PATIENT SAFETY IN OPHTHALMOLOGY

Summary

The role of professional organisations in the pursuit of quality care is long-established. The Royal College of Ophthalmologists champions excellence in ophthalmology for the benefit of patients and the public.

Safe care is fundamental to quality care and is strategic priority for health care organisations. Yet, the detail of how to improve patient safety is complex. To this end the College has provided guidance to improve ophthalmic patient safety. The last such paper was in 2008. Which patient safety incidents to report were then listed (see Appendix) and how to do so was also outlined. Such guidance remains unchanged in principle. In summary ophthalmologists should complete a local clinical incident report for all such patient safety incidents. Device/medication failures and adverse drug reactions should be reported to the MHRA and via the Yellow Card scheme respectively.

2010 saw a new Coalition government in the UK and the launch of a White Paper that will change the structure of NHS. The focus of the present review is to provide an update on the organisation of patient safety developments since the 2008 patient safety guidance was presented and as relevant to ophthalmology in these times of NHS structural change.

In conclusion 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 in these is again outlined and updated.

Prepared by members of the College’s Quality and Safety (Q&S) Sub-Committee in February 2011.
Index

Introduction ........................................... Page 3

Political change driving patient safety forwards .... Page 3

Patient Safety Reporting must continue ............. Page 4

Team Working and Culture ............................... Page 6

Healthcare Organisations; Developments .......... Page 8

Promoting safety for Patients with Disabilities .... Page 12

Role of the College ..................................... Page 12

CONCLUSION AND SUMMARY ......................... Page 13

References ............................................... Page 15

TABLE 1: Patient Safety Incidents (THEATRE) .... Page 16

TABLE 2: Patient Safety Incidents (CLINIC) ....... Page 17

TABLE 3: Patient Safety Incidents (MEDICATION) Page 17

TABLE 4: Patient Safety Incidents (WARD or DAYCARE) Page 18
1 Introduction

Healthcare quality and safety and clinical governance are interlinked. Standards of practice for ophthalmic care are available in guidelines from the College and the National Institute for Health 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 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, 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 Royal College of Ophthalmologists (the College) provided guidance on patient safety and which was also published as a review article in Eye in 2009.1,2 Key principles from that guidance remain unchanged. Some political and organisational changes which have occurred since then with implications for the patient safety arena in the UK are reviewed to bring the reader up to date.

2 Political change driving patient safety forwards

The former Labour government -in the ‘NHS Next Stage Review’- stressed that quality and safety along with increasing personalisation of care would shape the next stage of progress for the NHS in England.3 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 as a result also lead to the publication in 2009 of ‘Indicators for Quality Improvement’ for NHS care in England available at https://mqi.ic.nhs.uk
In July 2010, the new U.K. Coalition administration set out a bold and far reaching reconfiguration of NHS within the White Paper ‘Equity and Excellence: Liberating the NHS’. The White Paper declared that the NHS will “ensure that patient safety is at its heart” and that there will be no “trade-off between safety and efficiency”. That White Paper thus signalled that the new administration was also committed to the quest for quality and patient safety. The work of CQUIN and of a National Quality Board would see this translated into practice. In December 2010 the ‘NHS Outcomes Framework 2011/12’ stressed patient safety as a key domain for the NHS and proposes inter alia a number of general metrics related to patient safety.

The proposed structural changes following the White Paper in England will mean that 151 Primary Care Trusts (PCTs) will be replaced by a network of GP-led commissioning consortia, the number of these to be determined locally. The NHS Commissioning Board will begin life as a special health authority during 2011 and will become fully operational from April 2012. The new NHS Commissioning Board will combine functions of the Department of Health, Strategic Health Authorities, certain functions of PCTs, and some other NHS agencies, such as the National Patient Safety Agency. Changes to public health functions are also proposed.

3 Patient Safety Reporting must continue

Following several influential reports on patient safety, learning from clinical failure or incident is now widely regarded as a core principle underpinning improvement in patient safety. The National Patient Safety Agency (NPSA) (www.npsa.nhs.uk) was thus initiated. A patient safety incident (PSI) may be considered as an unintended or unexpected incident which could have or did lead to harm for one or more patients. This is also referred to as an adverse event/incident or clinical error and includes ‘near misses’. The NPSA includes a system for logging and gathering PSIs at national level following local reporting. Ophthalmologists and eye care teams should report such incidents using local clinical incident reporting systems at hospitals, both NHS and independent sector. NHS organisations in England and Wales forward all such reports to a national Reporting and Learning System (NRLS) repository database at the NPSA.
Following a review of Arms Length Bodies by the Department of Health it was announced that the NPSA is to be abolished in 2011. The College is disappointed that the NPSA will no longer exist in its current form. It is expected that NRLS will be taken forward by the NHS Commissioning Board.

At end of 2010 there were over 5 million patient safety incident reports -and circa 28,000 of which are from ophthalmology departments- on the NRLS database. If needed access to the NRLS database for review or research purposes is available to the College. Reports of clusters of endophthalmitis following intra-vitreal anti-VEGF injections have emerged at several hospitals in injection rooms in 2010 and via the NRLS. Breaches to aseptic no-touch technique may have been a factor. Delayed follow up of wet-AMD patients has also emerged as a patient safety concern in 2010 as did delayed follow up of glaucoma patients in 2009 and which lead to the NPSA rapid response report on glaucoma follow up patients. Problems with incorrect use of Luer lock syringes and insertion of ‘wrong’ IOLs have also come to attention via the NRLS and have been brought to the attention of College members.

Under-reporting is widespread and recent studies found that only a minority of NHS incidents are reported. In efforts to clarify and improve reporting the College gave direction on which specific, significant or ‘critical’ patient safety issues should be reported. That guidance remains unchanged. Patient safety incidents in ophthalmology, regarded by the College as critical, are shown in Tables 1-4. This list is intended to be a practical aid and is neither exhaustive nor exclusive. More disease specific patient safety incident examples are included in College Guidelines, as for example in the Cataract Surgery Guidelines.

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.
4 Team Working and Culture

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 has thus encouraged 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.10

Team Briefings, Checklist Use, De-Briefings
Parallels are often drawn between healthcare and aviation.11 It is recommended that clinical staff could adopt several safety traits of aviation; error assumption, procedure standardisation, and institutionalised safety. Checklist use similar to aviation pre-flight checklists has gained additional support with the World Health Organisation’s initiative ‘Safe Surgery Saves Lives’ (www.who.int/patientsafety/safesurgery/en/index.html) Both surgical checklist use and team training has provided evidence of benefit.12-15 In May 2010 the College and the NPSA launched a bespoke checklist for cataract surgery.16 In December 2010 the NPSA launched ‘5 Steps to Surgical Safety’.17

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.18 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 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. The former Chief Medical Officer’s report ‘Safety First’ provided a refreshed refocus on patient safety to NHS organisations. 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 UK and international academic providers. The recent NHS change agenda set out the 2010 White Paper is perhaps the most significant and complex that the NHS has faced. It will be undertaken in a highly challenging financial context, and at a time when staff and leaders across the NHS face personal and professional uncertainty about their futures. Given this context of structural reform it is vital that clinicians in NHS organisations remain focused on patient safety.

Vigilance

While 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 accidents could have been thwarted at the last minute if those on the frontline had acquired some degree of ‘error wisdom’ or vigilance. Simply stated this is being aware of the context of one’s work, the task in hand and one’s personal state and factors which may impinge upon these 3 domains. A training module on ‘foresight awareness’, largely based on Professor Reason's hypothesis on the desirability for error wisdom, is available.
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. While ‘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 inspirational clinical leadership at local and higher levels. Clinically led 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 cataract preoperative assessment (for example 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 on reducing wrong implant cataract surgery.

5 Healthcare Organisations; Developments

NHS Trusts
Systems failures for NHS patients remain 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 independent report by Robert Francis QC into failings in Mid Staffordshire NHS Foundation Trust has provided additional incentive to NHS Trusts to review their current clinical governance and reporting structures.\(^\text{22}\) The Corporate Manslaughter and Corporate Homicide Act now makes it easier to prosecute organisations for gross failures leading to death.\(^\text{23}\) From June 2010 there has been a requirement for NHS Trusts to produce Quality Accounts. The Quality Standards being
developed by the College may be an opportunity for ophthalmology departments to contribute to Quality Accounts.

**Independent sector organisations**
Independent sector providers have strengthened their quality and clinical governance frameworks for both ‘traditional’ private patients and for NHS patients treated in the independent sector, such as in some Independent Sector Treatment Centres (ISTCs) and in some laser refractive surgery facilities. 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, i.e. 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. 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

**Monitor**
Monitor is the independent regulator of NHS foundation trusts. Monitor looks to the CQC for judgements as to whether an NHS foundation trust is complying with their registration requirements and, more generally, in relation to the quality of care provided.

**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 section 5) from local services. The White Paper *Liberating the NHS* indicated that Strategic Health Authorities will cease by April 2012.

**National Patient Safety Agency**

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.

The NPSA developed the National Reporting and Learning System (NRLS) to develop learning about patient safety incidents. The NRLS receives patient safety incident reports from all English and Welsh NHS organisations, staff, contractor professions -such as general practitioners and optometrists- patients and their carers. Details of reported incidents are anonymised at the NPSA. Reports are received from Trusts via an electronic link to local automated clinical risk management systems. Direct electronic internet based reporting is also available at [https://www.npsa.nhs.uk/staffeform](https://www.npsa.nhs.uk/staffeform)

Following the review of Arms Length Bodies published by the Department of Health in 2010 the NPSA is to be abolished. We are disappointed that the NPSA will no longer exist in its current form. It is expected that NRLS will be taken forward by the NHS Commissioning Board. The expectation by the Information Strategy for the NHS is that incident reporting will continue to be a vital source of information and will be developed further to identify early warning signs of failure. The College will also seek to work with the NHS Commissioning Board to stress patient safety issues relevant to ophthalmology services. We advise continued reporting of patient safety incidents by College members via local clinical risk systems and we also request that the College be advised of any threats and indeed improvements to local patient safety and which may have wider implications.
Safer Care work stream QIPP
The Department of Health has launched the QIPP (quality, innovation, productivity, and prevention) agenda. QIPP has various work streams and includes a safer care work stream. Safety Express is a new scheme within this to increase the safety of patients in four clinical areas: falls in care, pressure ulcers, catheter associated urinary tract infections, and venous thrombo-embolism.

Medicines and Healthcare products Regulatory Agency (MHRA)
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. Furthermore there is an ophthalmic section on the MHRA 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 possible with the anonymised data of the RLS at 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 has been 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. There is under-reporting of ADRs by all professional groups, and reporting to the Yellow Card scheme is essential to ensure medications are under constant surveillance. Both the ocular adverse reactions of systemic medicines on the eye, and systemic and ocular adverse reactions caused by ocular medicines should be reported as ADRs via the Yellow Card scheme.
6. **Promoting safety for patients with disabilities**

Some disabled people, especially patients with learning disabilities, may require ophthalmologists to make “reasonable adjustments” in order for treatment to proceed safely. Eye care teams need to work with individuals and their supporters to ensure positive outcomes. Ophthalmologists should be aware that people may have a health action plan (or other document) which records their needs and how they prefer to be treated.

The Equality Act 2010 requires public bodies to take positive action to promote the needs of people who are at a disadvantage linked to a characteristic (e.g. disability). Positive action provision enables public sector organisations to take proportionate steps to help people overcome disadvantages or meet their needs.

The College is currently working to produce an addition to the suite of Ophthalmic Services Guidance Chapters entitled ‘The management of visual problems in adult patients who have learning disabilities.’ The document is expected to be launched during National Eye Health Week (13-19 June 2011).

7. **Role of the College**

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 while the College is not a regulator it has a responsibility under the terms of its Royal Charter for maintaining high professional standards in ophthalmology for the benefit of the public and has 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 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 (i.e. the quality and safety of care) and also of examples of good practice which raise standards of patient safety 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.

Quality and Safety 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. 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. There will be a statutory ‘duty of Quality Improvement’ and which was set out in the Health and Social Care Bill in January 2011. The duty will embed three dimensions of quality across all parts of the NHS:

- Effectiveness of treatment and care provided to patients
- Safety of the treatment and care provided to patients
- Experience patients have of their treatment and care

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 or commissioners.
CONCLUSION AND SUMMARY

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.’ 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. Strict attention to detail, a focus on safety and learning from adverse events and near misses enhances ophthalmic care. The College is committed to supporting steps that improve the safety of ophthalmic care at both individual and organisational levels. The College encourages vigilance in times of change and remains keen to learn from patient safety concerns and or quality improvements.

Acknowledgements

This paper is contained within Ophthalmic Services Guidance produced by the Royal College of Ophthalmologists. It is also available on the College website. Comments from colleagues at the NPSA and MHRA on a draft of this document are most gratefully acknowledged. The document was approved by the Professional Standards Committee, The Royal College of Ophthalmologists in February 2011.
References


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
ix. ‘Open’ category for adverse incidents causing concern among staff or patients for whatever reason, including anaesthetic matters

How to report?

- Complete local clinical incident form or online e-report. [Staff e-Form]
- For device failures also inform MHRA. [MHRA Ophthalmology]
- For adverse drug reactions complete Yellow Card report. [Yellow Card link]
TABLE 2

Patient Safety Incidents (CLINIC)

i. Delayed diagnosis of intra-ocular foreign body  
ii. Delayed/missed diagnosis of intra-cranial tumour  
iii. Delayed diagnosis of retinal tear  
iv. Failure to screen for retinopathy of prematurity  
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 e.g. learning disability patients)

How to report?

- Complete local clinical incident form or online e-report.  
- For device failures also inform MHRA.  
- For adverse drug reactions complete Yellow Card report.

TABLE 3

Patient Safety Incidents (MEDICATION)

i. Wrong drugs instilled or dispensed  
ii. Prescribed drugs not provided  
iii. Wrong prescription and wrong dose/method of application  
iv. Serious adverse drug-related incident  
v. Any adverse drug-related incident on a black-triangle medication (e.g. VEGF inhibitors)

How to report?

- Complete local clinical incident form or online e-report.  
- For device failures also inform MHRA.  
- For adverse drug reactions complete Yellow Card report.
### TABLE 4

**Patient Safety Incidents (WARD or DAYCARE)**

<table>
<thead>
<tr>
<th></th>
<th>Description</th>
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<tbody>
<tr>
<td>i.</td>
<td>Wrong patient on wrong ward</td>
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<tr>
<td>ii.</td>
<td>Patient misidentification</td>
</tr>
<tr>
<td>iii.</td>
<td>Poor control of ophthalmic patients' medical status e.g. diabetes</td>
</tr>
<tr>
<td>iv.</td>
<td>'Open' category for adverse incidents causing concern among staff or patients for whatever reason</td>
</tr>
</tbody>
</table>

**How to report?**

- Complete local clinical incident form or online e-report.  
  - Staff e-Form
- For device failures also inform MHRA.  
  - MHRA Ophthalmology
- For adverse drug reactions complete Yellow Card report.  
  - Yellow Card link