The ROYAL COLLEGE of OPHTHALMOLOGISTS

UKOPG

Ophthalmic Services Guidance

Eye Drops Instillation by Unregistered Health Care Professionals for use within NHS Ophthalmic Services

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1 Aim

The aim of this document is to provide a framework for ophthalmic services to facilitate the administration of necessary and appropriate eye drops by unregistered health professionals to patients under the care of the ophthalmic department. It outlines how this is possible and legal within the currently legal and regulatory systems.

2 Background

Ophthalmology is the highest volume outpatient specialty in the NHS, providing more than 8 million appointments a year. Many patients are seen in high volume assessment or diagnostic clinics which require the use of anaesthetic and pupil dilating drops to complete. This model of care makes it impractical for all dilating and anaesthetic drops to be prescribed for each patient. To continue delivering care we recognise numerous unregistered healthcare professionals are currently required to administer eye drops within the ophthalmic setting, including health care assistants, ophthalmic science practitioners, diabetic eye screeners and clinical scientists.

Ophthalmology has long standing capacity issues leading to recurrent episodes of harm and serious loss of sight. Numerous publications have highlighted this and made recommendations for much more care to be delivered in efficient face-to-face diagnostic pathways and virtual clinics based on high quality dilated imaging of the eye requiring drops (GIRFT, RCOphth, NHS England High Impact Intervention (HII) and EyesWise, HSIB).

With the recent cessation and ongoing reduction in capacity in ophthalmology due to COVID-19, it is crucial to significantly increase this mode of delivery to maintain patient safety. The involvement of non-registered health care professionals in the instillation of drops in eye outpatients is central to undertaking this and needs to underpin the planned NHSE& I eye care restoration and transformation programme and the RCOphth ophthalmology COVID-19 recovery guidance.

We hope this document will help centres to optimise patient safety and experience, whilst ensuring that dilation and anaesthesia can be undertaken in a timely manner.

3 Legal background and precedents

The Human Medicines Regulations 2012 (HMRs) consolidate the law of the United Kingdom concerning medicinal products for human use. This includes most of the Medicines Act 1968. Section 58(2) of the Act provided that no person shall administer a prescription only medicine (POM) unless he is an appropriate practitioner or a person acting in accordance with the directions of an appropriate practitioner. The provision is now reflected in Regulation 214 (2) of the HMRs. This states that

A person may not parenterally administer (otherwise than to himself or herself) a prescription only medicine unless the person is

(a) An appropriate practitioner other than an EEA health professional; or

Acting in accordance with the directions of an appropriate practitioner

An “appropriate practitioner” includes a doctor, dentist and a range of registered healthcare prescribers including nurse and pharmacist independent prescribers. The restriction in the Act no longer applies to non-parenteral medicines. In this context, parenteral administration is defined as administration by breach of the skin or mucous membrane.

As eye drops and other topical ocular medications are not administered parenterally, the administration restriction above does not apply to the topical administration of eye preparations.

The NHS National Diabetic Eye Screening Programme (DESP) which utilises dilating drops in their population screening of over 4 million diabetics annually in England, sought clarity from the MHRA regarding what impact this had on the instillation of eye drops as part of their service without a patient group direction or a patient specific direction (PSD). In 2006 the MHRA agency confirmed it is not against the law for POM eye drops to be administered by healthcare workers in the absence of a prescription, Patient Group Direction (PGD), Patient Specific Direction (PSD) or other orders. **This was subject to the requirement that the medicines had been lawfully obtained by a healthcare body, for example, a hospital.**

They advised that it is important, whatever the model of delivery, that ‘safe systems of work are in place governing the administration of eye drops.’ Therefore, there are no legal restrictions on who can administer/instil eye drops such as tropicamide and phenylephrine for the purposed of dilating the pupil for screening.’ The DESP uses pupil dilating drops (Tropicamide 1%) instilled by a Band 3 retinal screener for all patients without any PSD or individualised directive. The diagnosis of diabetes is the directive. The following extract from the DESP National Screening Committee Workbook (Appendix 1) explains the legal clarification:

The Medicines and Healthcare products Regulatory Agency (MHRA) advice

a) Is Tropicamide 0.5% and 1.0% a prescription only medicine (POM)?

Yes. However the medicines legislation regulates the requirement for a prescription in different ways depending on whether the eyedrops are being sold, supplied, administered parenterally (by injection) or externally.

b) Is Phenylephrine 2.5% a POM as well?
No. Phenylephrine 2.5% is a Pharmacy (P) medicine. P medicines may be obtained by anyone for administration in the course of a business provided they are to be used within their licensed indications.

c) Does that mean that screeners can only administer eye drops if there is a prescription or other order such as a Patient Group Direction (PGD) or Patient Specific Direction (PSD)?

Not necessarily. The MHRA says that medicines legislation places no legal restriction on who can administer/instil eye drops such as tropicamide 0.5% and 1.0% and phenylephrine 2.5%, for the purposes of dilating the pupil for screening. This advice, however, is limited to **administration** only and not to the sale or supply of tropicamide. It is the wholesale acquisition, sale and supply of these eye drops that is restricted by the legislation and this might affect which organisations and individuals can legally acquire eye drops.

d) So who can legally acquire eyedrops?

The wholesale supply of medicine is regulated by medicines legislation. Generally, the wholesale supply of POMs is restricted to specified classes of persons / establishments such as NHS Trusts, doctors and pharmacists. Some registered health professionals may also obtain certain POMs on a wholesale basis. This includes the wholesale supply of tropicamide to optometrists (but does not extend to dispensing opticians).

e) So how does that affect screening programmes in practice?

The following paragraphs are intended to provide information about the legalities of common scenarios involving the use of eye drops in retinal screening programmes. They are not definitive and while the MHRA is happy to offer further clarification where necessary, organisations should also be prepared to obtain their own legal advice.

i) NHS Organisations

Retinal screeners employed by NHS bodies such as hospitals and Primary Care Trusts can access eye drops obtained by those bodies for administration in the course of their business. No prescription, PGD, PSD or other order is required. It is possible that agency staff operating within a Trust and under close supervision, and covered by the trust's insurance may be in a similar position but the MHRA suggest that individual trusts that intend to rely on this take advice from the trust's lawyer before doing so. NHS bodies entering into an arrangement with an independent provider (or anyone else who is not part of their organisation) to provide screening services should be aware that unless they have a wholesale dealer's licence, they cannot legally supply stocks of POM and P medicines to that provider.

The RCOphth has also approached the MHRA Policy Division, which confirmed this statement reflects their longstanding legal position in relation to administration of non-injectable medicines which have been lawfully obtained by a healthcare body. In summary, to facilitate the smooth and safe running of the service, unregistered health professionals may administer eye drops without a prescription provided they have been lawfully obtained by a healthcare body.

Risks of pupil dilatation (mydriasis)

There have been a number of large reviews of the use of pupil dilating drops and an overview paper in the British Medical Journal in 2006 summarised these:

'A systematic review reported that out of an estimated 600 000 individuals who received mydriatic eye drops, 33 (0.006%) developed acute angle closure glaucoma, giving an estimated risk of 1 in 20 000. The same review found that in almost 4000 people whose pupils were dilated using tropicamide, none developed acute glaucoma as a result of the dilatation. We are aware of only two cases of tropicamide-induced angle closure glaucoma from the published literature. Thus, these studies place the risk of acute angle closure glaucoma caused by pharmacological pupil dilation at 1 to 6 per 20 000 people in the general population.

This review concluded that *pupil dilation is important for thorough fundoscopy, and the risk of precipitating acute angle closure glaucoma with routine use of mydriatics is* ***close to zero.'***

Putting this into practice

Whilst it is correct a prescription is not necessary to administer appropriate eye drops within ophthalmic outpatient clinics, it remains vital that an appropriate detailed trust specific protocol exists to allow the safe administration of eye drops for these patients. This should include indication, any patient exclusion or contraindication criteria, dosage information, information about adverse reactions and details regarding how the user can seek further advice if needed including as required access to medical advice in an emergency.

A formal process of education must also exist for the user to be signed off as competent and this should be revalidated at appropriate time intervals. The user must also be familiar with any side effects and patient advice relevant to the eye drops being administered. A process should be agreed to ensure the treatment episode is documented appropriately. Patients should also be made aware of the risk with regard to eye drops, actions they should take in the event of problems, and the fact it will not be safe to drive as after mydriatic eye drops their vision will be temporarily blurred.

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