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# Ophthalmic Devices and Products - MHRA Yellow Card Reporting

**Keri McLean[1,2], Jayavani Myneni[1], Rosalind M. K. Stewart[2,3], Stephen B. Kaye[1,2]**

**[1] St Paul's Eye Unit, Royal Liverpool University Teaching Hospital, Liverpool**

**[2] Department of Eye and Vision Science, Institute of Ageing and Chronic Disease, University of Liverpool**

**[3] Leeds Centre for Ophthalmology, St James's University Hospital, Leeds**

Ophthalmology relies heavily upon the use of devices for the treatment of various conditions, with common examples including intra-ocular lenses (IOLs) and contact lenses. Although ophthalmic devices have significant benefits there is also the potential for them to cause harm and therefore it is important that there is a mechanism for reporting device-related complications.

## MHRA Yellow Card Reporting

The Medicines and Healthcare products Regulatory Authority (MHRA) has established a Yellow Card reporting Scheme. This is a system for identifying and collecting information on adverse drug reactions, defective medicines, counterfeit medicines, or suspected problems and incidents involving medical devices. Accumulating adverse incident reports may identify a problem with a device that requires investigation, which may lead to changes to the product or its withdrawal from the market. Unfortunately, there is wide variation in the reporting of device-related complications which may lead to a failure to identify potential problems and expose patients to unnecessary risk.

Ophthalmologists may feel that they do not have sufficient time to report and provide detailed information, however, all that is needed is to complete a short form on the MHRA Yellow Card website (Figure 1).

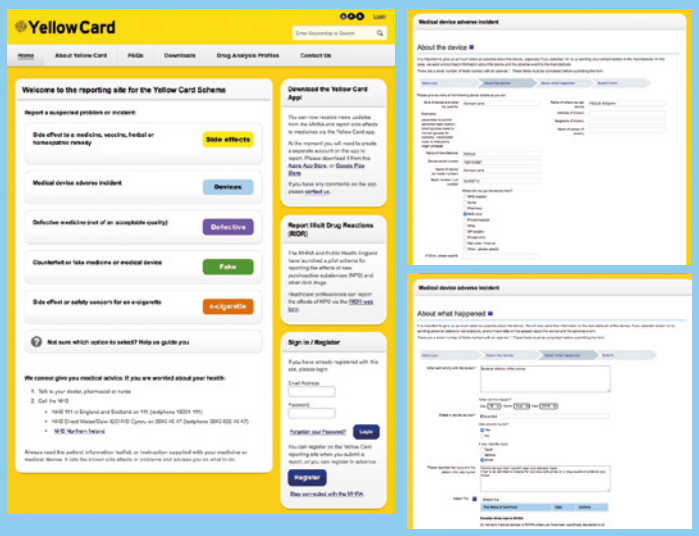


**Figure 1: MHRA Yellow Card** Scheme website **a)** Reporting homepage, **b** and **c)** Example of the 'Devices' reporting form.

## Medical devices

All equipment used for the diagnosis or treatment of disease, or for monitoring patients is considered a medical device. Ophthalmic medical devices in common usage include contact lenses and lens care products, intraocular lenses, glaucoma drainage devices, keratoprostheses, capsule tensions rings, artificial iris implants, orbital implants and prostheses. Diagnostic equipment such as slit lamps, tonometer prisms, fundus cameras, operating microscopes; fluorescein and Schirmer's strips, surgical instruments and low vision aids are also included in this category.

## What should be reported?

All adverse events involving medical devices need to be reported. Causes of incidents involving devices may include:

- Design or manufacturing problems,
- Inadequate servicing and maintenance,
- Unsuitable storage conditions,
- Poor user instructions or training resulting in incorrect user practice,
- Off-label use of a device,
- Local modifications etc.

## Who can report?

Although healthcare professionals usually make Yellow Card reports, they can be made by anyone including patients and carers. Indeed, patient self-reporting of adverse events is an important method that should be encouraged.[1] Manufacturers are required to report all incidents where their device may have resulted in a death or serious deterioration in health.

## How to report

There are three main ways to report to the Yellow Card Scheme:

- The easiest way to report is online at **https://yellowcard.mhra.gov.uk**
- Free Yellow Card App for adverse drug reactions only
- A paper Yellow Card form found in the BNF, MIMS and ABPI Compendium.

Device related incidents should be reported to the Northern Ireland Adverse Incident Centre (NIAIC) in Northern Ireland and to Health Facilities Scotland in Scotland. Private care facilities in Scotland should report to MHRA and the Care Inspectorate.

## What information is needed?

Step-by-step forms guide the reporter through what information is needed on a Yellow Card (Figure 1).

For device reports the following information needs to be included:

- Reporter details, device, indication and details of the incident,
- Further information about the manufacturer, model, catalogue number, serial number, manufacture date, expiry date and LOT/Batch number, as well as the action which has been taken is preferable.

### What happens to the information?

Medical safety experts evaluate the MHRA Yellow Card reports alongside information from other sources such as clinical trial data, medical literature or data from international medicines regulators, to identify previously unknown safety issues. If a new safety issue is found, the MHRA will review the way that the device can be used. Warnings are then issued to users, prescribers and patients. If reports suggest a defective medicine or device is a risk to public health, the manufacturer is responsible for recalling any affected batches or removing all batches of the product from the market. All 'Drug Alerts', manufacturer's 'Field Safety Notices' and MHRA 'Medical Device Alerts' are available to view in an interactive format on the MHRA website.

### Examples

### 1. Contact lenses

There are approximately 4.2 million contact lens wearers in the UK with the number continuing to rise; this is 9% of adults aged 15- 64 years.[2] While 65% of users choose daily disposable lenses, 31% use soft frequent replacement lenses.[2] Although contact lenses offer significant benefits there are also hazards, including the risk of microbial keratitis which can have a devastating effect on vision. Even relatively minor infections may result in corneal scarring, which may lead to irregular corneal astigmatism and neovascularisation. (figure 2 A-C).

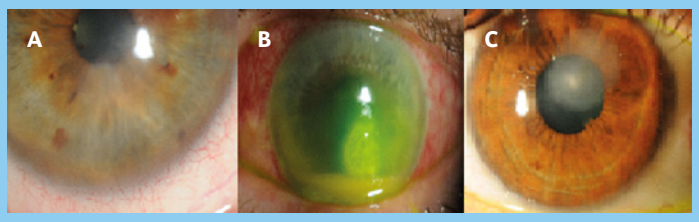


**Figure 2:** Microbial keratitis and resultant corneal scarring associated with contact lens wear. **a)** Paracentral scar, **b)** Active microbial keratitis with hypopyon, **c)** Corneal scarring affecting the visual axis.

Studies from several countries estimate that approximately 1 in every 2500 daily disposable lens users and 1 in every 500 extended wear soft lens users develop presumed microbial keratitis every year.[3] The actual magnitude of the problem, however, is less clear. In the five-year period from 2013 to 2018, the MHRA received only 41[4*] reports (approximately 8 per year) of contact lens related adverse incidents (Table 1). This suggests a gross underestimation given, for example, that there are approximately 6,000 cases of microbial keratitis per year in the UK of which approximately 25% are due to Pseudomonas aeruginosa which is often associated with contact lens wear. Similarly, the number of cases of Acanthamoeba keratitis, which is often associated with contact lens wear, has been increasing. Contact lens wearers are often unaware of the potential risks and are motivated to report the incident if informed to do so.[5] Ophthalmologists should direct the patient to the MHRA Yellow Card website and advise them to report the incident using the 'Devices' form.

### 2. Intraocular lenses

The MHRA received 681[4*] IOL-related reports over the last 5 years (Table 1). The commonest causes for incident reports were patient-device incompatibility, material degradation and optical issues. IOL-related incidents such as lens opacification, lens explantation due to halos, glare, starbursts, monocular diplopia, fracture or detachment of the lens haptic, failure of lens injectors etc. should be reported. A recent field safety notice was issued by the MHRA based on reports of IOL opacification after intracameral injection of alteplase for uveitis-related fibrosis.[6]

### 3. Glaucoma devices

The MHRA received <5[4*] reports related to glaucoma drainage devices over the last 5 years (all in 2017 – Table 1). After the recent withdrawal of the CyPass microstent (Alcon) further guidance is expected after MHRA consultation with the manufacturers. Following reports to the MHRA of eye injury associated with a new pipette design of container with preservative free Cosopt drops (MSD), the design was withdrawn. All problems with drainage valves, tubes and stents should be reported.

### Conclusion

Current data from the MHRA suggests that complications associated with ophthalmic medications and devices including contact lenses and IOLs is significantly under-reported. Yellow Card Reporting is vital to monitor the safety of all healthcare products. Reporting is a quick and easy process that can be completed by patients or practitioners.

**Andrew Tatham**
Editor, Focus

#### References

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|---|---|---|---|---|---|
| **Contact lenses** | Total: 41 | *Reported by members of the public: 30*<br>*Reported by healthcare professionals: 11* | | | |
| **Intraocular lenses** | Total: 681 | *Reported by members of the public: 66*<br>*Reported by healthcare professionals: 615* | | | |
| | *2013* | *2014* | *2015* | *2016* | *2017* |
| | 33 | 36 | 184 | 174 | 254 |
| **Glaucoma Drainage Devices** | *2013* | *2014* | *2015* | *2016* | *2017* |
| | 0 | 0 | 0 | 0 | <5 |
| **Orbital Implants** | *2013* | *2014* | *2015* | *2016* | *2017* |
| | <5 | 0 | 0 | 0 | 0 |
| **Keratoprostheses** | No reports | | | | |

**Table 1:** The number of Yellow Card Reports received by the MHRA between 01/01/2013 – 31/12/17 unless otherwise stated.[4*]

* This MHRA data is only a snapshot of reports available at the time of data extraction. The MHRA try to merge multiple reports where it is clear they are related to the same incident; however, this is not always possible. There is no reporting deadline therefore reports may be received years after the event. The criteria for reporting concerns about a device is that it might have been related to an incident, therefore it cannot be concluded that the device was at fault in all reports. The MHRA are required to report numbers between 1 and 5 as <5 to reduce the risk of identifying individuals. Caution is therefore needed when interpreting these results. MHRA data should not be used to make a judgement on the safety of a particular type of medical device or how likely it is to be involved in an adverse incident. 