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REVIEW

Guidance on patient safety in ophthalmology from the Royal College of Ophthalmologists

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Abstract

Objective and method **Safer care is a strategic priority for healthcare organisations. Yet, the detail of how to improve patient safety is complex. To this end the Royal College of Ophthalmologists has provided guidance to improve ophthalmic patient safety, and is presented in this paper. Which patient safety incidents to report and analyze in ophthalmic practice are outlined and how to do so is also discussed. The focus and setting of this review is on the current organisation of healthcare in United Kingdom and primarily—but not exclusively—within the National Health Service (NHS) provision, as relevant to ophthalmology.**

Conclusions **Efforts for improvement in ophthalmic patient safety and quality of care are vital and require professional leadership and engagement. The Royal College of Ophthalmologists' role and position in this regard is outlined.**

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Introduction

Healthcare quality and safety and clinical governance are interlinked. Standards of practice for ophthalmic care are available in guidelines from the Royal College of Ophthalmologists (the College), the National Institute for Health and Clinical Excellence (NICE), and others, and in position papers from the College's Professional Standards Committee. The maintenance of such standards in ophthalmology at organisational level is achieved through adequate staffing levels, proper facilities, and appropriate managerial support. The quality of ophthalmic care for National Health Service (NHS) patients has greatly improved with new technologies, care pathway modernisation, improved investment and shorter patient referral to treatment waiting times. Strict attention to detail and careful consideration of the patient pathway is needed to maintain and to enhance ophthalmic patient care and service delivery.

However, despite the above mentioned, clinical and non-clinical, or organisational errors, incidents, and complications will happen and often recur. Such events often provide a rich opportunity for learning, if properly considered. Actions taken in response to such incidents will reduce the risk of similar events recurring. In 2008 the College provided refreshed guidance on patient safety.[1] Key points from this guidance follow.

Quality safety and clinical governance

The road to improving patient safety is long and complicated, and remains an ongoing concern. Florence Nightingale's[2] observation on the organisation of healthcare, 'It may seem a strange principle to enunciate as the very first requirement in a hospital that it should do the sick no harm' is as relevant today as when written in 1863. Disastrous issues of unsafe ophthalmic care have also been long recognised.[3,4] Clinical governance is a duty of care also long recognised by clinicians. It was defined by the Department of Health in 1998 as, 'a framework through which NHS organisations are accountable for continuously improving the

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quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish'.

On the basis of this concept, effective clinical governance in ophthalmology should ensure the following:

- Continuous improvement of patient services and care.
- A patient-centred approach that includes treating patients courteously, involving them in decisions about their care, and keeping them informed.
- A commitment to quality, which ensures that ophthalmic teams are up-to-date in their practices and properly supervised, where necessary.
- The prevention of errors, wherever possible, and the commitment to learn from mistakes and sharing that learning with others in a no-blame (or shared-blame or shared-responsibility) environment and culture.
- Optimal use of resources. However, this was not a component of the Department of Health's definition of Clinical Governance in 1998.[4]

  Quality and safety of patient care are intimately interlinked with clinical and organisational governance and management. Good planning and then doing the correct thing for the correct patient in the correct setting, as well as learning from those occasions when incorrect care has occurred is a pragmatic lens through which these concepts can be viewed. Quality and safety are intuitively recognised when present and glaringly obvious when absent. Patient safety and quality of care, thus constitute the foundations of care and of service provision. There has been an explosion of interest in patient safety in the last decade globally, and the literature and citation counts reflect this interest.[4,5]

Clinical error and patient safety

Owing to large number of patients undergoing ophthalmic surgical and outpatient care, the complexity of care and overarching service and performance pressures, it is inevitable that some clinical errors or adverse patient safety incidents can or will occur. Further, patients requiring ophthalmic surgery are often of a higher clinical risk profile. They are frequently either elderly with concomitant medical conditions or young children, thus enhancing the dangers of surgery. Errors in healthcare have huge physical emotional and health economic consequences for all concerned. Increasingly, it is believed that systems failures, or organisational failures, underlie many patient safety incidents.

Clinical error

Clinical error may be regarded as failure of a planned clinical action to be completed as intended, or the selection of an incorrect action to achieve an aim. Errors can include problems in clinical practice and products, non-clinical procedures and systems. The adage 'To err is human' is recognised, however many errors can be prevented. Studies of errors, or accidents, in industry, transport, and military spheres have led to a much broader understanding of accident causation. In these industries there is less focus on blaming the individual who makes the error, and more on identifying any potential remedial organisational factors, or system failures. Clinical staff should also be encouraged to learn from their experience of delivering healthcare—both from failures as well as from successes. With an estimated 850 000 patient safety incidents occurring annually in the NHS, improving patient safety is vital.[8,9] Approximately one third of the adverse incidents lead to some form of disability or even death. Furthermore, there is consistent evidence that up to 50% of the fatal clinical incidents may be somehow preventable.[10,11]

With the recent and welcome reduction in waiting times and excellent progress towards the 18-weeks referral to treatment target time being achieved in most specialities in NHS care, the emphasis is now shifting to the continuation of improvements in the quality and safety of patient care, as well as to the sustainability of such short waiting times. Analysis of these topics in the light of the extra investment in healthcare in the United Kingdom and the NHS reforms since 1997 is currently topical.[12] Furthermore, in recent indications from government—in the '*NHS Next Stage Review*'—quality and safety along with increasing personalisation of care, will now shape the next stage of progress for the NHS in England.[13] The 2008 review of the next stages for the NHS by Lord Darzi also heralded the establishment of a 'Commissioning for Quality and Innovation' (CQUIN) scheme and has resultantly also lead to the publication in 2009 of 'Indicators for Quality Improvement' for NHS care in England available at https://mqi.ic.nhs.uk.

Patient safety

Patient safety applies to initiatives designed to prevent or reduce adverse outcomes from clinical error. Patient safety has been 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'*

Improvement in patient safety encompasses several activities: making errors visible, learning from errors, preventing errors, and mitigating the effects of errors. Clinical risk management, clinical audit, teamwork, total quality management, research, education, and

continuous professional development thus underpin the concept of patient safety. Patient safety is the watchword of quality patient care.

Why do errors occur?

In the great majority of cases, the causes of serious failures stretch far beyond the actions of those individuals immediately involved. Safety is a dynamic and not a static situation. In a socially and technically complex field, such as health care, a huge number of factors are at work at any one time that may influence the likelihood of failure. Studies from organisational psychology,[14,15] military history, and high-risk industries suggest that safety incidents are a combination of the following:

- Active failures: 'unsafe acts' committed by those working at the sharp end of a system, which are usually short-lived and often unpredictable.
- Latent conditions: that can develop over time and lie dormant before combining with other factors or active failures to breach a system's safety defences. They are long-lived and, unlike many active failures, can be identified and removed before they cause an adverse event. However, if systems are not monitored or scrutinised, then the latent conditions may become an accepted and embedded part of the culture.

How can patient safety be improved?

(Box 1)

Box 1 Seven Steps to Patient Safety—A Guide for NHS staff available at www.npsa.nhs.uk/sevensteps

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 public
Step 6	Learn and share safety lessons
Step 7	Implement solutions to prevent harm

Promote reporting

The report *An Organisation with a Memory*[9] acknowledged that there has been little systematic learning from adverse events and service failures in the NHS in the past, and drew attention to the scale of potentially avoidable events that result in unintended harm to patients. An *Organisation with a Memory* proposed solutions based on developing a culture of openness, the reporting of patient safety incidents and a greater safety consciousness within NHS organisations. This report led to the introduction of a new NHS system for identifying and reporting adverse events and near misses. Consequently the National Patient Safety Agency (NPSA) was formed.[16] All ambulance, mental health, acute hospital, and primary care NHS trusts in England and Wales now provide anonymised patient safety information to the NPSA through the Reporting and Learning System (RLS), which is connected to all local clinical risk management systems. The objective is to examine overlying themes and trends from that information, and to feed alerts and solutions back into clinical practice. Information can come from healthcare organisations and/or also directly from staff, patients and caretakers, using an e-form available on the NPSA's website. Currently there are over 3.4 million patient safety incident reports recorded on the RLS. Updated reports of patient safety incident data are published quarterly on the NPSA website.

Team meetings

Patient safety incidents should be analysed locally with a view to education of all team members and to aspire to prevent harm to future patients. The College thus encourages all ophthalmic teams to hold regular multi-disciplinary clinical governance meetings, and recommends that all Eye Departments have an identified Clinical Governance or Patient Safety Lead. Usually this person will have a role within the hospital Trust's Clinical Governance structure. He/she should organise the ophthalmic clinical governance meetings. Such activity should also help NHS Trusts securing compliance with risk management standards as recommended by the NHS Litigation Authority.[17]

Use and share information

Safety can be improved by taking into account safety-related information from a variety of existing reporting systems, for example the National Confidential Inquiry into Patient Outcome and Death (NCEPOD), formerly Peri-operative Deaths, the work of the British Ophthalmic Surveillance Unit (BOSU), the published literature and experience gained internationally. Regulator reports, such as (former) Healthcare Commission annual and investigation reports, legal reports, and medical defence society newsletters[18] are useful sources of patient safety and error knowledge. Several other sources of potential safety material may be available locally, such as incident reports, complaints, clinical audit results, clinical quality proxy measures—such as return to theatre data from Patient Administration Systems, case note reviews, etc. All can

be usefully combined to better understand and triangulate local organisational safety issues. The safety conscious ophthalmologist will also study the wealth of sources of information, which includes textbooks and reports, [19,20,21] websites, experience from other ophthalmic healthcare settings[22] to better inform and improve his/her practice and to underpin his/her CPD. Box 2

The World Alliance for Patient Safety aims to facilitate the development of patient safety policy and practice in all member states of the World Health Organisation.[23,24]

Analysis and feedback

If risks are identified, work can be undertaken to produce solutions to reduce the risk of future harm, and establish mechanisms to track progress. Improvement will best come from learning from past incidents and ensuring that both lessons learnt and solutions developed are fed back into healthcare at all levels, that is, both where treatment is commissioned, where commissioning is overseen, and where ever care is delivered. Action to reduce risks and learn lessons should be disseminated widely and rapidly. Training in retrospective incident analysis, or 'root cause' analysis, is available from the NPSA and others. Prospective failure mode and effects analysis (FMEA) is an analysis tool (with a military and engineering history), to examine safety proactively and to attempt to prevent or mitigate incidents.[25] Analysis of significant patient safety incidents should ideally take place both within the local organisation, and at regional and national levels.

Culture and leadership

Mistakes should be recognised as being part of human life and endeavour, and that they provide opportunities to learn. However, learning cannot take place in a context where information about mistakes is disconnected; feedback is limited and where clinical staff and hospital management do not recognise vital interdependencies.[26] An open and fair culture is needed, and is now slowly emerging, to overcome barriers to patient incident reporting. Clinical leadership has a key role in safety, and ophthalmologists should be the leaders of ophthalmic patient safety. A 'fair culture' is a culture where if an individual makes an honest mistake and reports it no blame or disciplinary action is taken unless gross negligence or incompetence is proven.

Organisational culture

A 'fair culture organisation' is a healthcare (or other) organisation that promotes such actions and importantly

Box 2 Patient Safety; useful web links

Organisation	*Website*
United Kingdom (Selected websites)	
Association of Surgeons of Great Britain and Ireland Confidential Reporting system for Surgeons	www.coress.org.uk
Dept of Health; Patient Safety web pages	www.dh.gov.uk/en/Publichealth/Patientsafety/index.htm
Care Quality Commission	www.cqc.org.uk
Medicines and Healthcare Products Regulatory Agency	http://www.mhra.gov.uk/ophthalmology www.yellowcard.gov.uk
National Patient Safety Agency	www.npsa.nhs.uk
Quest for Quality and Improved Performance Research Initiative Health Foundation	www.health.org.uk/qquip
Royal College of Ophthalmologists. Ophthalmic Services Guidance	www.rcophth.ac.uk/standards/ophthalmicservices
International (Selected websites)	
Agency for Healthcare Research and Quality	www.ahrq.gov
Australian Commission on Quality and Safety in Healthcare	http://www.safetyandquality.gov.au/
Health Information and Quality Authority	www.hiqa.ie
The International Society for Quality in Health Care	www.isqua.org
Joint Commission (Patient Safety section)	http://www.jointcommission.org/PatientSafety/
World Alliance for Patient Safety	www.who.int/patientsafety/en/
WHO Collaborating Centre on Patient Safety Solutions	http://www.ccforpatientsafety.org
Selected Journals; Patient Safety	
'Quality and Safety in Healthcare'	http://qshc.bmj.com
'International Journal for Quality in Healthcare'	http://intqhc.oxfordjournals.org/

an organisation management who listen to staff who highlight problems, which have the potential to threaten patient safety locally. NHS culture is a complex concept, and culture change and policy reform is a slow process.[27] It is uplifting that the '*Charter for the Safety of Patients*' now has around 30 signatory organisations including the Academy of Medical Royal Colleges, the NPSA, and the Healthcare Commission.[28] The Chief Medical Officer's report '*Safety First*' provided refreshed guidance and refocus on patient safety to NHS organisations.[29] This refreshed guidance also highlights the importance of training staff in patient safety and in sharing best practice. Instruction and taught courses in patient safety are available from the United Kingdom and international academic providers.

Vigilance

Although systems or organisational factors are increasingly recognised as causing (where weak) or preventing (where robust) patient safety incidents, it is also recognised that those in direct contact with patients, particularly junior clinical staff, often have little opportunity to reform systems. Professor James Reason has observed that some organisational accident sequences can be thwarted at the last minute if those on the frontline had acquired some degree of 'error wisdom' or vigilance.[30] Simply stated this is being aware of the context of one's work, the task in hand, and one's personal state and all factors which may impinge upon these three domains. A helpful online training module on 'foresight awareness', largely based on Professor Reason's hypothesis on the desirability for error wisdom, is available.[31]

Whose responsibility is patient safety?

Improving patient safety is a multi-faceted task and requires individual responsibility, and multi-disciplinary and organisational commitment. [32,33] Simply stated, it is everyone's responsibility. This is now further explored.

Professionalism

Significant improvement in attitudes to clinical quality and patient safety will only be achieved by doctors taking the lead in planning day-to-day care, and in the training of junior clinical staff in patient safety and quality improvement. Although 'key NHS Agencies' may 'facilitate' improvements and pronouncements on patient safety may be made from on high, and new regulations and legislation passed in Parliament, there will be little progress without effective and respected clinical leadership at local and higher levels. Clinically lead training and the development of a self-improvement culture in ophthalmic patient safety by eye-care staff are the key to safer care. For example, improved training of staff in biometry and better understanding of the principles to be used in complex cases (eg, in patients who have had previous corneal refractive surgery) by continued professional development are more likely to reduce the incidence of wrong IOL insertion in cataract surgery when used in conjunction with appropriate checklists than are diktats, especially if from non-clinical agencies, on reducing wrong implant cataract surgery

NHS trusts

Systems failures for NHS patients are the responsibility of the NHS Trust's Chief Executive Officer and his/her delegate under the Clinical Governance framework. As part of the Annual Health Check, NHS Boards have to declare compliance with '*Standards for Better Health*', 11 of which are safety-related, and which cover matters such as whether the organisation reports and learns from incidents. NHS Trust Boards require information from clinical directorates in order for them to assess whether the organisation is compliant or not. The Corporate Manslaughter and Corporate Homicide Act now makes it easier to prosecute organisations where gross failures in the management of health and safety leads to death.[34]

Independent sector organisations

Independent sector providers are also strengthening their quality and clinical governance frameworks for both 'traditional' private patients and for NHS patients treated in the independent sector, such as in Independent Sector Treatment Centres (ISTCs). The Healthcare Commission had responsibility since 2004 for regulating and inspecting the NHS and independent healthcare sector in England; the latter was previously the responsibility of the National Care Standards Commission. Responsibility for local inspection and investigation of the NHS and independent sector in Wales rests with the Healthcare Inspectorate Wales (HIW). Broadly equivalent bodies in Scotland and Northern Ireland, respectively, are the NHS Quality Improvement Scotland and the Regulation and Quality Improvement Authority. When NHS patients are treated in ISTCs they remain NHS patients. NHS Commissioners are responsible for overseeing clinical governance issues in these locations, as is the ISTC partner in their delivery. ISTCs are required to submit key performance indicators (KPIs) to the Department of Health, which were included at the outset as part of their individual Project Agreements, that is contracts, with sponsors. Such KPIs should include patient safety incidents.

Care Quality Commission

The Care Quality Commission (CQC) replaced the Healthcare Commission. It has taken on responsibility for the regulation of health and adult social care from April 2009. [35] In England and Wales, registered independent healthcare providers are obliged to comply with Private and Voluntary Healthcare Regulations 2001 (England) or 2002 (Wales). These include Regulation 28 (Regulation 27 in Wales)—Notification of Events, such as the death of a patient, any serious injury to a patient, the outbreak in an establishment of any infectious disease, and any allegation of misconduct resulting in actual or potential harm to a patient. Further details at www.cqc.org.uk

NHS strategic health authorities

Strategic Health Authorities have a responsibility for ensuring that clinical governance, including patient safety, is delivered across their geographical area and will receive Serious Untoward Incident reports (see later section) from local services. Regional NPSA Patient Safety Managers work closely with regional or strategic NHS offices. Strategic Health Authority clinical governance leads should be advised of any threats to patient safety that might be occurring across care commissioning or delivery boundaries. This is increasingly necessary with the introduction of novel healthcare purchasing and provision arrangements, often being developed regionally, such as ISTCs, polyclinics, Clinical Assessment and Treatment Services (CATS), overambitious outsourcing to optometry, and the use of overseas clinical teams.

What is a patient safety incident?

A patient safety incident (PSI) 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'. In the College's view this definition should be extended to all healthcare settings. An International Classification for Patient Safety (ICPS) is currently being developed and field-tested by the World Health Organisation. Patient safety incidents were sometimes referred to previously as adverse events/incidents. It should be noted that this definition also includes prevented PSIs, or incidents with no untoward consequences. These are commonly referred to as 'near misses', being similar to near collisions in aviation or motoring.

Serious untoward incidents

Serious untoward incident (SUI) reporting is designed to inform Strategic Health Authorities and the Department of Health about incidents that require urgent attention. SUIs are not restricted to patient safety incidents as they might include other matters, such as criminal acts or environmental incidents or issues thought to attract media attention or lead to litigation. An SUI panel is set up by the Trust concerned to investigate the incident within a stipulated period of time, as well as to provide support and assistance. If this is a clinical incident, the patient involved and/or her immediate relatives should be informed of this investigation and its progress. Ophthalmic incidents that might be considered as a SUI might include unexpected patient death during ophthalmic surgery, or an outbreak of several cases of post-operative endophthalmitis, or corneal decompensation due to intraocular medication adverse reaction. Although there are established general criteria available from Strategic Health Authorities for declaring an SUI, a degree of judgement in deciding whether to report an incident as an SUI, will need to be made by the local NHS management. A SUI panel investigation report and action plan should be generated within 60 working days of the incident being declared an SUI. In reality such work usually takes longer.

Which patient safety incidents should be reported?

Many treatments have associated adverse events or side effects. Some, such as ocular stinging from prescribed eye-drops, may be classed as discomforts, rather than minor adverse events, do not pose harm, and therefore do not require reporting. Also many aspects of healthcare have some degree of patient harm. For example, it is necessary to incise the cornea to remove a cataract. Serious adverse events from interventions that lead to significant or permanent harm, such as unexpected death or disability—such as loss of sight, or are a cause of concern to staff, or patients, should be especially reported and investigated. Furthermore, 'near misses' especially where remedial action was taken, provide rich educational benefits to healthcare staff, contributing to future patient safety. Thus, there is a view that most, if not all, patient safety incidents should be reported.

It is also recognised that many staff, especially medical staff, do not report patient safety incidents, for a variety of reasons. Under reporting is problematic.[36] In efforts to clarify reporting matters some Royal Colleges have given direction on which specific, significant, or 'critical' patient safety issues should be reported. A Critical Incident may be considered as a patient safety incident that either led to significant harm or could have led to such harm, if it had been allowed to progress. It may perhaps be preventable by a change of practice.

Patient safety incidents in ophthalmology, regarded as critical by the College, are shown in Tables 1–4. This list

Table 1 Patient safety incidents (THEATRE)

i	Unexpected peri-operative death
ii	Operation on the wrong eye, or wrong patient
iii	Wrong operation on correct eye, includes wrong implant
iv	Penetration or perforation of globe during periocular injections
v	Expulsive haemorrhage during eye surgery
vi	Endophthalmitis within 6 weeks of eye surgery
vii	Patient collapse requiring resuscitation during eye surgery
viii	Unplanned returns to theatre or readmissions
viii	Surgical device failure
ix	Missing case notes at surgery
x	'Open' category for adverse incidents causing concern among staff or patients for whatever reason, including anaesthetic matters

Table 2 Patient safety incidents (CLINIC)

i	Delayed diagnosis of intraocular foreign body
ii	Delayed/ missed diagnosis of intra-cranial tumour
iii	Delayed diagnosis of retinal tear
iv	Failure to screen ROP leading to visual loss
v	Missing case records
vi	Contact lens, or contact lens solution, related keratitis (patients may be encouraged to report incidents themselves)
vii	Opacified or faulty intraocular lenses
viii	Inappropriate discharge from OPD follow-up or DNA policies (a concern for the vulnerable, eg, learning disability patients)

Table 3 Patient Safety Incidents (MEDICATION)

i	Wrong drugs instilled or dispensed
ii	Prescribed drugs not provided
iii	Wrong prescription
iv	Wrong dose/method/route of application
v	Serious adverse drug-related incident (inform MHRA)
Vi	Any adverse drug-related incident on a black-triangle medication (eg, VEGF inhibitors)

Table 4 Patient Safety Incidents (WARD or DAYCARE)

i	Patient on wrong ward
ii	Patient misidentification
iii	Poor control of ophthalmic patients' medical status for example, diabetes
iv	'Open' category for adverse incidents causing concern among staff or patients for whatever reason

is intended to be a practical aid and is neither exhaustive nor exclusive. More disease specific patient safety incident examples are included in the College Guidelines, as for example in the Cataract Surgery Guidelines.[37] Critical incidents are sometimes known as 'sentinel events' in the United States of America and Australia. This concept emphasises both severity and (potential) preventability of an incident. For example, an anaphylactic reaction to penicillin is a recognised and serious adverse drug reaction. It is a critical incident however, if the patient's intolerance of penicillin was noted in his/her medical record chart, or communicated by the patient, and this information was not considered.

Although all patient safety incidents result from clinical management, not all may be preventable (ie, not all are wholly attributable to errors). For example, a patient having cataract surgery who suffers from postoperative endophthalmitis has had a serious patient safety incident.[38] Root cause analysis of the case history, peri-operative events, staffing issues, facilities, results of microbiology investigations, etc, may clarify if it was a potentially preventable adverse incident (such as a sterilisation equipment failure or failure to use appropriate pre-operative iodine chemo-prophylaxis), or not.

How to report patient safety incidents?

Local systems

Where patient safety incidents occur, local NHS Trust reporting procedures must be used. Such local risk management systems are often paper based but, increasingly, electronic solutions are available. This includes documentation of the clinical incident, in the patient's clinical case notes, and on the appropriate local clinical incident reporting paper or electronic forms. Patients should be fully informed, without delay, about incidents that affected them.

National system

The Reporting and Learning System (RLS) at the NPSA receives patient safety incident reports from all English and Welsh NHS organisations, staff, contractor professions—such as general practitioners and optometrists—patients and their caretakers. Reports are received either through an electronic link to local automated clinical risk management systems, or through a direct electronic internet based reporting form, for staff, available at http://www.npsa.nhs.uk/staffeform Details of reported incidents are anonymised.

The greater the quantity and quality of patient safety incidents reported, the more meaningful will be the analysis, which will assist in subsequent solution development. More patient safety reports do not imply worse care. Rather it is increasingly recognised that high reliability organisations and safety conscious individuals are more likely to report more incidents including minor incidents and near misses.

Reporting medication and device incidents

Adverse events from medications and devices (including contact lenses and prescribed spectacles) should be

reported to the Medicines and Healthcare products Regulatory Agency (MHRA). A portal for reporting ophthalmic device related incidents to the MHRA is available on the College website. The use of non-anonymised reports enables the MHRA to thoroughly investigate specific device-related incidents through close liaison with the reporting clinician and the manufacturer, a process not easily possible with the anonymised data of the RLS at the NPSA.

Ophthalmologists may have been reticent in reporting device related events, such as opacification of IOLs, possibly because of low awareness of device incident reporting protocols, or the complexity of reporting systems. We hope this will now improve.

Where an incident report made to the MHRA clearly indicates that the problem relates to the use of the device (ie, user error) rather than the manufacture, maintenance or function of the device itself, details of the incident may be forwarded, in an anonymous format, to the NPSA.

Yellow card scheme

Incidents involving defective medicines should be reported to the medicines sector of the MHRA. Suspected adverse drug reactions (ADRs), not thought to be consequences of defective products, should be reported to MHRA medicines sector through the Yellow Card Scheme. This scheme is in existence 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 Paper Yellow Cards are widely available and be found in publications such as the British National Formulary.

Role of the College

The Charter of the Royal College of Ophthalmologists states that the College should *'maintain proper standards in the practice of ophthalmology for the benefit of the public.'* Accordingly the College places great emphasis on patient safety and best clinical practice as educational features and competencies for ophthalmologists and recognises both as core features of good ophthalmic service provision. The General Medical Council and the Courts take similar views. However, although the College is not a regulator it does have a continuing interest in the integrity and reputation of its Fellowship. Developing an understanding of the principles of patient safety features heavily in the College's training curriculum. Patient safety aspects of ophthalmic care are featured in relevant College Clinical Guidelines and in the College guidance to commissioners.

Keep the College informed

The College would like to be advised of any threats to the good practice of ophthalmology services (ie, the quality and safety of care) and also of novel improvements therein emerging at local levels, so that a wider perspective might emerge. The College is therefore keen to learn from patient safety concerns and or quality improvements where ever they occur so that lessons can be shared and may be brought to wider attention, if required or appropriate.

The NPSA liaises with the College's Quality and Safety Sub-Committee when concern arises surrounding ophthalmic matters, where appropriate. Short articles have resultantly appeared in the College's newsletter *College News* based on searches of ophthalmic incidents on the RLS and otherwise coming to attention. Recent examples included items on errors with correct IOL implantation in the winter 2008 edition and errors with intraocular injections published in the summer 2009 edition. Specific alerts from the NPSA in relation to glaucoma patient follow-up have been released and to which the College has had significant input in 2009.

Quality improvement

The College welcomes Quality Improvement Reports in ophthalmology and encourages eye care professionals to submit such reports for presentation at College Congress or as memoranda or reports to the College's Quality and Safety (QaS) Sub-Committee or for peer reviewed publication. Suggestions on how best to present such reports in the literature are available.[39] Help from QaS Committee members is available to ophthalmologists seeking to improve the quality and safety of ophthalmic care and to those seeking to highlight or publicise such achievements.

College ECATs

The College is able and willing to provide specialist advice to the regulatory bodies, or directly to commissioners or providers on request. College External Clinical Advice Teams (ECATs) are available to be deployed by the College to assist with quality or safety issues in ophthalmology locally when needed and where requested by healthcare providers.

Conflict of interest

The authors declare no conflict of interest.

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