Measuring Levels of Harm in an Ophthalmic Setting

The ROYAL COLLEGE of OPHTHALMOLOGISTS

Assessing the level of harm can be complex but is an essential part of undertaking an investigation into any incident where a patient has come to harm. Using standard trust risk ratings and consequence categories, which often use mortality as the main indicator of the higher levels of harm, precludes ophthalmology patients being rated at the higher levels of harm which the incident warrants. In this document we have developed a list of patient outcomes and associated consequence categories which aim to help guide the assessment of patient harm for ophthalmology patients.

Harm Levels

In the below category system, we list several example patient outcomes however this is not an exhaustive list and clinical judgement must be used by the clinician undertaking any investigation into an incident of harm. Where an incident can be referred under multiple of these categories the highest should be selected.

Category of Harm	Example Patient Outcomes
Catastrophic	• Registered blind (severely sight impaired) • NPL in both eyes • Removal of both eyes
Major	• Best corrected visual acuity in one eye of less than 6/60 • An overall visual field deficit of ≥16 decibels • Removal of one eye • Registered sight impaired • Best corrected visual acuity less than 6/18 in both eyes
Moderate	• A loss of > 0.2 LogMAR or 2 Snellen lines of visual acuity in best corrected visual acuity score • A deterioration, above expected disease progression, in visual field deviation of ≥3 decibels • Best corrected visual acuity less than 6/18 in one eye • Requirement for additional unplanned treatment • Pain from treatment for a continuous period 28 days • Intractable diplopia requiring coverage of one eye
Minor	• A loss of > 0.1 LogMAR or 1 Snellen line in best corrected visual acuity in one eye • Longer healing time than expected from treatment • Pain from treatment for a continuous period < 28 days

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Other aspects to consider when assessing harm

Previous disease burden
An often overlooked aspect to measuring the harm caused to a patient is the level of disease burden before an incident occurred. Harm should be assessed on the basis of any addition effect an incident has on a patient above the level of normal disease progression. In other words, when an incident causes an outcome of counting fingers (CF) in one eye when before the incident the vision was 6/60 is very different from an outcome of CF when the vision before the incident was 6/6. It is therefore essential to have details such as previous visual acuity, visual fields and clearly written clinic notes to allow for an accurate assessment of the patient's previous disease burden.

Causation
It is necessary to separate out, where possible, the level of harm which was avoidable or directly due to the incident compared with harm which occurred as a consequence of the disease or which would have occurred even with good care. Harm should be assessed against the expected outcome from natural disease progression i.e. that deterioration which would likely have occurred in a patient receiving an acceptable standard of care. It is also necessary to consider whether the harm occurred as a direct consequence of an inappropriate treatment, a lack of treatment or delay in care. Would the correct treatment or care have prevented a poor outcome for the patient?

Effect on the patient's life
Incidents of patient harm are not just related to visual acuity but also the effect it has had on the patient's life. An assessment of non-clinical outcomes should also be used to fine tune the harm grading where possible:

- Has the patient lost their driving licence?
- Has the patient lost their employment?
- Has there been a financial impact on patients?
- Has the patient lost their independence?
- Does the patient have to make significant changes to activities of daily living?
- Is the patient now unable to fulfil any pre-existing caring responsibilities?
- Has the deterioration/loss of vision impacted on next of kin/spouse/partner?
- Is there any impact on wider health or social care resources such as referrals for psychological support or harm from a vision related fall?

Case studies of patient harm

Below we have some example cases where we have used the category system to measure harm in incidents below:

Case Study 1.
A 68 year old male patient, with excellent vision and health previously, attended an eye casualty with the classical symptoms of giant cell arteritis, including reduced vision in one eye. The patient was seen by a nurse who documented a reduced vision of 6/60 and a relative afferent pupil defect in the right eye and right optic nerve swelling was noted by the junior registrar.

The patient was referred to rheumatology, without the institution of systemic steroids, as the acute nature of the patient's condition was not conveyed and the patient was subsequently given an appointment for the following week's rheumatology clinic. The patient presented two days later with counting fingers in both eyes due to acute ischaemic optic neuropathy secondary to giant cell arteritis. Attempts to treat to improve the vision were unsuccessful and he is now registered as severely sight impaired (blind) and no longer able to live independently nor care for his infirm wife.

Harm Grade: Catastrophic

Case Study 2.
A 72 year old female glaucoma patient was being treated by the department. She had a visual acuity of 6/9 in the right eye and 6/12 in the left, an IOP of 17mmHg, bilateral moderate visual field loss and mild to moderate disc cupping. She was on a treatment plan utilising drops which were keeping the intra-ocular pressure at an acceptable level with stabilisation of visual field loss. She attended the eye clinic every 6 months for follow-up monitoring however she was lost to follow up when the hospital changed its PAS system. This led to her not being offered any further follow-up appointments or being prescribed any drops for about 3 years.

She was re-referred by her optometrist when her IOPs were found to be 29mmHg in the right eye and 34mmHg in the left. Her right eye vision and field had remained unchanged but her left eye visual acuity lowered to 6/24 with significant extra peripheral field loss and a very cupped disc. Subsequent changes to her medication brought her IOPs down to 14mmHg in both eyes and the patient's glaucoma is now stable.

Harm Grade: Moderate