
| **LEVEL** | **DESCRIPTOR** | **DESCRIPTION** |
| 0 | Negligible | No injuries. Little or no financial loss |
| 1 | Minor | First-Aid treatment. Low financial loss. |
| 2 | Moderate | Medical treatment required. Moderate environmental implications.  Moderate financial loss. Moderate loss of reputation. Moderate business interruption. |
| 3 | Serious | Serious injuries to one or more persons. Serious environmental implications. Serious financial loss. Serious loss of reputation. Serious business interruption. |
| 4 | Major | Excessive injuries. High environmental implications. Major financial loss. Major loss of reputation. Major business interruption. |
| 5 | Fatality/ies | Death or multiple deaths involving any persons. Potential closure of the business. |

Qualitative measures of likelihood:

|  |  |  |
| --- | --- | --- |
| **LEVEL** | **DESCRIPTOR** | **DESCRIPTION** |
| 0 | Impossible | The event cannot happen under any circumstances |
| 1 | Rare | The event may occur only in exceptional circumstances |
| 2 | Unlikely | The event could occur at some time |
| 3 | Moderate | The event should occur at some time |
| 4 | Likely | The event will probably occur in most circumstances |
| 5 | Almost Certain | The event is expected to occur |

Qualitative Risk Assessment Matrix – level of risk

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **CONSEQUENCES** | ***PROBABILITY*** | | | | | |
|  | Impossible  0 | Rare  1 | Unlikely  2 | Moderate  3 | Likely  4 | A/Certain  5 |
| Negligible – 0 | **0** | **0** | **0** | **0** | **0** | **0** |
| Minor – 1 | **0** | **1** | **2** | **3** | **4** | **5** |
| Moderate – 2 | **0** | **2** | **4** | **6** | **8** | **10** |
| Serious – 3 | **0** | **3** | **6** | **9** | **12** | **15** |
| Major – 4 | **0** | **4** | **8** | **12** | **16** | **20** |
| Fatality/ies – 5 | **0** | **5** | **10** | **15** | **20** | **25** |

**Key:**

No Risk (0)

Low Risk (1-3)

Moderate Risk (4-7)

Significant Risk (8-12)

High Risk (15-25)

Example Risk Assessment*Date:*

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Risk** | **Likelihood**  (1-5, with 1 least likely  and 5 most  likely) | **Impact**  (1-5) | **Total Risk**  (Likelihood  X Impact) | **Date Risk Identified** | **Nature of Risk**  (Clinical/ Non-Clinical) | **Management Strategy** | **Comments** | **Responsibility** | **Date Actioned** |
| 1. Equipment is incorrectly calibrated | 2 | 3 | 6 |  | Non-clinical | Ensure equipment is calibrated. |  |  |  |
| 1. Equipment failure | 2 | 2 | 4 |  | Non-clinical | Ensure patients are re-booked. Ensure support for equipment is in place for remediation. |  |  |  |
| 1. Patient contracts   infection in the consulting room | 2 | 3 | 6 |  | Clinical | Keep cross infection control procedures up to date. |  |  |  |
| 1. Referral letters not   received by GP | 2 | 3 | 6 |  | Clinical | Utilise secure fax to ensure delivery and receipt of patient details. |  |  |  |
| 1. IT System failure | 1 | 2 | 2 |  | Non-clinical | Alternative manual recording of patient records and all data collection. |  |  |  |

This Health and Safety Policy will be reviewed annually with commencement date [insert date].