WM QRS West Midlands Quality Review Service

NHS

Review of Clinical Governance

MidlandEye

Solihull Health Economy

Visit Date: 17th May 2016 Report Date: July 2016

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INTRODUCTION

This report presents the findings of the review of the MidlandEye ambulatory day surgery clinic that took place on 17th May 2016. The purpose of the visit was to review compliance with the following West Midlands Quality Review Service (WMQRS) Quality Standards:

- Clinical Governance V1.2 20160210

The aim of the standards and the review programme is to help providers and commissioners of services to improve clinical outcomes and service users' and carers' experiences by improving the quality of services. The report also gives external assurance of the care, which can be used as part of organisations' Quality Accounts. For commissioners, the report gives assurance of the quality of services commissioned, and identifies areas where developments may be needed.

The report reflects the situation at the time of the visit. The text of this report identifies the main issues raised during the course of the visit. Appendix 1 lists the visiting team that reviewed the services at MidlandEye, part of the Aspen Healthcare Group, in Solihull health economy. Appendix 2 contains the details of compliance with each of the standards and the percentage of standards met.

This report describes services provided or commissioned by the following organisations:

- MidlandEye, Aspen Healthcare Group
- NHS Solihull Clinical Commissioning Group

Most of the issues identified by quality reviews can be resolved by providers' and commissioners' own governance arrangements. Many can be tackled by the use of appropriate service improvement approaches; some require commissioner input. Individual organisations are responsible for taking action and monitoring this through their usual governance mechanisms. The lead commissioner for the service concerned is responsible for ensuring action plans are in place and monitoring their implementation, liaising, as appropriate, with other commissioners, including commissioners of primary care. The lead commissioner in relation to this report is NHS Solihull Clinical Commissioning Group.

ACKNOWLEDGMENTS

West Midlands Quality Review Service would like to thank the staff and service users and carers of MidlandEye, Aspen Healthcare Group for their hard work in preparing for the review and for their kindness and helpfulness during the course of the visit. Thanks are also due to the visiting team and their employing organisations for the time and expertise they contributed to this review.

ABOUT WEST MIDLANDS QUALITY REVIEW SERVICE

WMQRS is a collaborative venture between NHS organisations in the West Midlands to help improve the quality of health services by developing evidence-based Quality Standards, carrying out developmental and supportive quality reviews (often through peer review visits), producing comparative information on the quality of services and providing development and learning for all involved.

Expected outcomes are better quality, safety and clinical outcomes, better patient and carer experience, organisations with better information about the quality of clinical services, and organisations with more confidence and competence in reviewing the quality of clinical services. More detail about the work of WMQRS is available on www.wmqrs.nhs.uk

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MIDLANDEYE – ASPEN HEALTHCARE GROUP

Introduction

MidlandEye is an ambulatory day surgery clinic, established in 2003 and located in Solihull, West Midlands. The service is part of the Aspen Healthcare Group. Ophthalmic specialties provided by MidlandEye included care for patients with cataracts, glaucoma, wet and dry age-related macular degeneration and diabetic retinopathy. Oculoplastics and refractive and vitreo-retinal surgery were also provided. Patients were also seen who had dry eye, blepharitis or cysts or who required post-operative YAG laser treatment. The clinic offered specialist consultation rooms, on-site diagnostic testing and operating facilities for all eye conditions.

General Comments and Achievements

Facilities in the areas visited were clean and bright, although access to some staff areas was via steep stairs. A major refurbishment had been completed in April 2016, which had improved the reception areas and clinical environment. Information for patients and carers was clearly displayed in all areas.

Staff were extremely welcoming and were visibly responsive to patients attending the service.

The service was well led and there were good links with Aspen Healthcare corporate services. Staff retention was good and staff who met with the reviewing team were enthusiastic about the care they were able to deliver. A culture of openness and transparency was evident to the reviewers during the visit.

Good Practice

1 The flow of patients through theatres was impressive, with three procedures undertaken per hour. There was a high ratio of staff to patients, which enabled only one patient at a time to be in the theatre area, so staff attention was not diverted by caring for pre- and post-operative patients.

2 'Sit and see' observational audits were undertaken by administrative staff and had provided useful feedback. The team was planning to recruit and train user representatives to undertake observational audits in the future.

3 The staff had developed 'flash cards' for use in theatres in order to communicate with patients whose first language was not English. These cards were simple and were an effective way of communicating; they covered most of the languages of the service's client base.

4 The consent documentation was comprehensive. The documentation included patient information, risks associated with treatment and advice about aftercare.

5 The Aspen Healthcare Group corporate governance process for the development and review of policies and procedures was comprehensive and well-managed. All policies were easily accessible to all staff at MidlandEye.

6 Treatment and discharge letters were routinely sent to the referring optometrist as well as the patient's GP.

7 Staff had completed 'World Host' communication training. The training covers the skills and knowledge to improve customer service for any public-facing organisation. The interactive programme encourages staff to think about their own experiences of good and bad service, understand why their role has such an impact on your customers' experience and learn vital communication and listening skills.

8 'Investing in You' E-learning competency bundles had been developed for all roles within the service. The competence framework included all mandatory training and role-specific competency-based training. Staff who met with the reviewing team reported that they had good access to specialist training.

Immediate Risks: No immediate risks were identified.

Concerns

1 At the time of the visit, there were occasions when no member of staff with intermediate life support (ILS) or advanced life support (ALS) training was available. The latest Royal College of Anaesthetists Guidelines (Guidelines for the Provision of Anaesthetic Services, Ophthalmic Anaesthesia Services, 2015) advises that in isolated units where no anaesthetist or formal cardiac arrest team is immediately available, the team should have training in ILS, with at least one member trained to ALS level. Staff did have basic life support training, and ILS training for all relevant staff was to be completed in June 2016.

2 Reviewers were concerned that outcome data on refraction procedures and the 'Cataract National Audit Dataset' were not collected or audited. Reviewers were told that collection of data may be possible when the new Medsoft system is in place. Some data were collected on 'Patient Reported Outcome Measures' (PROMs) for those undergoing cataract surgery.

Further Consideration

1 Reviewers considered that specific guidance and policies should be developed to enable appropriate monitoring of the therapeutic interventions provided at MidlandEye. This would allow a more relevant clinical audit programme to be implemented. At the time of the visit the majority of clinical audits were based on the Aspen Healthcare Group programme.

2 Patients' records were retained longer than national guidance recommended. Reviewers were told that this was done particularly if refractive surgery had been undertaken so that records would be available if further treatment was required at a much later date. Although this practice had been agreed and included on the information governance risk register, reviewers considered that it was not usual.

3 Reviewers suggested that work on widening patient engagement in improving the organisation of the service should be undertaken.

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APPENDIX 1 MEMBERSHIP OF VISITING TEAM

Visiting Team

Mr Jeremy Diamond	Consultant Ophthalmologist	NewMedica
Carol Herbert	Clinical Quality Assurance Programme Manager	Birmingham Community Healthcare NHS Foundation Trust
Claire Roberts	Optometrist	Chair, Local Eye Health Network, Birmingham, Solihull and Black Country

WMQRS Team

Sarah Broomhead	Assistant Director	West Midlands Quality Review Service

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APPENDIX 2 COMPLIANCE WITH THE QUALITY STANDARDS

Analyses of percentage compliance with the Quality Standards should be viewed with caution as they give the same weight to each of the Quality Standards. Also, the number of Quality Standards applicable to each service varies depending on the nature of the service provided. Percentage compliance also takes no account of 'working towards' a particular Quality Standard. Reviewers often comment that it is better to have a 'No, but', where there is real commitment to achieving a particular standard, than a 'Yes, but' where a 'box has been ticked' but the commitment to implementation is lacking. With these caveats, table 1 summarises the percentage compliance for each of the services reviewed.

Table 1 - Percentage of Quality Standards met

Service	Number of Applicable QS	Number of QS Met	% met
Clinical and Quality Governance	83	75	90

These Standards use the pathway letter Q. The Standards are in the following sections:

Q-1	Public, Patient and Carer Involvement
Q-2	Human Resources
Q-3	Health and Safety
Q-4	Facilities and Equipment
Q-5	Clinical Safety and Effectiveness
Q-6	Health Records, Information Management and Information Systems
Q-7	Clinical Audit and Research
Q-8	Risk Management
Q-9	Quality and Clinical Governance

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CLINICAL AND QUALITY GOVERNANCE

Ref	Standard	Met? Y/N	Reviewer Comments
Q-101	**Board-level Lead – Public, Patient and Carer Involvement** A senior member of staff should have lead responsibility for ensuring public, patient and carer involvement is in place throughout the organisation.	Y	There was a Board Lead for both the Aspen Group and locally at MidlandEye.
Q-102	**Public, Patient and Carer Involvement Strategy** An up to date public, patient and carer involvement strategy should be in place.	N	A strategy was not yet in place though plans were in place to develop a strategy covering the requirement of the Quality Standard. The service was also in the process of inviting users and carers to join a focus group with the remit of looking more widely at service user engagement across the service. In practice quarterly patient user feedback surveys were undertaken by an independent company and 'sit and see' observational audits were undertaken by admin staff.
Q-103	**Communication with the Public** A system for ongoing communication with the public about services should be in place..	Y	Written and electronic information was in place which provided information about the service.
Q-104	**Information for Patients and Carers** Arrangements should be in place to support individual services in achieving service-level Quality Standards for information and support for patients and carers (QS **-100s) and to ensure the consistency and quality of this information.	Y	The Aspen Group had a process for developing and agreeing information for patients and carers. In theatres there was a good process for communicating with patients for whom English was not their first language with the use of 'flash cards'.
Q-105	**General Support for Patients and Carers** Patients and carers should have easy access to the following services, and information about these services should be easily available: a. Interpreter services, including British Sign Language b. Independent advocacy services c. Complaints procedures d. Social workers e. Benefits advice f. Spiritual support g. *HealthWatch* or equivalent organisation h. Relevant voluntary organisations providing support and advice	Y	

Ref	Standard	Met? Y/N	Reviewer Comments
Q-106	**Service-level Patient and Carer Involvement** Arrangements should be in place in all clinical services and departments (QS **-199) for: a. Receiving regular feedback from patients and carers about the treatment and care they receive b. Involving patients and carers in decisions about the organisation of the service c. Identifying common themes and sharing learning across services	N	All but 'b' was in place. See also comment at Quality Standard Q-102.
Q-107	**Involving GPs and Other Agencies** Arrangements should be in place for: a. Receiving regular feedback from GPs and other agencies about services provided b. Involving GPs and other agencies in decisions about the organisation of services	N	Ongoing arrangements for receiving regular feed-back from GPs was not yet in place. Some GPs had been involved with the ocular plastics service and the proposal for the 'WETMED' pathway.
Q-108	**Public, Patient and Carer Involvement in Clinical and Quality Governance** Public, patient and carer representatives should be members of decision-making clinical governance forums or committees including: a. Risk Management Committee b. Clinical Audit Committee c. Clinical and Quality Governance Committee	N	Public, patient and carer representatives were not members of any committees.
Q-109	**Training and Support for Public, Patient and Carer Involvement in Clinical and Quality Governance** Training and appropriate support should be available so that representatives of the public, patients and carers who are involved in clinical and quality governance forums and committees are able to contribute meaningfully.	N	Users and carers were not yet represented on clinical or quality governance forums.

Ref	Standard	Met? Y/N	Reviewer Comments
Q-110	**Complaints** A complaints procedure should be in use covering at least: a. Definition of a complaint b. Arrangements for handling complaints, including clear timescales for: i. Acknowledgement ii. Agreement on the appropriate approach to handling the complaint iii. Investigation iv. Reporting on progress v. Final response c. Responsibilities of staff involved in handling complaints d. Handling of complaints which involve other services within and outside the organisation e. Ensuring patients and carers are not treated differently as a result of raising a complaint f. Learning lessons from complaints and disseminating this learning to individual members of staff, services and throughout the organisation g. Feedback to the public, patients, carers and staff about complaints received and action taken h. Arrangements for monitoring and reporting achievement of timescales for handling complaints	Y	Standards for responding to and managing complaints were in place.
Q-147	**Public, Patient and Carer Involvement – Staff Training** Relevant staff throughout the organisation should have completed training in the communication with, and involvement of, the public, patients and carers.	Y	
Q-148	**Public, Patient and Carer Involvement – Support Staff** Staff with appropriate competences should be available to support the implementation of public, patient and carer involvement (QSs Q-101 to 147). Roles and responsibilities for these staff should be clearly defined.	Y	

Ref	Standard	Met? Y/N	Reviewer Comments
Q-149	**Public, Patient and Carer Involvement – Board Reporting** The Board (or equivalent) should review: At least monthly: a. Number and type of complaints received relating to each service or department (QS Q-110) b. Achievement of timescales for completion of all stages of the complaints procedure (QS Q-110) At least annually: c. Achievement of Quality Standards for public, patient and carer involvement (QSs Q-101 to 148) d. Uptake of staff training in public, patient and carer involvement (QS Q-147) e. Uptake of training by representatives of the public, patients and carers (QS Q-109) f. Involvement of representatives of the public, patients and carers in decision-making clinical and quality governance forums or committees (QS Q-108) g. Evidence of action taken as a result of public, patient and carer involvement	Y	
Q-201	**Board-level Lead – Human Resources** A senior member of staff should have overall organisational responsibility for human resources.	Y	A Board level Group Director for Human Resources (HR) was in place and locally the Clinical Operations Manager. HR leads from the company were assigned to MidlandEye to provide support and attend on-site for any HR issues.
Q-202	**Service-level Staffing** Arrangements should be in place for ensuring all clinical services have sufficient staff with appropriate competences for the usual number and case mix of patients (QS **-202 and 203).	Y	
Q-203	**Training Strategy** An up to date organisational training and development strategy should link organisational objectives with the following: a. Mandatory training for all staff b. Expected clinical and quality governance-related training (QS Q-147, Q-547, Q-647, Q-847) c. Service-level plans for ensuring staff achieve and maintain appropriate competences (QS Q-202) d. Individual Personal Development Plans resulting from individual appraisals e. Implications for the organisation and funding of training	Y	Competence 'bundles' were in place for each staff group. These bundles included mandatory and role-specific competences.

Ref	Standard	Met? Y/N	Reviewer Comments
Q-204	**Pre-Employment Checks** A system of pre-employment checks should be in place for permanent and temporary staff covering at least: a. Qualifications (where applicable) b. Registration with an appropriate professional body (where applicable) c. Criminal records.	Y	
Q-205	**Induction** All new permanent and temporary staff should complete an appropriate period of induction.	Y	
Q-206	**Mandatory Training** Mandatory training for staff should cover all relevant aspects of the clinical and quality governance strategy (QS Q-902) including at least: a. Equality and diversity b. Fire safety c. Hand hygiene d. Harassment and bullying e. Health and safety f. Incident reporting g. Infection control h. Information governance i. Inoculation incidents j. Moving and handling k. Safeguarding adults and children l. Slips, trips and falls m. Violence and aggression	Y	Mandatory training was via 'E-learning'. Processes were in place that would alert staff that training was required and direct them to the relevant training portal.
Q-207	**Appraisal and Continuing Professional Development** All staff should have an annual appraisal at which a Personal Development Plan should be agreed. For clinical staff these arrangements should ensure appropriate Continuing Professional Development is undertaken for: a. Maintenance of the competences expected by service-level competence frameworks (QS **-203) b. Meeting the requirements for re-registration and re-validation (where applicable)	Y	
Q-208	**Maintaining Competence in Small or Isolated Services** Clinical staff working in small or isolated services should have arrangements for networking and regular clinical experience within a larger service.	Y	

Ref	Standard	Met? Y/N	Reviewer Comments
Q-209	**Human Resources Policies** Policies should be in use throughout the organisation covering: a. Use of volunteers b. Lone working and staff security c. Clinical supervision d. Managing illness and sickness absence e. 'Whistle-blowing' f. Staff acting outside their area of competence g. Managing poor performance, covering mechanisms for the identification and management of poorly performing clinicians and the procedure to be followed when poor performance is identified h. Staff support and pastoral care	Y	'a' was not applicable as volunteers were not utilised by the service. 'c' was part of the groups wider policy but not explicit about which professional groups should access peer supervision. In practice staff could access peer support as required.
Q-210	**Clinical and Managerial Leadership Development** A programme of leadership development for clinical and managerial service leads should be in place covering: a. Ensuring new service leads have or develop appropriate leadership competences b. Ongoing maintenance and updating of leadership competences c. Development of the 'next generation' of service leads	Y	
Q-211	**Staff Communication and Feedback** A system of regular two-way communication with staff should be in place. This should include: a. Regular updates for staff on quality, safety and clinical governance-related issues b. Easy systems for staff to raise quality, safety or clinical governance-related concerns c. Regular reminders for staff about how to raise quality, safety or clinical governance-related concerns	Y	However minutes seen by the reviewers did not reflect the full governance agenda staff said was discussed at these meetings.
Q-248	**Human Resources – Support Staff** Staff with appropriate competences should be available to support the human resources aspects of clinical and quality governance (QSs Q-201 to 211). Roles and responsibilities for these staff should be clearly defined.	Y	

Ref	Standard	Met? Y/N	Reviewer Comments
Q-249	**Human Resources – Board Reporting** The Board (or equivalent) should review at least annually: a. Achievement of Quality Standards for the human resources aspects of clinical and quality governance b. Proportion of relevant staff completing: i. Pre-employment checks (QS Q-204) ii. Induction (QS Q-205) iii. Mandatory training (QS Q-206) iv. Annual appraisals and Personal Development Plans (QS Q-207) c. Rates of sickness, absence and staff turnover within each clinical service and department d. Results of staff feedback, and evidence of action taken on quality, safety or clinical governance-related concerns raised by staff.	Y	
Q-501	**Lead Clinician – Clinical Safety and Effectiveness** A senior registered healthcare professional should have lead responsibility for the implementation of safe and effective clinical practice throughout the organisation.	Y	The Clinical Operations Manager had overall responsibility for MidlandEye and there was also a Theatre Lead for day-to-day practice.
Q-502	**Clinical Safety and Effectiveness Strategy** An up to date clinical safety and effectiveness strategy should be in place which summarises the organisation's systems and arrangements for implementing and improving the delivery of safe and effective clinical practice.	Y	The service also had accreditation from the Association of Perioperative Practice (AfPP) for their theatre service.
Q-503	**Clinical Guidelines** Arrangements for approval and distribution of clinical guidelines for use within the organisation (QS **-500s) should be in place. These arrangements should ensure that: a. Clinical guidelines are based on evidence of effectiveness or recommended best practice (when available) b. Clinical guidelines are localised to show how evidence-based practice will be implemented in the local situation c. Guidelines are reviewed regularly to reflect changes in evidence of effectiveness d. Up to date guidelines are easily available to clinical staff in all relevant clinical situations	Y	'NETCONSENT' included a comprehensive suite of guidelines which was well governed at a corporate level. Guidance relating specifically to the therapeutic interventions undertaken by the MidlandEye ophthalmology service were limited.

Ref	Standard	Met? Y/N	Reviewer Comments
Q-504	**Introduction of New Drugs and Procedures** Arrangements for approval of drugs and interventional procedures for use within the organisation should be in place covering: a. Approval of new, and withdrawal of ineffective, drugs b. Approval of new, and withdrawal of ineffective, surgical procedures	Y	Good feedback and dissemination mechanisms were in place via the Medical Advisory Committee, which managed any arrangements for approval of drugs and interventional procedures.
Q-505	**'Horizon Scanning'** Arrangements for 'horizon scanning' should be in place which ensure: a. New evidence of clinical effectiveness is considered for inclusion in local guidelines (QS Q-503) b. New evidence on the effectiveness of drugs and interventional procedures is considered (QS Q-504)	Y	Arrangements were in place and information was included on the NETCONSNET system, however information seen was not relevant for the MidlandEye service.
Q-506	**Patient Safety Alerts** A system for cascading and implementing relevant patient safety, drugs and medical devices alerts should be in place which ensures that all relevant staff are informed of changes resulting from these alerts.	Y	The 'Datix' system was in place. Staff who met with the reviewing team felt the culture of the service was open and transparent about reporting incidences and receiving feedback.

Ref	Standard	Met? Y/N	Reviewer Comments
Q-507	**Infection Control** Infection control policies should be in use covering at least: a. Hand decontamination b. Staff clothing c. Personal protection equipment d. Blood and body fluid spills e. Disposal of sharps f. Decontamination of beds and equipment g. Waste management h. Patient isolation i. Management of outbreaks j. Transfer between healthcare organisations k. Peripheral cannulae techniques l. Blood culture techniques m. Antibiotic policy n. Management of patients with communicable diseases including norovirus, influenza, blood borne viruses, tuberculosis, Creutzfeld Jacob disease, respiratory viruses such as SARS, and malaria o. Management of patients with infections resistant to antibiotics including MRSA, Clostridium difficile, Carbapenem resistant organisms, ESBL and other multi-resistant gram negative organisms p. Staff exposed to or with communicable diseases q. Expected staff training in all aspects of infection control r. Monitoring information and audit arrangements s. Key performance indicators	Y	This Quality Standard was met for all infection control polices applicable to MidlandEye. Group pharmacist and infection control leads managed the policy development and monitoring for the whole company.

Ref	Standard	Met? Y/N	Reviewer Comments
Q-508	**Medicines Management Policies** Medicines management policies should be in use covering at least: a. Roles and responsibilities b. Prescribing of medicinal products c. Supply and return of medicines d. Storage and transportation e. Administration of medicinal products f. Delegation g. Disposal of medicinal products h. Unlicensed medicines i. Management of adverse events j. Controlled drugs k. Expected staff training l. Arrangements for monitoring implementation of the policy, including audit m. Key performance indicators Medicines management policies should cover fluids and electrolytes as well as other medicinal products.	Y	Aspen Group had a range of medicines management policies accessible via NETCONSENT.
Q-509	**Mental Health Act** Policies should be in place to ensure implementation throughout the organisation of the Mental Health Act.	Y	
Q-510	**Mental Capacity Act and Deprivation of Liberty Safeguards** Policies should be in place to ensure implementation throughout the organisation of the Mental Capacity Act and Deprivation of Liberty Safeguards.	Y	
Q-511	**Consent** A policy on consent for investigations and treatment should be in use covering at least: a. Definition of consent b. Roles and responsibilities c. Capacity and capability assessment d. Ensuring appropriate information has been given e. Process for obtaining consent, including in emergencies and when patients lack capacity to give consent f. Arrangements for obtaining consent in relation to babies, children and young people g. Refusal of investigations and treatment h. Any special arrangements i. Expected staff training j. Monitoring information and audit arrangements	Y	A comprehensive policy was in place. MidlandEye had also developed their own consent form building on national guidance and including patient information and aftercare.

Ref	Standard	Met? Y/N	Reviewer Comments
Q-512	**Safeguarding Policy** Policies on safeguarding children and vulnerable adults should be in use covering at least: a. Arrangements for investigation and, if necessary, referral of complaints and incidents relating to the care of children and vulnerable adults b. Expected staff training c. Who staff should contact if they have concerns about safeguarding issues d. Action to take when safeguarding-related allegations are made against a member of staff	Y	
Q-513	**General Clinical Guidelines** Guidelines should be in use covering: a. Management of violent or abusive patients b. Restraint and sedation c. Seclusion d. Resuscitation e. Blood transfusion and management of blood and blood products f. Prevention of venous-thromboembolism g. Recognition and management of the deteriorating patient h. Rapid tranquilisation Guidelines should specify the expected staff training and arrangements for monitoring implementation and audit.	Y	However there were two pathways covering the patient check into theatres, WHO Safer Surgery checklist and resuscitation. 'e' and 'h' were not applicable to MidlandEye.
Q-514	**Transfer of Care** Protocols should be in use covering: a. Handover of care between clinical teams within and outside the organisation b. Transfer of care following an in-patient admission	Y	Transfer Standard Operating Procedure was in place for the transfer of patients who needed emergency care. Elective patients were not transferred to other services.
Q-515	**Transition between Services** Guidelines should be in use covering patients whose care will transfer to another service; these should cover: a. The opportunity for the patient and, where appropriate, their carer to discuss the transfer of care with both services b. A named coordinator for the transfer of care c. A preparation period prior to transfer d. Written information about the transfer of care including arrangements for monitoring during the time immediately afterwards	N/A	

Ref	Standard	Met? Y/N	Reviewer Comments
Q-547	**Clinical Safety and Effectiveness – Staff Training** Relevant staff throughout the organisation should have completed training in the implementation of safe and effective clinical practice, including training in: a. Medicines management b. Consent c. Management of violent or abusive patients d. Restraint and sedation e. Seclusion f. Resuscitation g. Blood transfusion and management of blood and blood products h. Prevention of venous-thromboembolism i. Recognition and management of the deteriorating patient j. Rapid tranquilisation k. End of life policies *Note: Expected training in each of these areas is specified in QSs Q-508, 511 and 513.*	Y	Only 'a', 'b', 'c', 'f' and 'l', were applicable to MidlandEye.
Q-548	**Clinical Safety and Effectiveness – Support Staff** Staff with appropriate competences should be available to support the implementation of safe and effective clinical practice throughout the organisation (QSs Q-501 to 547). Roles and responsibilities for these staff should be clearly defined.	Y	
Q-549	**Clinical Safety and Effectiveness – Board Reporting** The Board (or equivalent) should review: At least monthly: a. Key performance indicators for: i. Infection control (QS Q-507) ii. Medicines management (QS Q-508) At least annually: b. Achievement of Quality Standards related to clinical safety and effectiveness (QSs Q-501 to 548) c. Uptake of staff training (QS Q-547) d. Evidence of action taken as a result of staff feedback on concerns about the implementation of safe and effective clinical practice	Y	
Q-601	**Board-level Lead – Health Records, Information Management and Information Systems** A senior member of staff should have lead responsibility for health records, information management and information systems throughout the organisation.	Y	

Ref	Standard	Met? Y/N	Reviewer Comments
Q-602	**Health Records, Information Management and Information Systems Strategy** An up to date health records, information management and information systems strategy should be in place. This strategy should summarise: a. The organisation's plans for achieving Quality Standards for health records, information management and information systems (QSs Q-603 to 648) b. Expected staff training required to support implementation of these plans	Y	Records were documented on two systems depending on referral route (DGL for private patients and for NHS patients APAS). Guidance was in place covering the scanning of paper records. Work was ongoing to implement 'APAS 2' with the view that only one system would then be required.
Q-603	**Data Protection Act** The organisation should have arrangements for ensuring ongoing compliance with the Data Protection Act. These arrangements should include an organisational map of datasets held, and responsibility for each dataset.	Y	
Q-604	**Health Records Management** Policies on the management of health records should be in use throughout the organisation covering at least: a. Roles and responsibilities b. Creation, tracking, storage and retrieval of health records c. Retention, disposal and destruction of health records d. Basic record-keeping standards which must be used by all staff e. Process for making sure a contemporaneous record of care is completed f. Clinical coding of all episodes of care g. Clinical coding of all interventional procedures h. Expected staff training in health record-keeping and clinical coding i. Monitoring information and audit arrangements	Y	
Q-605	**Information Systems** Information systems for storage, retrieval and transmission of patient information should be in use for patient administration, clinical records, outcome information and other data to support service improvement, audit and revalidation.	Y	

Ref	Standard	Met? Y/N	Reviewer Comments
Q-606	**Security of Information** Policies on security of information should be in use throughout the organisation covering at least: a. Patient confidentiality and information security b. Release of patient-identifiable data, including the role of the Caldicott Guardian c. Responsibility for prevention and management of threats to the security of electronically held patient-related information d. Responsibility for 'back up' of electronically held patient-identifiable data and other information required for the delivery of health services	Y	
Q-607	**Transmission of Patient-Identifiable Data** Policies should be in use throughout the organisation covering at least: a. Sharing of patient-identifiable data with other organisations b. Secure transmission of patient-identifiable data	Y	
Q-608	**Information Systems Risk Management** Risks relating to information management should be specifically identified, recorded and managed. The risk to patient care of interruption to or security breach of information systems should be specifically included.	Y	
Q-609	**Document Control** A system of document control of guidelines, policies and procedures for use within the organisation should be in place covering at least: a. Style and format b. Explanation of any terms used c. Consultation process d. Ratification e. Review arrangements f. Control including archiving arrangements g. Associated documents h. Supporting references i. How compliance with 'a' to 'h' will be monitored	Y	
Q-647	**Health Records, Information Management and Information Systems – Staff Training** Relevant staff throughout the organisation should have completed training in health records management (QS Q-604).	Y	

Ref	Standard	Met? Y/N	Reviewer Comments
Q-648	**Health Records, Information Management and Information Systems – Support Staff** Staff with appropriate competences should be available to support implementation of high quality health records, information management and information systems throughout the organisation (QSs Q-601 to 647). Roles and responsibilities for these staff should be clearly defined.	Y	
Q-649	**Health Records, Information Management and Information Systems – Board Reporting** The Board (or equivalent) should review at least annually: a. Achievement of Quality Standards related to health records, information management and information systems (QS Q-601 to 648) b. Evidence of action taken as a result of staff feedback about health records, information management and information systems	Y	
Q-701	**Lead Clinician – Clinical Audit and Research** A senior registered healthcare professional should have lead responsibility for the implementation of safe and effective clinical practice throughout the organisation.	Y	An executive lead for the Aspen Group was in place.
Q-702	**Clinical Audit Strategy and Policy** An up to date strategy covering clinical audit should be in place. A policy on implementation of the agreed strategy should be in use throughout the organisation which should cover at least: a. Criteria for agreeing audits b. Standards for the conduct of audits c. Links between audits and incidents, complaints and quality monitoring systems d. The requirement for multi-disciplinary, cross-organisation and cross-agency audits which cover whole patient pathways e. Arrangements for data collection for audit f. Participation in National Clinical Audits and use of comparative information produced by National Clinical Audit Programmes g. Participation in National Confidential Enquiries into Patient Outcomes and Death h. Responsibility for action plans following audits and review of their implementation i. Arrangements for transfer of learning from audits to relevant staff and services throughout the organisation.	Y	

Ref	Standard	Met? Y/N	Reviewer Comments
Q-703	**Clinical Audit Committee** A sub-committee of the Board (or equivalent) should meet regularly to agree the clinical audit strategy, policy and programme and to oversee their implementation. Membership of this committee should include the Lead Clinician for clinical audit (QS Q-701), other appropriate professional and service clinical leads and patient and carer representatives.	Y	
Q-704	**Clinical Audit Programme** A prioritised clinical audit programme linked to organisational objectives should be agreed by the Clinical Audit Committee.	N	A local clinical audit programme was not yet in place. The Aspen Group did have a clinical and governance audit programme covering all providers, but this did not include any specific ophthalmic audits. See also main report relating to participation in the national cataract audit programme. Aspen Group agreed KPI's (Key Performance Indicators) were reported.
Q-705	**Research and Development** A policy on research and development should be in use covering at least: a. Ensuring all research and development complies with relevant legislation and statutory guidance b. Organisational structure for the management and delivery of research and development c. Prioritisation of research and development d. Approval process for research and development including: i. Service user involvement ii. Assurance of appropriate protocols and agreements iii. Assurance of staff capability iv. Consideration by an Ethics Committee (or equivalent) e. Process for obtaining consent for participation in research and development f. Ensuring completion and that results are made available g. Systems for identification of fraud and misconduct h. Reporting of adverse events i. Data storage after trials	Y	Research Governance Policy formed part of the corporate policies suite.

Ref	Standard	Met? Y/N	Reviewer Comments
Q-748	**Clinical Audit – Support Staff** Staff with appropriate competences should be available to support the implementation of clinical audit throughout the organisation (QSs Q-701 to 705). Roles and responsibilities for these staff should be clearly defined.	Y	
Q-749	**Clinical Audit – Board Reporting** The Board (or equivalent) should review at least annually: a. Achievement of clinical audit-related Quality Standards (QS Q-701 to 748) b. Initiation, completion and consideration of results of audit projects c. Agreement and implementation of action plans following audits d. Significant variations from expected standards identified through audits e. Evidence of action taken as a result of staff feedback about clinical audit	Y	Clinical audits that had been agreed were reported. See also main report in relation to participation in clinical audits.
Q-801	**Board-Level Lead – Risk Management** A senior member of staff should have lead responsibility for risk management throughout the organisation.	Y	
Q-802	**Risk Management Strategy and Policy** An up to date strategy covering the identification and management of risk should be in place. A policy on implementation of the agreed strategy should be in use throughout the organisation covering at least: a. Clear definition of risks to be included on the risk register b. System for assessment of consequences and likelihood of risks c. Authorisation for managing different levels of risk within the organisation d. Responsibilities for maintenance of risk registers e. Expected staff training in relation to risk management f. Monitoring information and information to be reported to the Board (or equivalent)	Y	
Q-803	**Risk Management Committee** A Risk Management (or equivalent) committee should meet regularly to review the organisational risk management arrangements and responses to identified risks, incidents and 'near misses'.	Y	

Ref	Standard	Met? Y/N	Reviewer Comments
Q-804	**Risk Register** A risk register should be in place covering all services and departments within the organisation. This register should include: a. Date of identification of each risk b. An assessment of the consequences and likelihood of each risk c. Actions taken to mitigate or address each risk d. Assessment of residual risk and escalation if required e. Review date for each risk	Y	
Q-805	**Incident Reporting** An incident reporting system should be in use throughout the organisation. This system should include: a. Definitions of incidents and 'near misses' and thresholds for reporting b. Service level identification and reporting arrangements c. Arrangements for recording and reporting incidents that did not occur within the organisation d. Risk-based arrangements for investigation of incidents and 'near misses' including, where appropriate, root cause analysis e. Arrangements for agreeing action following incidents and 'near misses', and for monitoring that this has taken place f. Arrangements for implementing organisation-wide learning from incidents and 'near misses' g. Organisation-wide arrangements for summarising and analysing incidents and 'near misses'	Y	
Q-806	**Business Continuity** Arrangements for business continuity in the event of significant untoward events should be in place including: a. A business continuity plan which identifies risks to business continuity and action to be taken if they occur b. Regular exercises to test the business continuity plan	Y	
Q-847	**Risk Management – Staff Training** Relevant staff throughout the organisation should have completed training in: a. Identification, assessment and management of risks b. Investigation of complaints and incidents	Y	

Ref	Standard	Met? Y/N	Reviewer Comments
Q-848	**Risk Management – Support Staff** Staff with appropriate competences should be available to support the implementation of risk management throughout the organisation (QSs Q-801 to 847). Roles and responsibilities for these staff should be clearly defined.	Y	
Q-849	**Risk Management – Board Reporting** The Board (or equivalent) should review: At least monthly: a. Significant risks newly identified within each service or department b. Risks which are not resolved within agreed timescales c. Incidents and 'near misses' identified within each service or department d. Incidents and 'near misses' where investigation and action has not been completed within expected timescales At least annually: e. Achievement of risk management-related Quality Standards (QS Q-801 to 848) f. Summary of all risks identified within services or departments g. Evidence of action taken as a result of staff feedback about risk management	Y	
Q-901	**Board-Level Lead Clinician – Quality and Clinical Governance** A Board-level senior registered healthcare professional should have lead responsibility for the organisation's clinical and quality governance.	Y	
Q-902	**Clinical and Quality Governance Strategy** An up to date organisational clinical and quality governance strategy should be in place. This strategy should make clear the relationship and links between different aspects of clinical governance: a. Public, patient and carer involvement b. Human resources c. Facilities and equipment d. Clinical safety and effectiveness e. Health and safety f. Health records, information management and information systems g. Risk management h. Clinical audit and research	Y	

Ref	Standard	Met? Y/N	Reviewer Comments
Q-903	**Clinical and Quality Governance Committee** A Clinical and Quality Governance Committee should oversee all aspects of clinical and quality governance within the organisation. Membership of the committee should comprise, at least, the leads for each area of clinical governance (QS Q-*01) and public, patient and carer representatives.	Y	A Quality Assurance Committee was in place locally and a Medical Advisory Committee. The local groups reported to the Aspen Group Governance Committee.
Q-904	**Openness and Transparency** Arrangements should be in place to ensure a culture of openness and transparency about clinical safety and quality within the organisation including: a. Board (or equivalent) meetings held in public b. Policies on release of information held by the organisation ('Freedom of Information') c. Board-level engagement with two-way communication mechanisms with the public, patients, staff and other agencies	Y	
Q-905	**Board Training in Clinical and Quality Governance** All members of the Board (or equivalent) should have completed training in all aspects of clinical and quality governance.	Y	
Q-906	**Service-Level Clinical Leadership** The Board should ensure a registered health or social care professional is identified to provide clinical leadership for each service or department. *Note: This QS will be reviewed in detail as individual clinical services and departments are reviewed.*	Y	
Q-907	**Review and Learning** Arrangements should be in place for: a. Multi-disciplinary review and learning within each clinical service or department (QS **-798) including: i. Review of and implementation of learning from positive feedback, complaints, outcomes, incidents and 'near misses' ii. Review of and implementation of learning from published scientific research and guidance iii. Ongoing review and improvement of service quality, safety and efficiency b. Multi-service and multi-agency review and learning c. Identifying and acting on relevant external reports and recommendations	N	Arrangements were reliant on staff members reading notice boards and communication folders. It was not clear that multidisciplinary meetings which included attendance from all disciplines of staff were held.

Ref	Standard	Met? Y/N	Reviewer Comments
Q-908	**Service-Level Quality Standards and Quality Improvement Programme** Arrangements should be in place to ensure: a. Quality standards expected for each clinical service or department are identified and monitored by the service at least annually b. Key performance and outcome indicators expected for each clinical service or department are identified and monitored by the service at least annually c. Each service has a quality improvement programme covering its actions towards achieving relevant quality standards and further improving quality when standards are achieved.	Y	Aspen Group agreed Key Performance Indicators were in place and reported, but from the evidence seen, the quality improvement programme did not appear to link to the audit programme.
Q-909	**Key Performance Indicators** Key process and outcome quality indicators for each clinical service or department should be agreed and monitored.	Y	From the evidence seen it was not clear if any Key Performance Indicators had been agreed that specifically covered the eye service provided. Organisational-wide Key Performance Indicators were in place and collected by MidlandEye and reported and to the Group.
Q-910	**Internal and External Quality Assurance** A programme of internal and external quality assurance should: a. Review achievement of expected quality standards for each clinical service or department b. Monitor progress with actions following internal and external quality assurance	Y	

Ref	Standard	Met? Y/N	Reviewer Comments
Q-949	**Board Quality Monitoring** The Board (or equivalent) should consider: a. Reports on each aspect of clinical and quality governance, at least annually and more frequently if significant variations from standards or targets are identified, covering: i. Public, patient and carer involvement (QS Q-149) ii. Human resources (QS Q-249) iii. Health and safety (QS Q-349) iv. Facilities and equipment (QS Q-449) v. Clinical safety and effectiveness (QS Q-549) vi. Health records, information management and information systems (QS Q-649) vii. Clinical audit and research (QS Q-749) viii. Risk management (QS Q-849) b. Key performance and outcome indicators for each clinical service or department including significant deviations from standards or targets c. Reports on progress with internal and external quality assurance of clinical services and departments, including progress with agreement and implementation of action plans Board agendas should reflect the importance of safety, quality and clinical governance. Board discussions of quality should reflect an appropriate balance of local reporting, insight from elsewhere, 'horizon scanning' and strategic analysis	Y	'vii ': Audits that had been agreed were reported but the audit programme did not include many audits that related to the work of MidlandEye. Public, patient and carer involvement was not yet in place so not included in Board quality monitoring. A Quality Account was produced on an annual basis.

Ref	Standard	Met? Y/N	Reviewer Comments
XP-501	**Standard Operating Procedure** A Standard Operating Procedure should be in use for each out-patient procedure covering: a. Responsibility for giving patients written information about the procedure if applicable b. Indications for the procedure c. Exclusions from the procedure d. Offering a chaperone e. Assessment prior to the procedure including: i. identifications of allergies or contraindications to the procedure ii. Identification of relevant co-morbidities which may affect the procedure or peri-procedural management of the patient iii. Other issues relevant to the procedure iv. Assessment of mental capacity f. Obtaining and recording verbal consent g. Patient identification h. Site identification i. Management of pain j. Infection control, including screening k. Any specific points relating to the performance of the procedure, including implications for: v. Patients with allergies vi. Patients with diabetes or other co-morbidities l. Post-procedure care m. Recognition and treatment of common complications n. Follow up arrangements	N	Reviewers did not see a Standard Operating Procedure for the range of outpatient procedures undertaken at MidlandEye.