
Document name: Clinical Governance Policy
Date created: 21 April 2017
Author: Jane Smellie
Approved by: Jane Smellie

Primary Eyecare Cheshire Ltd: Clinical Governance Policy

1. Policy Overview

Primary Eyecare Cheshire Ltd has been established to specifically act as the lead for a network of local optical practices (“subcontractors”) dedicated to delivering excellent eyecare in the local community.

Primary Eyecare Cheshire Ltd’s clinical governance and performance lead will be the coordinating commissioner’s main point of contact within Primary Eyecare Cheshire Ltd.

Primary Eyecare Cheshire Ltd recognises that that clinical governance is a framework which is integral to, and underpins, all aspects of our service. Primary Eyecare Cheshire Ltd 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.

2. 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

The clinical governance policy, and its associated sub-policies, applies to Primary Eyecare Cheshire Ltd and its subcontractors.

3. Clinical Governance Structure and Oversight

Primary Eyecare Cheshire Ltd's Board of Directors has overall responsibility for the clinical governance programme.

The board will meet on a quarterly basis with clinical governance as a standing agenda item.

The meetings will be minuted and the Board is responsible for ensuring that all agreed actions, to address actual issues or to drive improvements in the quality of services, are implemented.

The clinical governance and performance lead, appointed by the Board of Directors, provides clinical leadership and is responsible for overseeing the service delivery including day-to-day monitoring of all clinical governance and quality assurance arrangements.

The clinical governance and performance lead is responsible for producing a quarterly Board report on overall service performance and will attend Board meetings.

Primary Eyecare Cheshire Ltd will identify a deputy to the clinical governance and performance lead, who will provide cover in the event that the lead is unavailable for any reason.

All subcontractors are required to appoint a named lead for clinical governance and to put into place procedures and processes which reflect the requirements of this policy [and sub-policies].

4. Professional & Regulatory Requirements

4.1. Subcontractor Practices

Primary Eyecare Cheshire Ltd requires all subcontractor practices to complete the relevant Quality in Optometry (QiO) checklists designed for community services. All subcontractor practices must also have completed Level 1 clinical governance as a requirement for the General Ophthalmic Services (GOS) Contract.

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

Subcontractor practices will be required to ensure that all practitioners participating in community services are registered annually with the General Optical Council.

Subcontractor practices will be required to 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 practice and service.

4.2. Ophthalmology Subcontractors

[To be completed if relevant.]

4.3 CPD Requirements

Primary Eyecare Cheshire Ltd's Policy on Meeting the CPD Requirements of the Professional and Regulatory Bodies can be found at Appendix 1.

5. 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.

6. Premises and Equipment

- All premises of subcontractor practices must comply with GOS and NHS Standard Contract 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.

7. Evidence-Based Guidelines and Protocols

- Primary Eyecare Cheshire Ltd's clinical governance and performance 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 by subcontractors to deliver the community services will be expected to work to Primary Eyecare Cheshire Ltd's guidelines.
- Subcontractors will be required to undertake a clinical audit as required by Primary Eyecare Cheshire Ltd to demonstrate adherence with the local guidelines and protocols.

8. Clinical audit

- Primary Eyecare Cheshire Ltd's clinical governance and performance 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.
- Subcontractors will be required to submit their results of clinical audit via the OptoManager IT platform.
- The clinical governance and performance lead is responsible for reviewing the results of clinical audit.
- Where a clinical audit identifies a significant outlier, Primary Eyecare Cheshire Ltd's clinical governance and performance 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 Primary Eyecare Cheshire Ltd's Managing Subcontractor Performance document.

9. Infection Control and Health Care Associated Infections (HCAI)

Primary Eyecare Cheshire Ltd's Infection Control and Health Care Associated Infections (HCAI) reduction plan can be found at Appendix 3.

10. Medicines Management

Primary Eyecare Cheshire Ltd's Medicines Management Policy can be found at Appendix 4.

11. Data and records

Primary Eyecare Cheshire Ltd's Information Governance and Data Management Policy can be found at Appendix 5.

12. Risk and Issue Management

Primary Eyecare Cheshire Ltd's Risk and Issue Management Policy can be found at Appendix 6.

13. Complaints

Primary Eyecare Cheshire Ltd's Complaints Policy and Procedures can be found at Appendix 7.

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

14. Serious Incidents

Primary Eyecare Cheshire Ltd's Serious Incident Policy can be found at Appendix 8.

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

15. Health and Safety

Primary Eyecare Cheshire Ltd's Health and Safety Policy can be found at Appendix 9.

Primary Eyecare Cheshire Ltd's Clinical Governance policy will be reviewed annually following commencement date January 2014.

Appendix 1

Document name: Meeting the CPD Requirements of Professional & Regulatory Bodies

Date created: 21 April 2017

Author: Jane Smellie

Approved by: Jane Smellie

Primary Eyecare Cheshire Ltd: Meeting the CPD Requirements of Professional & Regulatory Bodies

Primary Eyecare Cheshire Ltd has been established to specifically act as the lead for a network of local optical practices ("subcontractors") dedicated to deliver excellent eye care in the local community. Primary Eyecare Cheshire Ltd will also utilise a non-clinical subcontractor, Webstar Health.

Primary Eyecare Cheshire Ltd's clinical governance and performance lead will be the coordinating commissioner's main point of contact within Primary Eyecare Cheshire Ltd.

While management of general performance and conduct of staff will be the responsibility of the individual subcontractor practices, it is Primary Eyecare Cheshire Ltd's policy that all practitioners within its subcontracted practices receive training appropriate to the level of duties they carry out and continually develop in the interests of patients.

Primary Eyecare Cheshire Ltd's requires subcontractors to ensure that all optometrists and opticians engaged to deliver community services are registered 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 eyecare 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.

Primary Eyecare Cheshire Ltd requires subcontractors to ensure that all optometrists or opticians engaged by 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.

Primary Eyecare Cheshire Ltd will maintain a register of practitioners accredited to provide the community services.

Primary Eyecare Cheshire Ltd's clinical governance and performance lead will, if requested by the commissioner, as soon as possible and no more than twenty days following a written request, provide evidence demonstrating that practitioners employed by Primary Eyecare Cheshire Ltd's subcontractors are suitably qualified to deliver the service.

Subcontracting practices will be provided with an induction to the service by Primary Eyecare Ltd and supplied with an information pack including accreditation, guidelines and pathway details.

CPD for Ophthalmic Medical Practitioners

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

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

Primary Eyecare Cheshire Ltd 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.

Primary Eyecare Cheshire Ltd's Meeting Professional & Regulatory CPD Requirements Policy will be reviewed annually.

Appendix 2

Document name: Optometrists' Formulary – Community Optometry Service

Date created: 21 April 2017

Author: Jane Smellie

Approved by: Jane Smellie

Primary Eyecare Cheshire Ltd: Optometrists' Formulary – Community Optometry Service

Primary Eyecare Cheshire Ltd has been established to specifically act as the lead for a network of local optical practices ("subcontractors") dedicated to deliver excellent eye care in the local community.

Primary Eyecare Cheshire Ltd's clinical governance and performance lead will be the coordinating commissioner's main point of contact within Primary Eyecare Cheshire Ltd.

This is Primary Eyecare Cheshire Ltd's *Optometrists' Formulary* for the Community Optometry Service consisting of prescribing information for drugs relevant to this service:

Drug Name	Legal Classification	Available preparation	Drug type	Drug Classification

Primary Eyecare Cheshire Ltd's *Optometrists' Formulary* will be reviewed annually.

Appendix 3

Document name: Infection Control Policy and Health Care Associated Infection Reduction Plan

Date created: 21 April 2017

Author: Jane Smellie

Approved by: Jane Smellie

Primary Eyecare Cheshire Ltd: Infection Control Policy and Health Care Associated Infection Reduction Plan

Primary Eyecare Cheshire Ltd has been established to specifically act as the lead for a network of local optical practices ("subcontractors") dedicated to deliver excellent eye care in the local community.

Primary Eyecare Cheshire Ltd's clinical governance and performance lead will be the coordinating commissioner's main point of contact within Primary Eyecare Cheshire Ltd Ltd.

Primary Eyecare Cheshire Ltd stated policy is that all subcontractors must have their own infection control policy in place.

The use of appropriate hygiene procedures and precautions to prevent exposure to and reduce the risk of transmission of infectious diseases within subcontracting practices 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.

Subcontractors of Primary Eyecare Cheshire Ltd 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 in practices.
- Similarly, the bridge and sides of trial frames and forehead and cheek rests of refractor (phoropter) heads should be cleaned between each patient.
- Items coming into contact with a patient's eye should not be reused.
- Disposable tonometer prisms should be used when performing contact tonometry using either a Perkins or Goldmann tonometer.
- Alternatively, if reusable items are to be used then the College of Optometrist's Infection control guidance should be followed.

- 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 responsibility of the contractor to ensure that all staff comply with the above instructions.

This policy also acts as Primary Eyecare Cheshire Ltd's Health Care Associated Infection Reduction Plan.

This infection control policy will be reviewed annually.

Appendix 4

Document name: Medicines Management Policy

Date created: 21 April 2017

Author: Jane Smellie

Approved by: Jane Smellie

Primary Eyecare Cheshire Ltd: Medicines Management Policy

Primary Eyecare Cheshire Ltd has been established to specifically act as the lead for a network of local optical practices (“subcontractors”) dedicated to delivering excellent eyecare in the local community.

Primary Eyecare Cheshire Ltd’s clinical governance and performance lead will be the coordinating commissioner’s main point of contact within Primary Eyecare Cheshire Ltd.

Primary Eyecare Cheshire Ltd’s policy for medicines management requires that all subcontractors document and adopt procedures to 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

- As a minimum, subcontractors’ standard operating procedures must ensure that:
 - Prescription Only Medicines (POMs) are only ordered by, and administered or supplied under the supervision of a registered optometrist.
 - Medicines are stored appropriately 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 diagnosis.
 - 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 a subcontractor 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.
- Subcontractors are required to undertake an audit by Primary Eyecare Primary Eyecare Cheshire Ltd Ltd to demonstrate compliance with the medicine management policy.

This Medicines Management Policy will be reviewed annually.

Appendix 5

Document name: Information Governance and Data Management Policy

Date created: 21 April 2017

Author: Jane Smellie

Approved by: Jane Smellie

Primary Eyecare Cheshire Ltd: Information Governance and Data Management Policy

Purpose of the Policy

This policy sets out the procedures and management accountability and structures that have been put in place within Primary Eyecare Cheshire Ltd to safeguard the movement of personal data in Primary Eyecare Cheshire Ltd. This policy describes the data that we hold about patients, how we hold it, how we protect it, how we use and process it (including what patients need to be provided with) and how we transfer it (if necessary).

Primary Eyecare Cheshire Ltd has been established to specifically act as the lead for a network of local optical practices dedicated to delivering excellent eye care in the local community. Appropriate management of data is fundamental for Primary Eyecare Cheshire Ltd and our subcontractors.

Primary Eyecare Cheshire Ltd's clinical governance and performance lead will be the coordinating commissioner's main point of contact within Primary Eyecare Cheshire Ltd.

Primary Eyecare Cheshire Ltd is committed to meeting the requirements of Level 2 of the NHS Information Governance Toolkit.

Webstar Health

Primary Eyecare Cheshire Ltd utilises Webstar Health to provide the secure online OptoManager IT platform to collect data from the service and to manage billing and payment disbursement. Webstar Health meets the requirements of Level 2 of the NHS Information Governance Toolkit.

Primary Eyecare Cheshire Ltd and Webstar Health have developed a joint Business Continuity and Disaster Recovery Plan.

Optical Practice Subcontractors

Primary Eyecare Cheshire Ltd will collect evidence from all of its subcontractor practices confirming that an information governance audit has been completed and that the all of the required policies and procedures that relate to data management and information governance are in place.

Primary Eyecare Cheshire Ltd requires all subcontractor practices to specifically have in place:

- Named information governance lead
- Information Governance Policy
- Confidentiality clause within the contracts of all staff

- Staff training on information governance
- Evidence of compliance with DPA where data is processed outside the UK
- Procedures for seeking consent to use patient information
- Publicly available information leaflet
- Confidentiality Code of Conduct
- Information Asset Register
- Risk assessment (including working towards implementing any high priority security improvements identified)
- Mobile computing guidelines including encryption of mobile devices storing personal data (if applicable)
- Business continuity plan
- Incident management and reporting process
- Access control and password management procedures
- Data handling procedures

Primary Eyecare Cheshire Ltd reserves the right to inspect subcontractors' premises and/or policies to audit compliance.

Legislative Requirements

There are certain legislative requirements for every organisation to hold information. Information about this is provided below:

- Primary Eyecare Cheshire Ltd complies with the eight data protection principles under the Data Protection Act 1998 in its processing of personal data in that such data is:
 - fairly and lawfully processed
 - processed for limited purposes
 - adequate, relevant and not excessive
 - accurate and up to date
 - not kept for longer than is necessary
 - processed in line with patients' rights
 - secure
 - not transferred to other countries without adequate protection
- Primary Eyecare Cheshire Ltd will appoint a named information governance lead trained in and responsible for procedures relating to confidentiality and data management.
- Primary Eyecare Cheshire Ltd is registered with the information commissioner:
 - Registration No. XXXXXX
 - Security No. XXXXXX
- Primary Eyecare Cheshire Ltd has an up to date Freedom of Information Act Statement and this is available to patients.
- A notice on handling patient data is available to patients on Primary Eyecare Cheshire Ltd website.

What information Primary Eyecare Primary Eyecare Cheshire Ltd Ltd holds and how it holds it

- Primary Eyecare Cheshire Ltd holds patients' clinical records electronically within the secure online OptoManager IT platform.

How Primary Eyecare Primary Eyecare Cheshire Ltd Ltd protects this information

- All directors have a confidentiality clause within their contracts.
- All personal information contained on clinical records is considered confidential.
- Primary Eyecare Primary Eyecare Cheshire Ltd Ltd's directors are aware of the importance of ensuring and maintaining the confidentiality of patients' personal data and that such data must be processed and stored in a secure manner.
- Primary Eyecare Cheshire Ltd has an IT security policy regarding specific access to electronic information
- Any suspected breaches of security or loss of information are reported immediately and are dealt with appropriately by the person responsible for confidentiality and data management.

How Primary Eyecare Primary Eyecare Cheshire Ltd Ltd uses and processes this information

- Primary Eyecare Cheshire Ltd may use the information to audit clinical outcomes and our performance. This enables it to monitor and improve the quality of care that it offers.
- Wherever possible (i.e. if Primary Eyecare Cheshire Ltd does not need to know who an individual patient is) it will only analyse trends from anonymised information.
- Primary Eyecare Cheshire Ltd's clinical governance and performance lead may need to access individual patient information if a complaint or incident requires investigation.

How Primary Eyecare Cheshire Ltd transfers information (if necessary)

- The commissioner will have access to anonymised information on quality and outcomes of the service.
- Primary Eyecare Cheshire Ltd is obliged to provide information to authorised persons within the NHS (who are in turn subject to a duty of confidentiality) if they request this. Primary Eyecare Cheshire Ltd always transfers data in a secure manner.

Accountability for this Policy

The designated information governance lead in Primary Eyecare Cheshire Ltd is responsible for overseeing day to day information governance issues; developing and maintaining policies, standards, procedures and guidance; coordinating information governance in Primary Eyecare Cheshire Ltd; raising awareness of information governance and ensuring that there is ongoing compliance with the policy and its supporting standards and guidelines.

The Board of Directors is responsible for ensuring that sufficient resources are available to support the implementation of information governance procedures in order to ensure compliance with legal, professional and the NHS information governance requirements.

Supporting Policies and Procedures – Directors’ Responsibilities

All directors, personnel and associates of Primary Eyecare Primary Eyecare Cheshire Ltd Ltd are responsible for ensuring that they remain aware of the requirements incumbent upon them and will be required to adhere to the following:

- **Confidentiality Code of Conduct** (sets out the standards expected of directors, staff and subcontractors in maintaining the confidentiality of patient information)
- **Mobile computing guidelines and encryption of mobile devices storing personal data** (provides guidance on the use of portable devices)
- **Access control and password management procedures** (sets out procedures for the management of access to computer-based information systems)
- **Data transfer procedure** (sets out procedures around the secure transfer of data, collecting consent and maintaining confidentiality within Primary Eyecare Cheshire Ltd including the use of safe havens)
- **Business continuity procedures** (sets out the procedures in the event of system failure)
- **Serious Incident Policy** (sets out the procedures for responding to a security breach)

Policy Review

This policy will be reviewed annually.

Sanctions

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

Appendix 6

Document name: Risk and Issue Management Policy

Date created: 21 April 2017

Author: Jane Smellie

Approved by: Jane Smellie

Primary Eyecare Cheshire Ltd: Risk and Issue Management Policy

Primary Eyecare Cheshire Ltd has been established to specifically act as the lead for a network of local optical practices (“subcontractors”) dedicated to delivering excellent eyecare in the local community.

Primary Eyecare Cheshire Ltd’s clinical governance and performance lead will be the coordinating commissioner’s main point of contact within Primary Eyecare Cheshire Ltd.

Primary Eyecare Cheshire Ltd recognises the importance of risk assessment in all aspects of our service. Primary Eyecare Cheshire Ltd 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.

This policy describes how risk will be assessed by Primary Eyecare Cheshire Ltd.

Primary Eyecare Cheshire Ltd’s Board has overall accountability for risk and issue management and appoints Primary Eyecare Cheshire Ltd’s named Senior Information Risk Owner (SIRO).

The SIRO is responsible for:

- Overseeing and co-ordinating the approach to issue and risk management.
- Reviewing the risk and issue registers each month.
- Preparing a quarterly Board report highlighting risks and issues which have arisen.
- Escalating serious risks and issues, to the Board, outside of the standard quarterly reporting framework on an “as required” basis.

All subcontractors are required to be expected to implement an appropriate risk management policy and procedure.

Once Primary Eyecare Cheshire Ltd 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 Escalate to Board (if applicable)	Escalate to the Board Implement Serious Incident procedure (if applicable)

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

The following are definitions of terms as used in any risk assessment produced by Primary Eyecare Cheshire Ltd.

QUALITATIVE MEASURES OF IMPACT/CONSEQUENCE

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.
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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
Equipment is incorrectly calibrated	2	3	6		Non-clinical	Ensure equipment is calibrated.			
Equipment failure	2	2	4		Non-clinical & clinical	Ensure patients are re-booked. Ensure support for equipment is in place for remediation.			
Patient contracts infection in the consulting room	2	3	6		Clinical	Keep cross infection control procedures up to date.			
Referral letters not received by GP	2	3	6		Non-clinical & clinical	Utilise secure fax to ensure delivery and receipt of patient details.			
IT System failure	1	2	2		Non-clinical	Alternative manual recording of patient records and all data collection.			

As part of Primary Eyecare Cheshire Ltd's commitment to improving the quality of our service it will use the root cause analysis model below to drive patient outcomes:

	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:					

Primary Eyecare Cheshire Ltd's Risk and Issue Management Policy will be reviewed annually.

Appendix 7

Document name: Complaints Policy
Date created: 21 April 2017
Author: Jane Smellie
Approved by: Jane Smellie

Primary Eyecare Cheshire Ltd: Complaints Policy

Primary Eyecare Cheshire Ltd has been established to specifically act as the lead for a network of local optical practices (“subcontractors”) dedicated to delivering excellent eyecare in the local community.

Primary Eyecare Cheshire Ltd’s clinical governance and performance lead will be the coordinating commissioner’s main point of contact within Primary Eyecare Cheshire Ltd.

Primary Eyecare Cheshire Ltd will endeavour to deliver a service whereby the likelihood of complaints being made is very low. However, if complaints do occur, Primary Eyecare Cheshire Ltd is well placed to address these and implement lessons learned (lessons learned meaning experience derived from service provision leading to an improvement in quality of our service provision) in the interests of patients. This review/analysis mechanism allows Primary Eyecare Cheshire Ltd to identify areas for improvement.

Primary Eyecare Cheshire Ltd will hold overall responsibility for complaints handling management and compliance. Primary Eyecare Cheshire Ltd adheres to the Local Authority Social Services and National Health Service Complaints (England) Regulations 2009 and all local requirements on complaints management. The clinical governance and performance lead is responsible for Primary Eyecare Cheshire Ltd’s compliance with the regulations, and is the designated complaints manager. Primary Eyecare Cheshire Ltd will identify a deputy to the clinical governance and performance lead, who will act as the deputy complaints manager in the event that the lead is unavailable for any reason.

Central to Primary Eyecare Cheshire Ltd’s complaints policy is an emphasis on transparency for all parties.

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 (dealt with by a separate procedure). 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.

Primary Eyecare Cheshire Ltd’s and its subcontractors will make information available to the general public about their arrangements for dealing with complaints about NHS services.

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 Board quarterly, and to the commissioner as required by the contract.

A service improvement plan is produced and implemented where appropriate, in accordance Primary Eyecare Cheshire Ltd's quality and continuous improvement policy. Primary Eyecare Cheshire Ltd requires subcontractor practices to:

- Report any complaints relating to the community services immediately to the complaints manager via OptoManager (or telephone in emergency).
- Provide information as the complaints manager deems appropriate to manage the complaint or to report to the board for learning points to be gained.
- Seek input from the complaint manager before responding to any complaint (except for attending to any urgent clinical care needs of the individual affected).

Primary Eyecare Cheshire Ltd'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. Primary Eyecare Cheshire Ltd 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. Primary Eyecare Cheshire Ltd and its subcontractors will make information available to the general public about their arrangements for dealing with complaints about NHS services.

6. Primary Eyecare Cheshire Ltd 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.

Primary Eyecare Cheshire Ltd will report complaints to the commissioner as per the terms of the contract for this 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 - Primary Eyecare Cheshire Ltd's serious incident policy will be activated.

Primary Eyecare Cheshire Ltd's Complaints Policy will be reviewed annually.

Appendix 8

Document name: Serious Incidents Policy
Date created: 21 April 2017
Author: Jane Smellie
Approved by: Jane Smellie

Primary Eyecare Cheshire Ltd: Serious Incidents Policy

Primary Eyecare Cheshire Ltd has been established to specifically act as the lead (“prime contractor”) for a network of local optical practices (“subcontractors”) dedicated to delivering excellent eyecare in the local community. Primary Eyecare Cheshire Ltd will also utilise a non-clinical subcontractor, Webstar Health.

Primary Eyecare Cheshire Ltd’s clinical governance and performance lead will be the coordinating commissioner’s main point of contact within Primary Eyecare Cheshire Ltd.

Primary Eyecare Cheshire Ltd 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 2015.

Primary Eyecare Cheshire Ltd’s policy incorporates full support for its subcontractors in ensuring they are part of the overall process, while seeking to avoid focus on particular individuals. Subcontractor practices must have in place and maintain staff suitably trained and competent in emergency preparedness, resilience and response. Primary Eyecare Cheshire Ltd’s Incident Response Plan below demonstrates the process for subcontractor practices to notify the company in the event of a serious incident occurring.

Primary Eyecare Cheshire Ltd has *incorporated transparency for all parties as a core theme in its serious incidents policy as the Company considers this is the only way to understand how serious incidents occur and how these can be mitigated in the future.* Primary Eyecare Cheshire Ltd 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. Primary Eyecare Cheshire Ltd will ensure that patients are informed when things go wrong, why they have gone wrong and what steps Primary Eyecare Cheshire Ltd 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. Primary Eyecare Cheshire Ltd will notify the person concerned (and their GP where appropriate) when a *reportable Patient Safety Incident occurs or is suspected to have occurred involving moderate to severe harm.*

As the prime contractor, Primary Eyecare Cheshire Ltd recognises its accountability to the commissioning body.

Primary Eyecare Cheshire Ltd'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 Primary Eyecare Cheshire Ltd'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, Primary Eyecare Cheshire Ltd will contact the police as soon as made aware of the incident.

Primary Eyecare Cheshire Ltd will appoint a named accountable emergency officer. The accountable emergency officer will be responsible for patient safety, incident management and reporting to all appropriate bodies. Primary Eyecare Cheshire Ltd will work collaboratively with other bodies in managing serious incidents. It will:

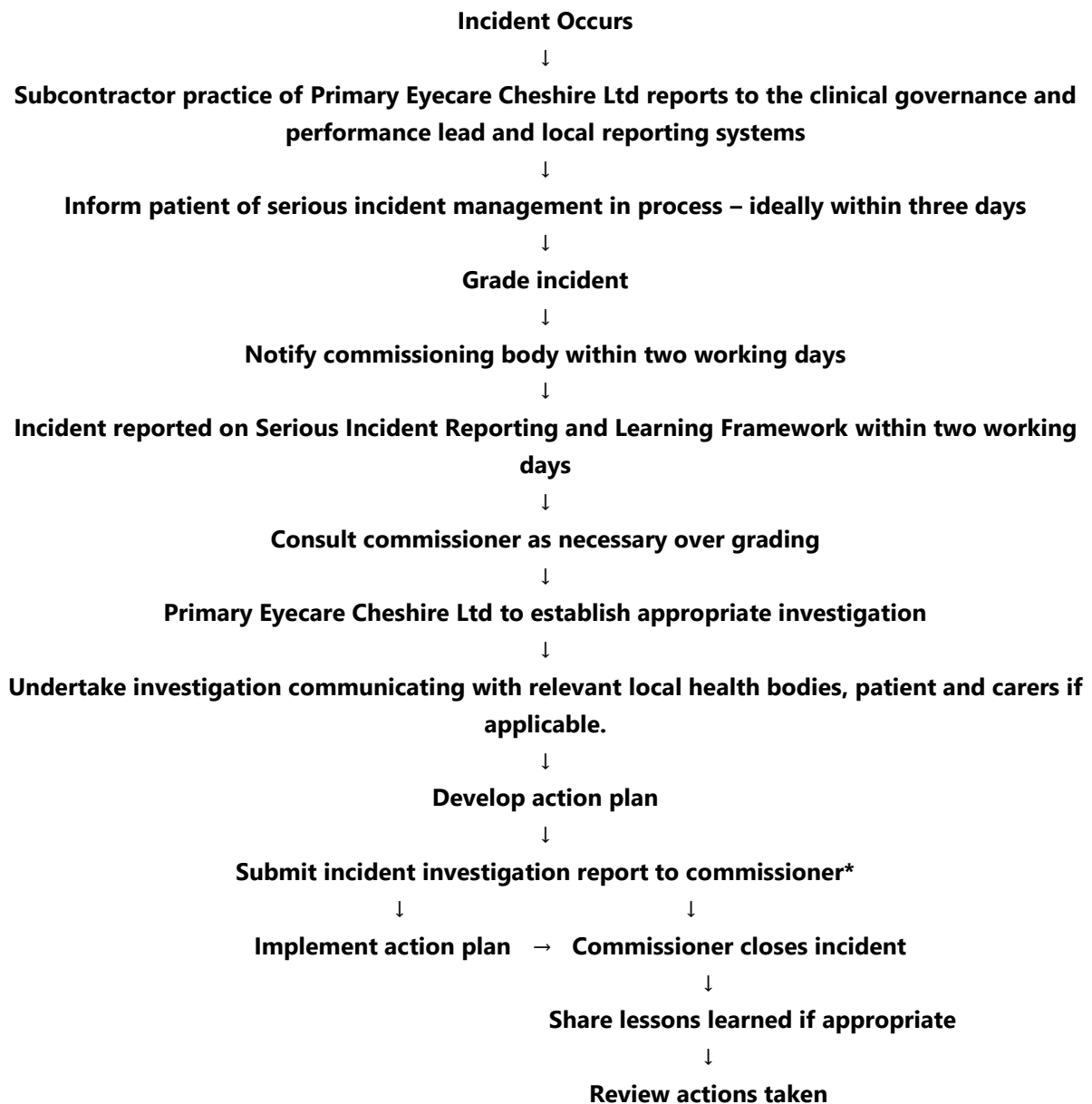
- Publish data (excluding information affecting patient confidentiality).
- Support and train staff in communicating information to patients.
- Communicate with commissioners and all relevant bodies as appropriate.
- Implement actions as required.
- Close cases in a timely manner.
- Review and analyse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

Primary Eyecare Cheshire Ltd will implement a root cause analysis protocol as a methodical and systematic process to identify the specific factors that contributed to an incident. Primary Eyecare Cheshire Ltd'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.

Primary Eyecare Cheshire Ltd's subcontractor practices do not have access to Strategic Executive Information System (STEIS). Primary Eyecare Cheshire Ltd will therefore build in reporting via the appropriate commissioning body for incident logging.

The Operations Centre of Primary Eyecare Cheshire Ltd's subcontractor, Webstar Health, will be the Incident Coordination Centre.

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



See below for Primary Eyecare Cheshire Ltd's **grading/threshold charts** of serious incident levels, their impacts/consequences and root cause analysis model we will use to continuously improve the overall quality of service.

Serious incident grading chart

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

Root Cause Analysis Investigation Model

Primary Eyecare Cheshire Ltd will ensure it has sufficient expertise in root cause analysis. The clinical governance and performance lead will lead this process and report to the coordinating 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.

Appendix 9

Document name: Health and Safety Policy
Date created: 21 April 2017
Author: Jane Smellie
Approved by: Jane Smellie

Primary Eyecare Cheshire Ltd: Health and Safety Policy

Primary Eyecare Cheshire Ltd has been established to specifically act as the lead for a network of local optical practices ("subcontractors") dedicated to delivering excellent eyecare in the local community.

Primary Eyecare Cheshire Ltd's clinical governance and performance lead will be the coordinating commissioner's main point of contact within Primary Eyecare Cheshire Ltd.

The health and safety of both our service users and the staff of our subcontractors is fundamental to Primary Eyecare Cheshire Ltd.

Primary Eyecare Cheshire Ltd delivers services through a wide number of subcontracting practices to provide patient services in the community and whilst not directly responsible for health and safety in these subcontracting practices it is Primary Eyecare Cheshire Ltd's policy that all subcontracting practices and any other subcontractors, have their own health and safety policies in place, recognising that staff and patients should be safe, and their responsibilities in regard to this.

We have a duty to ensure that these practices have appropriate mechanisms through which to identify and, where appropriate, respond to any significant concerns in regards to commissioned services.

We will ensure that subcontractors meet acceptable standards by requiring our subcontractors to have their own health and safety policies and providing assurance of this to Primary Eyecare Cheshire Ltd.

All subcontractors should meet legislative requirements; particularly the requirement to perform and have written health and safety policy when more than five people are employed in a practice as per the Health and Safety at Work etc Act 1974, section 2(3). If a practice employs fewer than five people, having a written health and safety policy is still recommended to our subcontractors.

Subcontractors' written health and safety policies should include:

- A statement of general health and safety policy, signed and dated (the policy statement should be reviewed and possibly revised in the light of experience, or because of operational or organisational changes and/or annually).
- Responsibilities: overall, day-to-day, specific areas.
- Health and safety risks: what they are, action needed to remove/control, the staff member responsible, review timetables.
- Consultation with employees: information on employee representatives, and consultation procedure.

- Safe plant and equipment: the people responsible for identifying when maintenance is needed, drawing up of maintenance procedures, reporting problems to, the purchasing of new equipment.
- Safe handling and use of substances (if applicable): who identifies hazardous substances; who is responsible for undertaking control of substances hazardous to health assessments, informing employees, reviewing assessments.
- Information, instruction and supervision: display of the Health and Safety Law Poster or the issue of the equivalent leaflets, supervision and training of new members of staff.
- Competency for tasks and training: induction training, job specific training, retainment of training records.
- Accidents, first aid and work related ill health: who requires, arranges and keep records of health surveillance, where first aid equipment stored, the appointed person / first aider, people responsible for record keeping, and reporting under Reporting of Injuries, Diseases and Dangerous Occurrences Regulations.
- Monitoring: who monitors conditions and safe working practices, who investigates accidents and work related sickness.
- Emergency procedures: who carries out fire risk assessments and how often the following are checked: escape routes, fire extinguishers, alarms, evacuation procedures.

NHS England maintains a Safety Alert Broadcast System (SABS). Primary Eyecare Cheshire Ltd's subcontractors should ensure that any appropriate action has been taken in response to the SAB. For effectiveness, each recipient should send an acknowledgement that the alert has been received and any appropriate action has been taken. Practices should ensure that staff opening mail, report these alerts to the contractor straight away.

Prevention, segregation, handling, transport and disposal of waste must be properly managed so as to minimise the risks to the health and safety of staff and patients (please see Primary Eyecare Cheshire Ltd's Environmental Management System for more information).

This Health and Safety Policy will be reviewed annually.