

Patient safety in cataract surgery

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REVIEW

Abstract

Purpose The recent focus on healthcare errors and safety suggest that practitioners and policy makers might appraise their cataract surgical care from a patient safety perspective. This paper reviews patient safety issues relevant to cataract care. Causation and consequences of incidents in cataract surgery, with implications for policy, are discussed.

Methods Models of accident causation from other domains were drawn on and empirically applied to cataract care. Consultation was undertaken with experts in cataract surgery, patient safety, and in risk management. Feedback on patient safety was included from presentations made to staff and patients and from personal insights.

Results Ophthalmology teams should embrace steps to improve patient safety. The role of incident reporting is advanced, including the provision of a prompt menu of cataract patient safety incidents as suggested by the Royal College of Ophthalmologists.

Conclusions Strict attention to detail, risk assessment, and careful consideration of the patient pathway is needed to enhance cataract care. Clinical errors, near misses and complications happen, and may provide an opportunity for learning to reduce the risk of similar events in the future. Investment in staffing and training, appropriate equipment, and development of a safety culture with patient involvement are key elements of safe cataract surgical care. Patients and the public expect that safe cataract care should be commissioned for them. Critical patient safety incidents, including incidents that have led to permanent harm, require careful analysis of underlying systems and/or root causes.

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Introduction

Currently cataract surgery is the most frequently undertaken surgical intervention in healthcare; over 300,000 cataract operations were undertaken in 2003–2004 under UK National Health Service (NHS) care.¹ High volume day-care surgery is now standard and given the large numbers of patients, the complexity of care, and overarching performance pressures, it is inevitable that some adverse patient safety incidents will occur. Furthermore, patients requiring cataract surgery may be very elderly with concomitant medical or social conditions that may enhance dangers. Recent policy statements have supported a commitment to quality in NHS care.^{2,3} A multidisciplinary approach to quality is required to deliver safe high-volume surgery, such as cataract surgery. Aspects of these are reflected upon in this review.

Safety, risk, and outcomes

Change in visual acuity can be used as an outcome marker but is a crude index of patient experience, and of the quality, safety, or reliability of care. Most noncomorbidity cataract patients have a good visual acuity outcome. The indications for, and methods, of cataract surgical care, have evolved so rapidly in recent years that comparisons of current outcomes with previous national audits quickly become outdated.

The ideal test of an ophthalmic operation would be both long-term visual benefit and improvement in quality of life. However, such outcome markers are unlikely to be measured for individual surgeons or institutions in a way that can help produce relevant and timely reports. Individual surgeon's mortality results in cardiothoracic surgery are now available in the UK, but the concept remains controversial because of the potential, unintended negative effects on surgeons and increasing recognition that individual results are strongly influenced by different institutional influences.⁴

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When patients in Australia were asked their views about healthcare, they expressed a preference for being 'in safe hands' and also requested accountability for staff's actions and an opportunity to feedback.⁵ A recent government consultation exercise in England suggests that people want accessible, good quality service at convenient locations.⁶ While communicating clinical risks to patients is intuitively desirable and is a requirement for informed consent, the challenges are complex.⁷

A small number of systematic failures in cataract surgery have come to the attention of the Professional Standards Committee of the Royal College of Ophthalmologists in recent years. The College recommends the reporting of defined 'critical incidents' (Table 1). There is no central register of such reported events in the UK and while analysis of closed medico-legal claims is of interest, litigation is a poor proxy measure for patient safety incidents.⁸ Under-reporting of patient safety incidents in healthcare, especially by medical staff, is problematic.⁹⁻¹²

Risk management in healthcare has traditionally been for the defence of providers. A more enlightened view is that clinical risk management, focusing on patient safety outcomes, will enhance the quality of clinical care while reducing the burden of harm.¹³

Background to patient safety

The publication of the Institute of Medicine's report *To Err is Human: Building a Safer Health System*¹⁴ in the USA

Table 1 Critical patient safety incidents; cataract care

1	Operation on the wrong eye
2	Wrong operation on correct eye
3	Missing case notes at surgery
4	Penetration or perforation of globe during periocular injections
5	Expulsive haemorrhage during cataract surgery
6	Endophthalmitis following cataract surgery
7	Patient collapse requiring resuscitation during cataract surgery
8	Death
9	'Open' category for incidents causing concern among cataract care staff or patients for whatever reason. Whether these patient safety incidents require further analysis is a policy matter for local organisations. Examples pertinent to cataract surgery might include: <ul style="list-style-type: none"> ● IOL miscalculation/wrong power ● dropped nucleus/fragment ● requirement for IOL explantation ● corneal decompensation within 3 months of surgery ● inadequate or unsafe staffing levels
10	Unplanned readmission or return to operating theatre within 28 days of cataract surgery for treatment of the same eye

These are suggested incidents to report; this is intended to be a practical aid and is neither exhaustive nor exclusive.⁶⁰

and the UK report on patient safety, *An Organisation with a Memory*,¹⁵ have increased awareness of patient safety and clinical error issues. 'Patient safety' is defined as 'the process by which an organisation makes patient care safer. This should involve: risk assessment; the identification and management of patient-related risks; the reporting and analysis of incidents and the capacity to learn from and follow-up on incidents and implement solutions to minimise the risk of them recurring'.¹⁶ A growing body of evidence shows that errors in healthcare have huge consequences to all concerned.

The National Patient Safety Agency (NPSA) was established in response to these concerns.³ A 'patient safety incident' is defined by the NPSA as any 'unintended or unexpected incident which could have or did lead to harm for one or more patients receiving NHS funded healthcare. This is also referred to as an adverse event/incident or clinical error, and includes near misses'.¹⁶

Improving the safety of cataract surgery

Improving the safety of healthcare requires an understanding of clinical performance, patient pathways and human and organisational factors. Systematic change is likely to be more productive in reducing clinical errors than targeting and punishing individual healthcare personnel. It is believed that most medical errors cannot be prevented by perfecting the technical work of individual practitioners. Improving patient safety usually involves the coordinated efforts of all members of the healthcare team, who may adopt strategies from outside healthcare such as aviation, nuclear safety, human factors and organisational theory.¹⁷ Such strategies include analysis of adverse events; selective and appropriate use of technology; aviation-style standard operating procedures or checklists; promoting a 'culture of safety'; team training, the use of simulators or wet-labs in training; and integrating human factors theory into the design of medical devices.¹⁷

Systems failures for NHS patients are the responsibility of the hospital Trust's Chief Executive Officer. Independent sector (IS) providers have also strengthened their quality and clinical governance frameworks. NHS patients treated in the IS remain NHS patients¹⁸ and the referring or commissioning Trust organisation maintains governance responsibility along with the IS provider.

Improving the safety of healthcare requires high-level organisational commitment.^{19,20}

Systems approach to accident and incident factors

Models of organisational accident causation can be applied to facilitate greater understanding of medical

error.^{21,22} Such accident causation theory distinguishes between ‘active failures’ and ‘latent conditions’. Active failures are errors, mistakes and violations that are committed by people at the service delivery or sharp end of the system, and usually have an immediate impact on safety. Most human error or failure is a mistake (understanding failure), a slip (attention failure), or a lapse (memory failure). Violations also occur (routine, situational, or exceptional), defined as intentional deviations from a procedure or accepted way of carrying out a task. They are rarely malicious. Latent conditions result from poor planning, weak processes and procedures, or an inappropriate organisational culture. These may manifest themselves in decisions made at higher levels, for example, not investing in appropriate staffing or replacing outdated equipment, failure to risk-assess novel cataract care commissioning plans and focusing on performance or financial targets rather than on patient outcomes or safety. Latent conditions lead to weaknesses in the organisation’s defences, which, under error-producing conditions (eg, fatigue, task complexity, external pressures or environmental factors) increase the likelihood that when active failures occur they will combine with existing preconditions and result in an organisational accident.²²

Insight into human factors in patient safety has been applied to some areas of surgery.^{23,24} Errors can be classified by causation or consequence. Traditionally, consequential classification has been used in healthcare (eg, wrong intraocular lens (IOL) implant being inserted). Causal classification of the same event may reveal, for example, that the wrong biometry formula was applied because of lack of using evidence-base after insufficient continuing professional development resulting from service pressures restricting study leave. Technical skill in cataract surgery, although very important and requiring constant updating, cannot overcome poor case selection, inappropriate indications for surgery or dangerous working environments. The most common reason for human failure, on a differing industrial and psychological classification, is unfamiliarity with the task, which increases the likelihood of error by up to 17-fold.²⁵

Systems approach to improving safety

Surgical outcomes and risk

All surgery carries some risk. Control of all clinical risk is impossible, but efforts should strive to eliminate, avoid, or minimise potential adverse events, where identified. There are difficulties in studying either the features of surgical excellence or poor surgical outcomes. Commitment, self-belief, positive imagery, mental

readiness, full focus on the surgical task, controlling distractions and constructive evaluation (that is, learning from previous cases) have been suggested as characteristics of surgical excellence.²⁶ Behavioural markers have proven a useful method to explain performance differences between paediatric cardiac surgeons.²⁴ While there may be occasional poorly performing surgeons, most errors are committed by well-trained, well-motivated individuals.²⁷ Variability in clinical outcomes has been attributed to the complex interplay of multiple factors including: surgical ability, surgical technique, case mix, case volume, institutional systems influences, perioperative care and anaesthetic care.^{4,28,29} Just as optimisation of organ dysfunction is beneficial before surgery for the individual patient, optimisation of organisational logistics and systems matters are beneficial strategies for surgery provider organisations. Steps to improve patient safety have been suggested by the NPSA (Table 2).¹⁶ Ophthalmic teams should consider applying these suggestions to cataract care. The careful cataract surgeon and healthcare policymaker should constantly consider and risk-assess practice at both an individual patient level and at an organisational level. Major changes in cataract surgical technique or policy delivery should be fully risk assessed before they are introduced. Prospective failure mode and effects analysis (FMEA) is a tool, with a military and engineering history, to examine safety proactively and to attempt to anticipate incidents before they happen.³⁰ Contingency planning concepts to deal with potential, usually foreseeable risks, should be planned for in advance.

Causational risks

Consideration should be given to the following ‘root’ or underlying causes of unsafe cataract surgery.

- Clinical staff not relying on evidence-based medicine (eg, not using preoperative povidine iodine).³¹
- Commissioning plans or service specifications being deployed that do not risk assess and robustly plan for potential postoperative problems. Recent examples include the provision of visiting cataract teams in

Table 2 Seven steps to patient safety—a guide for NHS staff¹⁶

Step 1	Build a safety culture
Step 2	Lead and support staff in patient safety
Step 3	Integrate risk management
Step 4	Promote reporting of patient safety incidents
Step 5	Involve and communicate with patients and the public
Step 6	Learn and share safety lessons
Step 7	Implement solutions to prevent harm

mobile units in UK healthcare without adequate provision or planning for the management of post-operative complications.³²

- Staff not following good clinical practice guidelines, such as College guidelines (eg, not using the recommended biometry formula).³³
- Failure to collect cataract patient outcomes (eg, lack of clinical audit, clinical governance, and/or patient experience analysis).
- Insufficient continuing professional development of cataract surgeons and healthcare personnel.
- Lack of team working of the cataract team. Team training, as used in aviation, has been suggested to be of merit in surgical care.³⁴
- Inappropriate staffing levels with appropriate skills and/or lack of effective clinical leadership.³⁵
- Lack of continuity of clinical care (eg, the dangers of medical bussing, inappropriate transfer of care, and dangers of shift handovers).
- Poor infrastructure, including lack of investment in appropriate cataract surgical facilities and dedicated day-care area.
- Failure of timely and appropriate management of surgical complications including early referral to tertiary centres.
- Lack of an integrated patient care pathway for cataract surgery.
- Interruptions and distractions during surgery. Last minute changes (eg, late changes to operating lists or unexpected emergency admissions).
- Rushing and insufficient checking with a focus on production or throughout rather than on quality and safety.
- Inappropriate teaching and supervision of trainees
- Inadequate maintenance of equipment.
- Inadequate sterilisation of surgical equipment leading to intraocular infection.³⁶

Safeguards that can be deployed

Reflection on the above items will allow for insight into what systematic measures are required to overcome unsafe situations. Additional methods, summarised below, should also be deployed.

Governance. Regular peer review and multidisciplinary clinical governance meetings where patient safety incidents are discussed are advisable. Referral of concerns and/or solutions for improvements up to higher organisational levels for action.

Audit. The use of national and regional cataract audits, use of computerised audit systems to track outcomes, and the development of regional clinical networks.

Surveillance. Surveillance methods to capture and analyse rare events in cataract care are helpful. Such

work has been undertaken by the British Ophthalmic Surveillance Unit.³⁷

Systems approaches. Organisations should encourage safer practice and the avoidance of dangerous practice. For example having a systems approach to attempt to eliminate wrong site surgery; avoiding the use of dangerous or confusing abbreviations and having standard operating procedures or checklists in place.

Patient involvement. Patients and their carers need to be involved in their cataract diagnosis and subsequent care pathway, for example asking the patient to state their identity and condition to help prevent wrong site surgery. Ensure that postoperative care plans are both communicated to patients and understood. Patients should be fully informed without delay about any incidents that affected them.

Teamwork. Ensure that the team is suitably trained and familiar with the activity required. Taking 'time out' before surgical intervention to ensure that all team members are in agreement, or understand, the intended procedure.

Use of evidence base and standards. Not conforming to evidence-based medicine presents risks.³³ Extra resources may be required to put in place mitigating actions to reduce these risks.

Incident reporting. Major international studies from the USA,³⁸⁻⁴⁰ Australia,⁴¹ and UK⁴² have consistently shown both the magnitude of patient safety incidents and the under-reporting of such incidents. Doctors under-report, or have major barriers to reporting, patient safety incidents.^{12,43} Where reporting systems are based on reports submitted by only one professional group, the data are likely to be inaccurate.⁹ The experience from other sectors, such as the aviation industry, shows that as reporting levels increase, the number of serious incidents begins to decline. Experience also suggests that the features of successful reporting systems include confidential reporting systems that are systems orientated with both timely feedback and expert analysis.⁴⁴

Patient safety incident reporting

Patient safety incidents or adverse events should be reported for all NHS patients, regardless of whether treatment took place in the NHS or in the independent sector so that the learning can be shared. The NPSA has developed the National Reporting and Learning System (NRLS) to develop learning about patient safety incidents with a view to solution development (see www.npsa.nhs.uk). The NRLS will receive patient safety incident reports either via an electronic link from local clinical risk management systems or through a direct electronic internet-based reporting form from all English

and Welsh NHS organisations and contractor professions (such as general practitioners and optometrists), and in time, from patients and their carers.

Medication and device reporting

Adverse events relating to medical devices (including contact lenses and prescribed spectacles), medical device/user interface issues in England and Wales should be reported to the MHRA Devices Adverse Incident Centre (see www.mhra.gov.uk). The MHRA has been successful in improving designs or processes in many such matters. An annual report describes device-related adverse incidents and how these were dealt with.⁴⁵ Safety information from the MHRA is communicated to device users through Medical Device Alerts. All acute NHS Trusts have an MHRA Liaison Officer (usually located in the clinical risk department); he/she should be informed of all medication and device incidents.

Suspected adverse drug reactions should be reported to the MHRA medicines sector through the Yellow Card Scheme. This scheme has existed since the thalidomide tragedy highlighted the urgent need for routine post-marketing surveillance of medicines. An electronic Yellow Card is available at <http://www.yellowcard.gov.uk> and paper Yellow Cards are also widely available.

Consequential patient safety incidents in cataract care

The following examples illustrate some consequential patient safety incidents that require analysis.

Medication risks. Potential patient safety incidents arising from medication errors related to cataract surgery are listed in Table 3.

Healthcare acquired infections. Infections such as surgical site infections, which includes postoperative presumed infectious endophthalmitis, are topical.⁴⁶ Methods of prevention of endophthalmitis have been considered.³¹ Timely treatment of both the individual patient with postoperative endophthalmitis and the investigation of endophthalmitis are needed. It is wise to have standard operating procedures for the antibiotic treatment of presumed infectious endophthalmitis cases prepared in advance, guidance for investigation of outbreaks are available from the Royal College of Ophthalmologists.⁴⁷

Correct site surgery. The ophthalmic surgeon is ultimately responsible for assuring that the correct operation is carried out on the correct patient's correct eye. The Royal College of Surgeons advises marking the surgical site to be operated on.⁴⁸ Abbreviations and acronyms should be avoided. The patient should be involved in confirming the correct site. Care should be

Table 3 Medication patient safety incidents, cataract surgery

- Infusion fluid issues: additives to intraocular infusions; mix-up of concentrations and dilutions.
- Errors with viscoelastic and other medications injected into eye.
- Retinal or endothelial toxicity from incorrect dose of drug, or correct dose injected into wrong compartment of eye, for example, antibiotic intended for subconjunctival injection given into the anterior chamber or topical agents (eg methylcellulose) injected intraocularly.
- Wrong eye drops prescribed, dispensed or instilled.
- Allergy: patient known allergy ignored or not-requested.
- Potentially predictable adverse drug reactions or interactions in at risk patients, for example acetazolamide and retention of urine, beta-blocker eye drops and asthma.

Table 4 Potential causes of incorrect IOL implantation

- Incorrect measurement of axial length.
- Incorrect keratometry readings.
- Data entry errors into the IOL calculation program or use of incorrect formulae.
- Incorrect labelling or packaging of IOL by manufacturer.
- Mistakes in providing the correct IOL, such as mix-ups with an IOL for another patient or not having the correct implant in stock on the day.

taken where patients have similar names. Marking of the correct eye for surgery is recommended.⁴⁹ The Correct Site Surgery Alert is now available at www.npsa.nhs.uk. Cataract surgeons and provider organisations, who do not mark the eye preoperatively, should ensure that they have robust alternative systems in place to prevent wrong site surgery (WSS). Litigation claims are often associated with ophthalmic wrong site surgery events.⁵⁰

Wrong IOL placement. The surgeon is ultimately responsible for assuring that the correct implant is placed at the time of surgery.⁵¹ Potential risks leading to incorrect IOL placement are summarised in Table 4.

Failure of implanted devices. This can result in IOL opacification, IOL dislocation, poor IOL quality (leading to uveitis–glaucoma–hyphema syndrome), or unwanted optical images that may require IOL explantation.

Anaesthesia hazards. Anaesthesia hazards from either general or local anaesthesia, including ocular perforation from local injections. Access to resuscitation and arrangements for swift transfer to high dependency or intensive care should be considered by both providers and commissioners of cataract care.

Surgical misadventures. Problems include phacosurge, incision site burns, expulsive haemorrhage, dropped nucleus and may result from lack of familiarity of staff with equipment and/or technique.

High-risk patients. Stratification of risk or complexity of cataract surgery for known patient risk factors has been

recently proposed,^{52,53} and may assist in appropriate patient selection for surgery for ophthalmic trainees.⁵⁴

Communication problems. Poor written or verbal communication may enhance risk. Poor handwriting in case notes is a potent source of error. Patients should be encouraged to ask questions about their cataract care. Language barriers are important when the patient's first language is not English or in individuals with learning difficulties or hearing impairments. Poor communication may also be a risk where the first language of clinical staff is not English. Problems have surfaced with the advent of overseas clinical teams providing care in the UK (oral communication at the North West Regional Ophthalmology Audit Meeting, January 2003). The risks of surgery and required care plans may not have been adequately communicated to, or understood by, the patient. When asked, cataract patients want to know about both the potential risks and benefits of cataract surgery.⁵⁵ Good-quality printed or multimedia patient information and timely preassessment and booked admissions are suggested, and has been shown to reduce anxiety and promote recovery.⁵⁶ Caution needs to be deployed when offering 'patient choice' to ensure that patients are given sufficient information on safety to make an informed choice.⁵⁷

Equipment problems. Failure or nonavailability of equipment is a potential cause of risk during cataract surgery. Regular servicing and preoperative checking of equipment is good practice. Before cataract surgery, ensure that anterior vitrectomy surgical equipment is available if required. It is important to plan in advance for potential 'surprises'.

Staff orientation. Considerable caution should be taken by staff working in unfamiliar surgical environments and with unfamiliar equipment, particularly paramedical and nursing agency and 'bank' staff, medical locums, and 'itinerant' cataract surgeons. The latter individuals may have multiple problems of unfamiliarity with the patient, with the surgical team, with local equipment and with established local or national guidelines. Purchasers need to undertake robust risk assessment of such high-risk care. Staff should receive both orientation and training with local equipment and practice on appointment with regular updates as needed.

Barriers to incident reporting

There are still many barriers to reporting patient safety incidents: such as cumbersome and nonstandardised local paper reporting formats; not knowing what to report; a litigious and blame culture that deters open reporting and discussion; the criminalisation of medical error;⁵⁸ difficulty with identifying and reporting errors of omission; a long interval between error and adverse

outcome (eg, corneal de-compensation following traumatic cataract surgery); deficiencies in information synthesis, poor analysis of reports; lack of feedback; and failure of institutions to address improvements in processes of care.^{44,59}

Critical patient safety incidents in cataract care

Serious adverse events leading to significant harm such as unexpected death or lasting disability (eg loss of sight), or that are a cause for concern by staff or patients, may be regarded as 'critical incidents'. A critical incident may be considered as a significant patient safety incident event that either led to permanent harm or death, or could have done so, if it had been allowed to progress. This concept emphasises both severity and potential preventability of an incident.

Table 1 displays the critical patient safety incidents in cataract care proposed by the Royal College of Ophthalmologists.⁶⁰ These events might be regarded as 'action points' to analysis of root causes. This list is intended to be practical and is neither exhaustive nor exclusive. Close attention should also be paid to patient complaints. While all patient safety incidents result from clinical management, not all are preventable (ie, wholly attributable to avoidable errors). A patient having cataract surgery who suffers from postoperative endophthalmitis has had a serious patient safety incident. The analysis of the case history, perioperative events, staffing issues, facilities, and results of microbiology investigations may clarify if it was a potentially preventable incident, such as a sterilisation equipment failure, or a procedural failure, for example, failure to use appropriate preoperative iodine chemoprophylaxis. Alternatively, no specific plausible root causation may be found.

Conclusion

Clinical incidents and both expected and unexpected surgical complications will occur and may provide an opportunity for future learning to reduce the risk of similar events occurring. The Royal College of Ophthalmologists is committed to supporting measures to improve the quality and safety of cataract care at both individual patient and surgeon level and at organisational levels. Investment in staffing levels, training in patient safety, appropriate equipment and facilities provision and development of a safety culture with patient involvement are key elements to modern safe cataract care. Planning for patient safety is required both at the individual patient level and importantly at commissioning and policy-making levels.

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