

SpaMedica Ltd

SpaMedica Bedford

Inspection report

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This report describes our judgement of the quality of care at this service. It is based on a combination of what we found when we inspected, information from our ongoing monitoring of data about services and information given to us from the provider, patients, the public and other organisations.

Ratings

Overall rating for this location		Good	
Are services safe?		Good	
Are services effective?		Good	
Are services caring?		Good	
Are services responsive to people's needs?		Outstanding	
Are services well-led?		Good	

Summary of findings

Overall summary

This is the first time we inspected this service. We rated it as good because:

- The service had enough staff to care for patients and keep them safe. Staff had training in key skills, understood how to protect patients from abuse, and managed safety well. The service controlled infection risk well. Staff assessed risks to patients, acted on them and kept good care records. They managed medicines well. The service managed safety incidents well and learned lessons from them.
- Staff provided good care and treatment, gave patients enough to eat and drink and gave them pain relief when they needed it. Managers monitored the effectiveness of the service and made sure staff were competent. Staff worked well together for the benefit of patients, advised them on how to lead healthier lives, supported them to make decisions about their care, and had access to good information. Key services were available seven days a week.
- Staff treated patients with compassion and kindness, respected their privacy and dignity, took account of their individual needs, and helped them understand their conditions. They provided emotional support to patients, families and carers.
- The service planned care to meet the needs of local people, took account of patients' individual needs, and made it easy for people to give feedback. People could access the service when they needed it and did not have to wait too long for treatment.
- Leaders ran services well using reliable information systems and supported staff to develop their skills. Staff understood the service's vision and values, and how to apply them in their work. Staff felt respected, supported and valued. They were focused on the needs of patients receiving care. Staff were clear about their roles and accountabilities. The service engaged well with patients and the community to plan and manage services and all staff were committed to improving services continually.

However:

- Staff did not always complete medicines records accurately.
- Staff did not always ensure incidents were investigated in a timely manner.
- The hospital did not have a closed-circuit television (CCTV) policy in line with guidance issued by the Information Commissioner's Office (ICO) such as explaining the purpose of the recording, including the name and contact details of those operating the surveillance scheme and how people could request the recordings.

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Surgery	Good 	We have not previously inspected the service. We rated it as good. See the overall summary above for details.

Summary of findings

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Summary of this inspection

Background to SpaMedica Bedford

SpaMedica Bedford is operated by SpaMedica Ltd and registered with the CQC in November 2019. The service is a private clinic that offers cataract surgery and yttrium aluminium garnet (YAG) laser capsulotomy services for NHS patients. YAG laser capsulotomy is a special laser treatment used to improve vision after cataract surgery. The service did not treat children.

SpaMedica Bedford is registered to provide the following regulated activities:

- Diagnostic and screening procedures
- Surgical procedures
- Treatment of disease, disorder or injury

The hospital is located close to the town centre, in a business park with car parking facilities.

The ophthalmic team consists of:

- Ophthalmology consultants
- Optometrists
- Registered nurses
- Ophthalmic technicians
- Administration staff

How we carried out this inspection

We inspected this service using our comprehensive inspection methodology. We carried out the unannounced part of the inspection on the 13 September 2022. The team that inspected the service comprised a CQC inspector and a specialist advisor.

During the inspection visit, the inspection team:

- Spoke with a surgeon, the management team and four members of staff
- Spoke with four patients
- Looked at a range of policies, procedures, audit reports and other documents relating to the running of the service.

You can find information about how we carry out our inspections on our website: <https://www.cqc.org.uk/what-we-do/how-we-do-our-job/what-we-do-inspection>.

Outstanding practice

We found the following outstanding practice:

- The hospital consistently exceeded expectations and outcomes for patients against relevant national standards. Outcomes for patient visual acuity following surgery for both eyes were consistently better than overall National Ophthalmology Database Audit (NODA) rates.

Summary of this inspection

- Referral to treatment times were much better than the national average.
- The hospital had a low risk of readmission, with no patients returning to theatre between September 2021 and August 2022.
- The post-surgical complication rate was 0.01% in the previous 12 months.
- The service provided free transport to patients who lived within a set distance from the location.
- Patients stories were available as DVDs or on the website for patients to review prior to their procedure.
- The service ran accreditation evenings for local opticians to enable them to support patients post-operatively in the community.
- Staff carried out a risk stratification assessment at pre- assessment clinic for cataract surgery and patients' post-operative medicine regime was then tailored accordingly. The stratification took account of a range of factors including ethnicity and social factors. The risk stratification had been designed and validated by the medical director following a clinical study.
- The hospital offered a one-off steroid injection rather than eye drops for patients who may find it difficult to use eye drops due to social factors such as homelessness or who posed a significant infection risk completing their own drops.
- People were always treated with dignity by all those involved in their care, treatment and support. Consideration of people's privacy and dignity was consistently embedded in everything that staff do, including awareness of any specific needs as these were recorded and communicated. Staff ensured patients' needs were established at pre-assessment and appropriate support put in place to assist patients who had mental health needs and learning disability.

Areas for improvement

Action the service SHOULD take is because it was not doing something required by a regulation, but it would be disproportionate to find a breach of the regulation overall, to prevent it failing to comply with legal requirements in future, or to improve services.

Action the service SHOULD take to improve:

- The provider should ensure medicines records are always completed accurately.
- The provider should ensure incidents are always investigated in a timely manner.
- The provider should ensure there is a closed-circuit television (CCTV) policy in line with guidance issued by the Information Commissioner's Office (ICO).

Our findings

Overview of ratings

Our ratings for this location are:

	Safe	Effective	Caring	Responsive	Well-led	Overall
Surgery	Good	Good	Good	☆ Outstanding	Good	Good
Overall	Good	Good	Good	☆ Outstanding	Good	Good

Surgery

Safe	Good 
Effective	Good 
Caring	Good 
Responsive	Outstanding 
Well-led	Good 

Are Surgery safe?

Good 

We have not previously inspected the service. We rated it as good.

Mandatory training

The service provided mandatory training in key skills to all staff and made sure everyone completed it.

Staff received and kept up-to-date with their mandatory training. The service provided statutory and mandatory training using a combination of 'face to face' training and e-learning. Compliance with mandatory training for all staff was 92%, against a target of 95 %. We were told this was lower as there were eight new employees who were in the probationary period, and they partially completed their mandatory training.

The mandatory training was comprehensive and met the needs of patients and staff. Mandatory training included courses covering basic and paediatric life support, infection control, safeguarding children and adults, health, safety and welfare, fire safety, manual handling and equality and diversity.

Managers monitored mandatory training using a training matrix and alerted staff when they needed to update their training. Managers monitored mandatory training and staff received alerts when training needed to be refreshed. Clinical staff were required to complete annual refreshers and demonstrate their competency where necessary. Mandatory training was monitored at the board level quarterly and annually to check the rates of staff compliance. Staff we spoke with told us they received reminders to complete mandatory training and were also reminded at staff meetings. Staff we spoke with told us they had enough time to complete their mandatory training.

Consultants completed mandatory training within their substantive NHS employer and provided annual confirmation of completion of this training to the service in line with the organisation's practising privileges policy.

Safeguarding

Staff understood how to protect patients from abuse and the service worked well with other agencies to do so. Staff had training on how to recognise and report abuse and they knew how to apply it.

Staff received training specific for their role on how to recognise and report abuse. Safeguarding children and adults formed part of the mandatory training programme and staff received training which corresponded to their role. Staff told

Surgery

us they had received safeguarding training. Clinical staff received safeguarding training for adults and children level 2 which was at 92% compliance. We were told this was lower than the expected 95% because of new employees who had partially completed their safeguarding training. The service had a safeguard lead trained to level three who was able to support staff in escalating their concerns and supporting referral processes to the relevant local authorities. Staff also had access to two level four trained members of the corporate team.

Staff knew how to identify adults and children at risk of, or suffering, significant harm and worked with other agencies to protect them. Staff gave examples of concerns they would report and knew the contact details for the agencies they would report to. There were posters throughout the hospital informing staff on how to raise safeguarding concerns. An up-to-date safeguarding children and adults policy, with flow charts for the escalation of concerns was available. The hospital completed a safeguarding audit to ensure it followed policies and procedures and this showed 98% compliance in the previous 12 months.

Staff could give examples of how to protect patients from harassment and discrimination, including those with protected characteristics under the Equality Act. Staff understood the importance of supporting equality and diversity and ensuring care and treatment was provided in accordance with the Act. Staff gave examples which demonstrated their understanding and showed how they had considered the needs of patients with protected characteristics.

The hospital's mandatory training included a module on preventing radicalisation which helped staff identify patients and find ways to prevent people being drawn into terrorist or extremist groups and/or activity. Records showed 84% of staff completed this training. We were told this was lower as there were new employees who had partially completed their mandatory training.

The hospital had a defined recruitment pathway and procedures to help ensure that the relevant recruitment checks had been completed for all staff. These included a disclosure and barring service (DBS) check, occupational health clearance, references and qualification and professional registration checks.

The hospital had an up-to-date chaperone policy.

There were no reported safeguarding incidents in the previous 12 months.

Cleanliness, infection control and hygiene

The service generally controlled infection risk well. The service used systems to identify and prevent surgical site infections. Staff used equipment and control measures to protect patients, themselves and others from infection. They kept equipment and the premises visibly clean.

Clinical areas were visibly clean and had suitable furnishings which were visibly clean and well-maintained. The operating theatres, ward and recovery areas we visited were visibly clean and had suitable furnishings which were visibly clean and well-maintained. Seamless easy-clean floor covering was used throughout all clinical areas, waiting rooms and toilets. Storage areas were tidy and free from clutter. We observed clinical staff cleaning equipment after each patient use. However, we observed the floor of the pharmacy was visibly unclean. The manager explained that a staff member needed to be present when the floor of the pharmacy was being cleaned and when staff were in clinics this was missed. We discussed this with the manager who told us this would be addressed.

All other equipment was cleaned after patient contact. Items seen were visibly clean and dust-free and we saw completed daily cleaning check lists.

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Staff followed infection control principles including the use of personal protective equipment (PPE). Hand-washing and sanitising facilities were available for staff and visitors. The service provided staff with personal protective equipment (PPE) such as gloves and masks.

The service performed well for cleanliness. From September 2021 to August 2022 the service achieved 100% compliance for infection prevention and control and 98% for hand hygiene audits. We were told new cleaning audits were being developed in line with the National Standards of Cleanliness and these audits had been piloted. The new audits were due to start in September 2022. There was a comprehensive management of cleaning policy which contained protocols for cleaning all areas of the hospital.

Staff worked effectively to prevent, identify and treat post-surgery infections. Data showed that there had been no cases of endophthalmitis (inflammation of the internal eye tissue) or infection in 12 months prior to our inspection. Patients at higher risk of infection were identified during pre-assessment and alternative after care treatment was put in place to reduce the risk of infection.

Environment and equipment

The design, maintenance and use of facilities, premises and equipment kept people safe. Staff were trained to use them. Staff managed clinical waste well.

The service had suitable facilities to meet the needs of patients' families. The building was modern, and the service was located on the ground floor. The admission area/ ward, theatres and recovery area were designed to allow a smooth flow. There was appropriate ventilation in the operating theatre. Access to all clinical areas was restricted with keypad or swipe access.

Patients could reach call bells and staff responded quickly when called. Each bay within the ward area where patients were seated had a call bell. The admissions nurse carried out regular comfort checks on patients waiting in the ward area prior to surgery.

The service had undertaken a Legionella, fire and health and safety risk assessment. Records showed that action plans had been put in place to mitigate the risks identified. Staff demonstrated how they had access to evacuation routes in the event of a fire. Water outlets and sinks were flushed to reduce the risk of Legionella build-up in line with Health and Safety Executive (HSE) guidance.

Staff carried out daily safety checks of specialist equipment. Staff carried out checks on equipment such as the resuscitation trolley. Resuscitation equipment was located on a purpose-built trolley and was visibly clean. Single-use items were sealed and in date. Resuscitation equipment had been checked daily and an up-to-date checklist confirmed all equipment was ready for use.

The ward and theatre areas were well equipped and faulty or damaged equipment was repaired or replaced quickly. An external maintenance provider attended the hospital to service and safety check medical equipment. We reviewed equipment logs and saw that equipment used was serviced within appropriate time frames. Stock and equipment, including disposable instruments, were well managed and recorded.

Staff disposed of clinical waste safely. Clinical waste disposal was provided through a service level agreement. Clinical waste and non-clinical waste were correctly segregated and collected separately.

Surgery

Assessing and responding to patient risk

Staff completed and updated risk assessments for each patient and removed or minimised risks. Staff identified and quickly acted upon patients at risk of deterioration

The service provided ambulatory care where no general anaesthesia or sedation was used. All treatment was carried out as day surgery under local anaesthetic. The hospital had clear inclusion and exclusion criteria, which were reviewed regularly. Staff worked with local opticians and GPs to ensure they understood the criteria before referring a patient. Patients identified as needing more complex surgery were referred to the hospital or other locations with specialist surgeons.

Staff ensured they had adequate knowledge of the patient's health, any relevant test results and their medicines history. There was a comprehensive pre-operative assessment process that was used for all patients. The hospital had a robust process for assessing patients before admission. Patients had a pre-operative assessment to ensure they met the inclusion criteria for surgery and to allow any key risks, that may lead to complications during the anaesthetic, surgery, or post-operative period, to be identified.

Staff completed risk assessments for each patient on arrival or admission, using a recognised tool, and reviewed this regularly, including after any incident. Risk assessments were carried out for patients which included falls, mobility, dementia and anxiety. Patients were also assessed to check that they could tolerate lying flat during the procedure.

Staff completed the World Health Organisation (WHO) safety checklist for cataract surgery that had been adapted and improved following learning from incidents in the organisation. The WHO checklist is a simple tool designed to improve communication and teamwork by bringing together the surgeons, and nurses involved in care to confirm that critical safety measures are performed before, during and after an operation. Theatre staff completed safety checks before, during and after surgery. WHO check list compliance was audited and for the previous 12 months there was 100% compliance.

Staff responded promptly to any sudden deterioration in a patient's health. The hospital had an escalation policy which was to call 999 and transfer the patient to an acute NHS hospital. Staff were trained in basic life support and clinical staff such as nurses were trained in immediate life support. At the time of inspection, staff who had not completed resuscitation training had recently joined the hospital. All were booked onto upcoming planned courses.

The service did not have any deteriorating patients in the previous 12 months.

Staff knew about and dealt with any specific risk issues. The hospital had an endophthalmitis box in case of an emergency. Endophthalmitis is an infection of the tissues or fluids inside the eyeball caused by infection. It is an urgent medical emergency and immediate treatment is vital.

Following surgery patients had access to a 24-hour helpline for any concerns and staff were available for emergency situations. Patients were provided with a discharge booklet that included information about how to access support. The service audited urgent care responses and found 99% compliance from September 2021 to August 2022.

The organisation had developed a post-operative review service with accredited community optometrists. Four weeks following surgery patients attended an appointment in the community or at the service to review the results of the treatment.

Surgery

Staff shared key information to keep patients safe when handing over their care to others. Staff sent discharge letters to the patients' GPs and referring community optometrist. We observed the morning safety huddle and saw all appropriate staff attended and relevant information was shared.

Nurse staffing

The service had enough nursing and support staff with the right qualifications, skills, training and experience to keep patients safe from avoidable harm and to provide the right care and treatment. Managers regularly reviewed and adjusted staffing levels and skill mix, and gave bank and agency staff a full induction.

The service had enough nursing and support staff to keep patients safe. The theatre team for the surgical list included a surgeon, two registered general nurses (RGN), two healthcare technicians (HCT) and two RGNs for admission and discharge. Staffing levels reflected demand on the service and known treatment support needs. The organisation had agreed minimum staffing for the hospital and surgery could only proceed when the standard of skill-mix was confirmed.

Managers accurately calculated and reviewed the number and grade of nurses and ancillary staff needed for each shift in accordance with national guidance. There was a standard staffing model which was regularly reviewed. The service held weekly activity meetings to assess and plan in line with activity.

The manager could adjust staffing levels daily according to the needs of patients. All theatre lists were pre-planned so the number of staff required for each shift could be pre-determined. Hospital managers liaised across the region to support and plan staffing. At the time of inspection, there were no vacancies for clinical staff.

Managers limited their use of bank staff and requested staff familiar with the service. The service used bank and agency staff who were familiar with the service. At the time of inspection, the hospital had completed a recruitment exercise and the new employees were in post. There were no vacancies.

All staff had a period of induction, and supervision where required, on commencing work at the hospital. All bank and agency staff were required to undergo the same competency training as employed staff. Nursing staff had completed their Nursing and Midwifery Council re-validation checks and updates to develop their competencies.

The hospital regularly reviewed staff absence and recruitment and retention information.

Medical staffing

The service had enough medical staff to keep patients safe. There were seven surgeons working under practising privileges.

Assessments of applications for practising privileges, from doctors and allied health professionals, were carried out by the medical director to ensure the appropriate practising privileges were completed. The granting of practising privileges is a well-established process within independent healthcare whereby a medical practitioner is granted permission to work in an independent hospital or clinic, in independent private practice, or within the provision of community services. The hospital monitored compliance with their practising privileges policy.

Records

Staff kept detailed records of patients' care and treatment. Records were clear, up-to-date, stored securely and easily available to all staff providing care.

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Patient notes were comprehensive, and all staff could access them easily. The hospital used paper and electronic records, to document patient information securely. Paper records were maintained for consent, demographics, copy of biometry, outcome forms and referrals. All scans could be viewed electronically. Biometry scans could be viewed electronically as well as printing of hard copies if required at the hospital. Records could be accessed across the departments, allowing continuity of record keeping. Bank staff could access the records they required.

We viewed six patient care records, which contained the patient's consent form, pre-assessment, procedure and discharge information. Records we reviewed were completed appropriately.

Records were stored securely. Paper records were stored securely in a locked cabinet when not in use. Staff completed training in information governance with a compliance rate of 96%. A record keeping audit from September 2021 to August 2022 found 93% compliance in line with the service's audit process.

Medicines

The service used systems and processes to safely prescribe, administer and store medicines. However, staff did not always complete medicines records accurately.

Staff followed systems and processes to prescribe and administer medicines safely. Staff followed best practice when prescribing, administering and storing medicines. The hospital had a medicines management policy, which ensured staff practices were in line with national guidance.

The service used topical and local anaesthesia to the eye only. Drops were prescribed using patient specific directions (PSD). A PSD is a written instruction, signed by a prescriber for medicines to be supplied and/or administered to a named patient after the prescriber has assessed the patient on an individual basis.

These were administered by health care technicians who recorded on the paper PSD. The service also had PGDs in place. A patient group direction (PGD) is a written instruction that includes the administration of medicines to groups of patients who may not be individually identified before presentation for treatment.

There was only one controlled medicine stored in the hospital. It was stored securely and checked daily, and the controlled medicines record book was fully completed.

Staff stored and managed all medicines and prescribing documents safely. Medicines were stored in locked cupboards away from the patient areas. The hospital had a digital temperature monitoring application that alerted staff when the temperature was out of range. From September 2021 to August 2022 the medicines management audit found 99% compliance.

Staff reviewed patients' medicines regularly and provided specific advice to patients and carers about their medicines. Staff said patients were given advice about medicines before surgery as well as post-surgery and patients we spoke with confirmed this. During discharge patients were given clear verbal instructions about the administration of their eye drops. They were also provided with written instructions and a checklist that they could use to record when they had administered the drops to help them follow the correct post-operative regime.

Staff did not always complete medicines records accurately. We observed stock levels did not always reconcile for chloramphenicol eye drops and sodium chloride eye drops because the count was one less than the medicines record stated. Records we checked showed staff raised a similar discrepancy as an incident in May 2022. We discussed this with the management team who confirmed the procedure would be reviewed with staff and regular stock checks completed.

Surgery

Incidents

The service managed patient safety incidents well. Staff recognised and reported incidents and near misses. Managers investigated incidents and shared lessons learned with the whole team and the wider service. However, staff did not always ensure incidents were investigated in a timely manner.

Staff knew what incidents to report and how to report them. The hospital had an open incident reporting culture and staff were able to tell us what incidents they would report and how they would report them. They told us the hospital was very proactive in encouraging staff to record incidents on the incident reporting system. Staff said they were encouraged to report 'near miss' situations.

Staff raised concerns and reported incidents and near misses in line with the hospital's policy. We reviewed the incidents reported in the previous 12 months and found they were reported and investigated in line with the hospital's procedure. Incidents were categorised into no, low, moderate or severe harm. The actions taken, and lessons learned were recorded where applicable. We observed that from 03 August 2022 there were 21 incidents where there were no outcomes recorded, and these were recorded as to be confirmed.

The service had no never events. Records provided by the hospital showed there were no never events from August 2021 to September 2022. The reported incidents were mainly low harm or no harm and none were reported as severe harm. The hospital policy was to escalate incidents of severe harm to the board and a comprehensive root cause analysis would be conducted and the learning shared with all staff.

Staff understood the duty of candour. They were open and transparent and gave patients and families a full explanation if and when things went wrong. Staff could give an example of an incident where the duty of candour requirements applied.

There was evidence that changes had been made as a result of feedback. For example, staff assessed and monitored patient's mobility needs throughout their pathway and implementing additional support, if required, to maintain safety.

Managers investigated incidents thoroughly. Patients and their families were involved in these investigations. The service used a root cause analysis approach to investigate incidents. Themes and trends were reviewed with any learning shared through clinical governance, medical advisory committee (MAC) and health & safety committees.

Are Surgery effective?

Good 

We have not previously inspected the service. We rated it as good.

Evidence-based care and treatment

The service provided care and treatment based on national guidance and evidence-based practice. Managers checked to make sure staff followed guidance. Staff protected the rights of patients subject to the Mental Health Act 1983.

Surgery

Staff followed up-to-date policies to plan and deliver high quality care according to best practice and national guidance. Hospital policies we reviewed were up to date and had gone through the appropriate governance processes. The policies referenced, and were developed, in line with the Royal College of Ophthalmologists (RCOphth) standards. There were standard operating procedures and established pathways to support staff on the organisation's intranet and staff knew how to access the documents.

Compliance with relevant guidelines was monitored through governance processes. There were systems to ensure policies, standard operating procedures and clinical pathways were up to date and reflected national guidance. Any amendments to the patient pathway were reviewed at board level, through clinical effectiveness and operational meetings. When agreed they were then piloted and evaluated before cascading via area and hospital managers and to all staff within relevant departments.

There was a truly holistic approach to assessing, planning and delivering care and treatment to all people who use services. For example, patients who may not be able to administer eye drops at home, such as those with manual dexterity issues, an alternative long-term injection could be given, or staff would contact the district nurses who could support patients.

New evidence-based techniques and technologies were used to support the delivery of high-quality care. Following research by the organisation's medical director, an injection during surgery, could be given as an alternative to discharge eye drops was introduced for certain groups of patients.

The service consistently reviewed its performance and compliance with policies and procedures through a series of audits including IPC, WHO surgical checklist, laser safety and urgent care. The results showed a high level of compliance against recorded measures of 99% - 100%. Staff implement an action plan when an audit identified compliance of less than 95%.

During care and treatment planning, staff routinely referred to the psychological and emotional needs of patients, their relatives and carers. Staff worked with the patients GP and district nurses for patients who needed additional support in the community.

Nutrition and hydration

Staff gave patients enough food and drink to meet their needs.

The service provided treatment under local anaesthetic so there was no restriction on diet or fluids before surgery. This meant that patients were free to eat and drink as normal both pre- and post-surgery. The service provided snacks, water and hot drinks.

Pain relief

Staff assessed and monitored patients regularly to see if they were in pain, and gave pain relief in a timely way.

Staff prescribed, administered and recorded pain relief accurately. All patients received anaesthetising eye drops and a local anaesthetic eye block before their procedure.

Staff assessed patients' pain during and after surgery and gave pain relief when required. We observed staff completing discharge consultations, staff asked patients if they had any pain and gave advice on managing any pain at home. Advice on pain relief was included in the discharge booklet given to all patients.

Surgery

Patients were asked about pain following their surgery. From September 2021 to August 2022 most patients reported mild or no pain.

Patient outcomes

Staff monitored the effectiveness of care and treatment. They used the findings to make improvements and achieved good outcomes for patients.

All staff are actively engaged in activities to monitor and improve quality and outcomes. The service participated in relevant national clinical audits. The hospital submitted data to the National Ophthalmology Database Audit (NODA) run by the Royal College of Ophthalmologists. NOD measures the outcomes of cataract surgery.

Outcomes for patients were positive, consistent and met expectations, such as national standards. Between September 2021 and August 2022, the rate of posterior capsular rupture (PCR) following cataract surgery was 0.33%. This was against a performance of 0.5% for the provider nationally and a national average of 1.10% across all cataract surgery. PCR is the most common potentially sight-threatening intraoperative complication during cataract surgery.

Data provided from September 2021 to August 2022 showed average outcomes for patient visual acuity following surgery for both eyes was 98% which was consistently better than the NODA average of 90%.

The hospital had a low risk of readmission, with no patients returning to theatre between September 2021 and August 2022.

Opportunities to participate in benchmarking were proactively pursued. The hospital benchmarked themselves against other hospitals in the provider network and they performed consistently to a high standard. Staff said post-surgery complications were rare. The service collected data on post-surgery complications such as incorrect eye operated on, incorrect lens inserted, iris trauma and surgical error. The post-surgical complication rate was 0.01% in the previous 12 months.

Managers and staff used the results to improve patient outcomes. Staff completed regular audits and performed consistently well over a 12-month period scoring on average over their target of 95%. Patients reported on the outcomes of their surgery.

Competent staff

The service made sure staff were competent for their roles. Managers appraised staff's work performance and held supervision meetings with them to provide support and development.

Staff were experienced, qualified and had the right skills and knowledge to meet the needs of patients. The hospital undertook regular reviews of staff competencies through a programme of self-assessment and appraisals including clinical skills. There was a comprehensive set of competencies which included pre-operative assessments, admitting patients for surgery, using the YAG laser and dispensing medication. The service maintained a skills matrix that showed staff who had been trained and deemed competent for certain roles and responsibilities. Newly appointed surgeons had a period of supervised practice overseen by the medical director.

Managers gave all new staff a full induction tailored to their role before they started work. Staff who completed the induction spoke positively about their experience and said managers and clinical leads were supportive.

Surgery

There was a leadership programme for hospital managers who completed peer reviews at other hospitals within the organisation.

Managers supported staff to develop through yearly, constructive appraisals of their work. Appraisal completion rates were 100%. Staff told us they used this process to establish goals for the rest of the year and that it was motivational. Senior staff were focused on staff development as part of a strategy to maintain stability and loyalty amongst the team.

Consultants with practising privileges had arrangements for external appraisal within their NHS work. Assurances were provided through the governance process as well as the overview from the medical advisory committee (MAC). There was an effective process for validating and monitoring the credentials of any consultant or health professional with practising privileges working within the hospital.

The medical director oversaw training and supervision for the medical staff. The organisation assessed clinical performance as well as bedside manner. Each surgeon was given a rag rating (red, amber or green) which was reviewed through governance processes with actions taken to address any shortcomings.

Staff are proactively supported and encouraged to acquire new skills. Healthcare technicians (HCT) had the opportunity to train to undertake YAG admissions and instil eyedrops. They could also train to undertake post-operative cataract discharges where pre-ordered and labelled eye drops from pharmacy were provided to patients at discharge.

Managers encouraged staff to complete other learning modules above mandatory training as a part of self-directed learning. Records showed staff completed training on how to use lasers, dementia care, medicines management and supporting patients with learning disabilities.

Managers made sure staff attended team meetings or had access to full notes when they could not attend.

Multidisciplinary working

Doctors, nurses and other healthcare professionals worked together as a team to benefit patients. They supported each other to provide good care.

Staff worked across health care disciplines and with other agencies when required to care for patients. Multidisciplinary working was a fundamental aspect of the service and underpinned all elements of care. Staff held regular and effective multidisciplinary meetings to discuss patients and improve their care. All staff worked as a team to plan and deliver seamless treatment pathways. The service implemented a daily safety huddle which provided a forum for staff to communicate relevant issues and escalate any concerns for immediate action.

We observed a safety huddle which helped to ensure the service provided a safe environment. The manager monitored the effectiveness of the huddles through audits ensuring the records for each huddle were completed fully.

We heard positive feedback from staff of all grades about the excellent teamwork. We observed staff working effectively together.

Staff worked across health care disciplines and with other agencies when required to care for patients. Patients could be seen across other SpaMedica sites if this was their preference as they had a central recording system. Staff worked effectively with referring partners such as general practitioners (GP) and community optician. Staff shared information with the patients GP and referring optometrist to ensure continuity of care.

Surgery

Seven-day services

Key services were available seven days a week to support timely patient care.

The hospital was open Monday to Saturday from 7:30am to 5:30pm.

There was a national contact centre open from 8am to 6pm Monday to Saturday. Patients were informed of this on all discharge and information leaflets given and on the website. Patients were provided with 24 hours a day, seven days a week contact number for any urgent concerns or queries. Staff triaged these calls and transferred to an emergency on call optometrist if appropriate.

Health promotion

Staff gave patients practical support and advice to lead healthier lives.

The hospital had relevant information promoting healthy lifestyles and support. The hospital had a dementia noticeboard which included information on how to access support groups.

Staff assessed each patient's health when admitted and provided support for any individual needs to live a healthier lifestyle considering both physical and mental well-being.

The services' website included information from patients regarding eye health that included wearing sunglasses, medicines and driving advice.

Consent, Mental Capacity Act and Deprivation of Liberty Safeguards

Staff supported patients to make informed decisions about their care and treatment. They followed national guidance to gain patients' consent. They knew how to support patients who lacked capacity to make their own decisions.

Staff gained consent from patients for their care and treatment in line with legislation and guidance. Staff worked in line with the provider's consent policy. Staff used consent forms and records showed signed consent forms were documented in the patient's records.

Practices around consent and records were actively monitored and reviewed to improve how people were involved in making decisions about their care and treatment. Staff clearly recorded consent in patient records. They provided information on the potential risks, intended benefits and alternative options before each treatment. The service had a two-stage consent process by obtaining written consent at pre-assessment which was re-confirmed on the day of the procedure. Staff audited this process by reviewing documented evidence in care and treatment records. Staff performed highly and consistently in this measure.

Staff understood how and when to assess whether a patient had the capacity to make decisions about their care. Staff said this was a rare occurrence. Staff understood how and when to assess whether a patient had the mental capacity to make decisions about their care.

Surgery

Are Surgery caring?

Good 

We have not previously inspected the service. We rated it as good.

Compassionate care

Staff treated patients with compassion and kindness, respected their privacy and dignity, and took account of their individual needs.

Staff were discreet and responsive when caring for patients. Staff took time to interact with patients and those close to them in a respectful and considerate way. We spoke with three patients who provided positive feedback on the service. Patients said, “staff are friendly, helpful and reassuring”, “staff were exceptional”, “efficient, the driver collected me on time and took me home” and “very prompt”. Patients told us staff were polite and considerate.

The results of the patient satisfaction survey completed from September 2021 to August 2022 showed patients highly rated their overall experience at the hospital

Patients said staff treated them well, with kindness and were very helpful and reassuring. Staff answered patient enquiries and interacted with patients in a friendly and sensitive manner. We saw staff treating patients with respect and dignity. We witnessed staff knocking on doors before entering a room and staff introduced themselves.

Patients said staff were polite and considerate and listened to what they had to say. All consultations and treatment were carried out in individual rooms. Doors were closed when patients had treatment and staff knocked before entering, ensuring privacy.

Emotional support

Staff provided emotional support to patients, families and carers to minimise their distress. They understood patients' personal, cultural and religious needs.

Staff understood the impact that patients care, treatment and condition had on the patient's wellbeing. There was a strong focus on 'patient centred care' with a holistic assessment of patient needs. Staff we spoke with stressed the importance of treating patients as individuals with different needs. They took time to reassure patients who were anxious about their procedure. Patients told us staff were always available to help from pre-operative assessment to surgery.

The hospital had a porter who greeted patients when they arrived for their appointment, assisted them with signing in and directed them to the appropriate area for parking. Patients were assisted to their vehicles after surgery.

Staff gave patients and those close to them help, emotional support and advice when they needed it. Staff gave examples of how they would reassure nervous patients and answer any questions. Patients said staff helped them to feel calm and relaxed.

Staff understood the emotional and social impact that a person's care, treatment or condition had on their wellbeing and on those close to them. Patients were provided with the organisation's "patient stories" DVD where previous patients described their experience to help relieve anxiety. Videos were also available on the organisation's website. There was an option for staff to hold the patient's hand in theatre if a patient was particularly nervous.

Surgery

Staff understood and respected the individual needs of each patient and showed understanding and a non-judgmental attitude when caring for or discussing patients with mental health needs. Staff had access to information on dealing with patients with dementia and had completed dementia friends training.

Understanding and involvement of patients and those close to them

Staff supported patients, families and carers to understand their condition and make decisions about their care and treatment.

Staff made sure patients and those close to them understood their care and treatment. The service provided patients with information on their procedure. Staff asked patients about their procedure to ensure they understood. We spoke with three patients and they told us they felt involved in their care and had received the information they needed to understand their treatment. The patient satisfaction survey showed patients understood what happened during the procedure.

Patients and their families could give feedback on the service and their treatment and staff supported them to do this. We observed staff were proactive in engaging with patients about their experiences and frequently asked how they were doing. Staff encouraged each patient to complete a feedback form following their appointment.

Are Surgery responsive?

Outstanding



We have not previously inspected the service. We rated it as outstanding.

Service delivery to meet the needs of local people

The service planned and provided care in a way that met the needs of local people and the communities served.

The service was flexible, provided informed choice and ensured continuity of care. The hospital had streamlined its service to treat NHS patients through contracts with the local NHS trust and commissioners. Patients were referred by their GP or optometrist. Managers planned and organised services, so they met the changing needs of the people who use the service. Surgeries were performed six days a week and appointments were scheduled at a time to meet the needs of the patient group. Patients we spoke with confirmed being able to access the service in a timely manner.

The organisation's centralised bookings teams managed the patient referrals on an electronic patient administration system. Patients chose to attend the service, including which clinic location was preferable. Free patient transport was offered within a 10-mile range of the hospital with patients' safety to travel risk assessed individually. Drivers collected patients from their home with a reminder the day before of the expected time.

The hospital had an inclusion and exclusion criteria and a comprehensive pre-operative assessment. The pre-operative assessment ensured patients were fit for surgery. Patients were offered an appointment within two weeks of the pre-operative assessment. However, if a patient needed to defer due to holidays, work commitments or religious festivals this was readily accommodated. The service had optometrists who were accredited to provide post-operative care. Patients could choose to have their post-operative follow up with one of these services if it was more convenient.

Surgery

Managers worked to keep the number of cancelled operations to a minimum. Patients were contacted prior to their appointment to minimise missed appointments. From September 2021 to August 2022 the service reported 1.8% of appointments were missed. Staff contacted patients who had failed to attend to re-book their appointment or referred back to the NHS hospital. The patient's GP was informed of any changes.

Staff monitored the reasons for any cancelled appointments which was reported each month. From September 2021 to August 2022 the service reported 8.4% surgeries were cancelled by the hospital and this included theatre lists that were combined for efficiency. When patients had their admissions cancelled, staff ensured they were rearranged as soon as possible. We were advised that where procedures had been cancelled patients would be placed on the next scheduled surgical list where possible.

Meeting people's individual needs

The service was inclusive and took account of patients' individual needs and preferences. Staff made reasonable adjustments to help patients access services.

The service was fully accessible to patients with limited mobility and wheelchair users and there were disabled parking bays.

Managers made sure staff, and patients, loved ones and carers could access interpreters or signers when needed. Information on interpreting services was readily available. Staff used the electronic pathway to document information that helped them deliver tailored, individualised care. For example, staff checked where patients had needs in relation to language, hearing, sight and mobility. Interpreters attended appointments.

Staff understood and applied the policy on meeting the information and communication needs of patients with a disability or sensory loss. The hospital had information in large print and a hearing loop was available to assist patient's wearing a hearing aid.

Staff made sure patients living with mental health problems, learning disabilities and dementia, received the necessary care to meet all their needs. There was a dementia champion available at the hospital who had undertaken additional training to promote the needs of people living with dementia. There was a dementia folder which was a support pack to help staff support patients with dementia including hints and tips. For patients living with a learning disability or autistic spectrum disorder, they were offered additional visits with those close to them being able to help with preparations for surgery and pre- and post-operative consultations.

To be suitable for surgery patients needed to be able to lie flat and still for 15 minutes. Many patients were anxious about the procedure, so the hospital devised the 'bed test'. At the assessment stage, patients were given the opportunity to lie on a bed and were timed to check if they could lie flat and still for 15 minutes. This quick and simple test alleviated patient anxiety and helped to prevent cancellations.

Following cataract surgery, all patients were given complimentary eye drops to use if their eyes became dry.

The hospital had a patient journey map which was displayed on a notice board for each type of condition and treatment which gave clear information on what to expect at each stage of treatment. This information was also available on SpaMedica's website so patients could follow their treatment pathway.

Surgery

Patients were given a choice of food and drink to meet their cultural and religious preferences. Patients were day cases who did not require overnight stays and they were provided with light refreshments such as biscuits, tea, coffee and water. The hospital introduced gluten free and vegan snacks to meet patient preferences.

Access and flow

People could access the service when they needed it and received the right care promptly. Waiting times from referral to treatment and arrangements to admit, treat and discharge patients were in line with national standards.

People could access services and appointments in a way and at a time that suits them. Staff worked together to facilitate access to services. Patients were offered the first available appointment. From September 2021 to August 2022 the service completed 4645 procedures. There was an 18-week referral to treatment (RTT) pathway. The service proactively collaborated with the trust and clinical commissioning groups (CCG) on waiting times.

The hospital reported the average RTT from September 2021 to August 2022 was five weeks. There were no patients waiting more than 52 weeks.

Staff planned patients' discharge individually. This included those who were in vulnerable circumstances or who had complex needs. All patients had a discharge consultation with a registered nurse after their procedure. We observed a discharge consultation and saw patients were given appropriate guidance and information both verbally and in writing. Staff made sure patients were safe to leave and travel home.

There was a comprehensive pre-operative assessment to reduce risks and complications. This ensured the patients were fit for surgery and reduced delays to their treatment pathway.

Learning from complaints and concerns

It was easy for people to give feedback and raise concerns about care received. The service treated concerns and complaints seriously, investigated them and shared lessons learned with all staff. The service included patients in the investigation of their complaint.

Patients, relatives and carers knew how to complain or raise concerns. Information on how to make a complaint was available at the service. The complaint procedure explained the stages of the complaint process including investigation resolution and independent external adjudication. Patients treatment was funded by the NHS, so the hospital provided information on how to contact the Parliamentary and Health Service Ombudsman (PHSO), if patients were not happy with the outcome of a complaint. This was available on the website and patient information leaflets.

Staff knew how to acknowledge complaints. Staff understood the complaints policy. Staff were trained to resolve minor concerns as part of an approach to meeting individual expectations and avoid minor issues escalating into a formal complaint. We spoke with staff who were able to identify how to support a complaint, be it informal or formal, and how it was escalated and managed by senior managers.

Managers shared feedback from complaints by emails and meetings and learning was used to improve the patient's experience. From September 2021 to August 2022 the service received three complaints. Records showed the complaints were reported and investigated in line with the service's complaints procedure.

Staff could give examples of how they used patient feedback to improve the service. For example, a new waiting times board was introduced to keep patients informed of any delays.

Surgery

Are Surgery well-led?

Good 

We have not previously inspected the service. We rated it as good.

Leadership

Leaders had the skills and abilities to run the service. They understood and managed the priorities and issues the service faced. They were visible and approachable in the service for patients and staff. They supported staff to develop their skills and take on more senior roles.

Leaders at all levels demonstrated high levels capacity and capability needed to deliver sustainable care. There was an organisational structure with a chief executive, chief operating officer, medical director and head of clinical services. These were supported by other senior managers that included infection, prevention and control leads, regional directors and an advanced nurse practitioner.

The hospital's manager was supported by the area manager and hospital director (south). Each manager had clearly defined roles and responsibilities. This was supported by an effective recruitment program ensuring that the skills and abilities of leaders matched the job profiles required within the hospital.

We found all managers had the skills, knowledge and experience to run the service. Leaders demonstrated an understanding of the challenges to quality and sustainability for the service. For example, the recruitment and retention of staff, adequate staffing levels to match the increase in activity and the impact of COVID-19.

There was a system of leadership development and succession planning. The organisation supported managers in their roles and managers new to their roles had mentorship from an operational development manager. There was a hospital manager training plan to support managers in developing key skills. The hospital manager completed a peer review exercise which involved visiting other locations to observe practice and share learning.

Managers demonstrated leadership and professionalism. Staff we spoke with said managers were accessible, visible and approachable.

Vision and Strategy

The service had a vision for what it wanted to achieve and a strategy to turn it into action, developed with all relevant stakeholders. The vision and strategy were focused on sustainability of services. Leaders and staff understood and knew how to apply them and monitor progress.

The hospital had a clear vision and strategy. The hospital followed the SpaMedica vision of 'every patient, every time: no exception, no excuses'. Staff were guided by the values of safety, integrity, kindness and transparency and patients were put at the centre of delivery of care and treatment.

The strategy for SpaMedica covered five main areas which were growth, quality, leadership, governance and infrastructure.

Surgery

Plans are consistently implemented and had a positive impact on quality and sustainability of services. The strategic objectives were regularly reviewed to ensure the sustainability of the service and to measure its success. The hospital would achieve its objectives by working as a team, with patients and stakeholders such as GP and optometrists. Quality measures included patient experience, clinical outcomes, staff engagement, recruitment, retention and development.

Staff we spoke with understood the vision and quality measures of the service and how it had set out to achieve them. The staff worked in a way that demonstrated their commitment to providing high-quality care in line with this vision.

The service had a statement of purpose which outlined to patients the standards of care and support the service would provide.

Culture

Staff felt respected, supported and valued. They were focused on the needs of patients receiving care. The service provided opportunities for career development. The service had an open culture where patients, their families and staff could raise concerns without fear.

Managers supported an open and honest culture by leading by example and promoting the service's values. We heard this was promoted by having an open-door policy, interacting with staff daily and doing a walk around the service every day.

Staff said they enjoyed working at the service; they were enthusiastic about the care and services they provided for patients. They described the hospital as a good place to work. The organisation had an incentive reward scheme and a staff recognition scheme.

The service provided opportunities for career development. The previous hospital manager had been promoted to the area manager.

All staff we spoke with said they felt their concerns were addressed, and they could easily talk with their managers. Staff reported that there was a no blame culture when things went wrong. The hospital created a learning environment so staff could learn from feedback, incidents and complaints. Conflict resolution was a part of mandatory training, and most staff completed it.

All managers and staff worked collaboratively to improve care, treatment outcomes, quality and patients experience throughout the entire hospital.

Governance

Leaders operated effective governance processes throughout the service. Staff at all levels were clear about their roles and accountabilities and had regular opportunities to meet, discuss and learn from the performance of the service.

Quality governance was incorporated into every level of the organisation through a variety of process from the ward to the board and from the board to the ward. Information was filtered up from and down to staff. This was done by the area managers who had weekly meetings with the senior team. There were various committees with a lead responsible for the meetings and escalating issues.

Surgery

There was an effective clinical governance structure which included a range of meetings that were held regularly. Clinical governance meetings were held bimonthly. We reviewed three sets of meeting minutes and observed they were well attended by the representatives from the senior leadership team, hospital managers and clinical leads. Agenda items included clinical governance, quality, risk, compliance and audit. All levels of governance and management worked effectively together.

Significant incidents and themes were reported and discussed at the organisation's national clinical governance and clinical effectiveness bimonthly meetings, medical advisory and health and safety committees.

The MAC represented the professional needs and views of medical practitioners and advised the senior leaders on medical policy and standards. The MAC reviewed the clinical performance of staff who have been granted practising privileges. They provided a quarterly forum for consultation and communication between medical practitioners and the hospital's senior management team.

Staff were clear about their roles and accountabilities. Clear accounting lines and accountabilities were utilised to ensure oversight and timely information was provided on key performance indicators.

The service had effective systems, such as audits and risk assessments, to monitor the quality and safety of the service. There was a comprehensive audit schedule of clinical and non-clinical audits. Records showed audits were discussed at various management and staff meetings.

Management of risk, issues and performance

Leaders and teams used systems to manage performance effectively. They identified and escalated relevant risks and issues and identified actions to reduce their impact. They had plans to cope with unexpected events.

There was a systematic programme of clinical and internal auditing to monitor quality and operational processes. The service had a comprehensive list of audits and risk assessments that were completed on a regular basis. Staff understood the risk management strategy and actively contributed to it.

The hospital collated patient outcomes and submitted data to national audit to benchmark their performance against other service providers. The data provided showed that they met or exceeded the performance targets for all indicators.

The service reviewed how it functioned and ensured that staff at all levels had the skills and knowledge to use those systems and processes effectively. The service had key performance indicators (KPI's) which were regularly reviewed. Managers planned services and used resources effectively to ensure they met referral to treatment times which were much better than the national average. The service continuously monitored safety performance these outcomes which were discussed at regular management, governance and staff meetings.

Senior managers were committed to providing quality care for patients. The surgeon's performance was monitored quarterly using a dashboard that included outcomes of surgery and bedside manner on a red, amber, green (RAG) rated system. Consultants who operated at the hospital were rated green.

Risks were identified and addressed quickly and openly. There was a risk management strategy, setting out a system for continuous risk management. The service had a risk register which showed the actions taken to mitigate risks. Examples of risks included slips, trips and falls, COVID-19 and use of the evacuation chair in the event of a fire. Staff discussed the risks to the service at various meetings and documented the progress of any outstanding actions. Progress on each action was reviewed at subsequent meetings.

Surgery

The service had a business continuity plan that could operate in the event of an unexpected disruption to the service.

Information Management

The service collected reliable data and analysed it. Staff could find the data they needed, in easily accessible formats, to understand performance, make decisions and improvements. The information systems were integrated and secure. Data or notifications were consistently submitted to external organisations as required.

The information used in reporting, performance management and delivering quality care was consistently accurate, valid, reliable, timely and relevant. The service had an electronic quality management system, which monitored the performance of the service through data collection on all aspects of the service including incidents, complaints, mandatory training and audits.

Integrated reporting supported effective decision making. All staff had access, by secure logins, to the organisation's intranet to gain information relating to policies, procedures, national guidance and e-learning. All staff were able to demonstrate the use of the system and retrieve information.

There were systems in place to ensure data and statutory notifications were submitted to external bodies. The registered manager, who was the hospital manager, was responsible for submitting notifications to the Care Quality Commission and had done so in the case of a serious incident.

The hospital submitted 100% of data to the National Ophthalmology Database Audit (NODA).

The service had arrangements and policies to ensure the availability, integrity and confidentiality of identifiable data, records and data management systems were in line with data security standards. The service provided information governance training and most staff completed it.

The hospital had a General Data Protection Regulation (GDPR) which briefly mentioned the use on closed-circuit television (CCTV). However, the policy did not include relevant information in line with guidance issued by the Information Commissioner's Office (ICO) such as explaining the purpose of the recording, including the name and contact details of those operating the surveillance scheme and how people could request the recordings.

Engagement

Leaders and staff actively and openly engaged with patients and staff to plan and manage services.

Managers and staff understood the value of engagement in supporting safety and quality improvements. Staff actively sought patient feedback and patients provided this through surveys, online feedback and emails. The service engaged with patients to ensure they had a high response to the patient survey. The service performed highly and consistently in all the questions on the survey. Staff acted on patient feedback and there was a "you said, we did" poster displayed which informed patients about the changes that were made.

The hospital completed an annual staff survey. Results from the 2021 survey showed that 93% of staff felt that the work they did had a positive impact on patients' lives, 93% said they had the resources to do the job and were trusted by managers to perform their duties. The hospital had a staff forum and regular meetings where staff could discuss their concerns. One staff suggestion that was implemented was a wellbeing and health calendar poster for each month to raise awareness of monthly cultural and wellbeing events.

The website had a section specifically for health professional referrals and information.

Surgery

There was a weekly bulletin so staff could share news and achievements.

Learning, continuous improvement and innovation

All staff were committed to continually learning and improving services. They had a good understanding of quality improvement methods and the skills to use them. Leaders encouraged innovation and participation in research.

Improvement was seen as the way to manage performance and used to promote learning within the organisation. The senior leadership team and staff shared a wide range of innovation and research within the organisation that were improving outcomes for the organisation and patients. For example, the medical director had carried out research into social deprivation and the impact it is had on cataracts. This was presented at ophthalmic conferences and was published in a national journal for the medical profession.

The provider had four digital dry labs throughout England and pop-up dry labs that enabled ophthalmology trainees to learn and practice cataract surgery. The dry labs were also used by surgeons to perfect techniques and practice using the providers standard instruments.

The service had implemented a point of care finger prick testing of international normalised ratio (INR). Patients did not need to go to the warfarin clinic or require a district nurse to check their INR seven days prior to surgery because this was offered by the hospital. This reduced the burden on the NHS and streamlined the pathway for the patients.

Staff carried out a risk stratification assessment at pre- assessment clinic for cataract surgery and patients' post-operative medicine regime was then tailored accordingly. The stratification took account of a range of factors including ethnicity and social factors. The risk stratification had been designed and validated by the medical director following a clinical study.