

Use of preserved eye preparations — is the Society's guidance still relevant?

By hospital ophthalmic pharmacists **Valerie Haylor**, of Sheffield, and **Jacqueline Jones**, of Nottingham

The Royal Pharmaceutical Society's 2001 guidance on the use of eye preparations was a welcome revision of the 1975 guidance and carries the endorsement of the Department of Health. It covers the presentation and labelling of conventional ophthalmic preparations and their terms of use within hospitals and care homes; the use of unlicensed preservative-free eye-drops is not covered. One of the key practice changes was that the hospital in-use expiry of preserved eye-drops for inpatients was extended from seven to 14 days. Current BNF advice still recommends that eye-drops in hospital are discarded seven days after first opening.

In general, ophthalmic pharmacists accept the 2001 guidance in relation to the use of unit dose containers and single use of multiple dose containers in outpatient and theatre settings. However concerns have been raised regarding the clinical evidence base and relevance to current care setting of the guidance, in particular the methods of use of preserved eye-drops on wards and on discharge. The guidance recommends that a fresh supply of eye-drops should be made on admission to hospital and also after eye surgery. Separate bottles should be supplied for each eye where both eyes need treatment and the patient has an open eye infection or when medical opinion dictates. The period of use of each opened ward bottle should not exceed 14 days, including both inpatient and post-discharge use. On discharge a 28-day "user life" can be apportioned to unopened containers.

In 2004 the UK Ophthalmic Pharmacists Group surveyed all members on use of preserved eye-drops. The terms of the guidance were explained and used to confirm current practice. In addition the survey obtained information on the profile of participating hospitals, including policies. Twenty-seven (48%) of 56 questionnaires were returned.

The survey showed that the 27 responding eye centres were not fully compliant with the 2001 guidance for preserved eye-drops. For example, only three centres supplied fresh eye-drops on admission to hospital and 16 centres gave an in-use expiry not exceeding 14 days (non-antibacterial drops) for inpatients and post-discharge patients. On eye wards, limits set for infected eyes were often shorter than that recommended by the guidance. Some specialist centres set limits to the

reuse period of all eye-drops at discharge in terms of hours, days or number of times opened on wards. All centres complied with a 28-day maximum in-use expiry at discharge.

So is the 2001 guidance for preserved eye-drops relevant to current practice? The hospital profiles in the survey provide a fair reflection of UK ophthalmic care provision. Samples ranged from hospitals and units with fewer than 200 beds, including Moorfields Eye Hospital, to those (the majority) that had more than 600 inpatient beds. Surgery was undertaken in dedicated eye theatres or surgical day case units. Less than a third of the centres had a dedicated eye

ward and many nursed eye patients on mixed surgical or medical wards.

Difficulties in applying the guidance to hospitals may be due to:

- Recent trends to undertake elective eye surgery as day cases, in particular for cataract extraction
- The increase in laser eye surgery
- The use on wards of patients' own drugs (PODs) and self-administration policies

Risk assessment of potential microbiological contamination of eye-drops in different clinical areas must be agreed locally. Is the risk of bacterial keratitis or endophthalmitis greater if a general nurse, rather than an ophthalmic trained nurse, administers eye-drops on an eye ward? Might this also be the case if a patient self-administers drops on a mixed surgical ward with meticillin-resistant *Staphylococcus aureus* infection present or in a care home? Ophthalmic inpatients are likely to be short stay (no more than five days), while medical and care of the elderly wards may have long-stay patients on eye medication. Also patients' own home environments differ in terms of hygiene, and patients differ in their general understanding of how to store and use eye-drops. Poor visual acuity may limit ability to comply with instructions. Can there really be one rule for all in terms of in-use expiry dates?

The microbiological evidence base to support the guidance is weak. Our literature search post-2000 found no relevant studies on preserved eye-drop contamination and infection risk. The extension of the 14-day in-use expiry of preserved eye-drops in the guidance

was based on one ward study in 1998 of non-antibacterial eye-drop contamination in predominantly polyethylene bottles with integral droppers and excluded samples from patients with infected eyes or following an operation.

Under current European guidance for evaluation of medicinal products, a licence holder presenting a product in a multidose container must establish efficacy of the antimicrobial preservative under simulated in-use conditions and label with an appropriate in-use expiry date. Recent innovative developments in eye-drop delivery used in CE-marked devices have extended in-use expiries well beyond 28 days. Therefore the risk of infection to eye patients from eye-drops is unlikely to be product-dependent but to relate to the environment and the frequency of exposure of the drops to possible contaminants. Through clinical governance, hospital and care home staff must take responsibility for writing and implementing safe practices and procedures to minimise the "bioburden" to levels not exceeding those that the manufacturer has proven efficacy.

What of the cost implications of adhering to the guidance? Following a two-week audit in 2002 for a 23-bed dedicated eye ward and eye day case unit in a large teaching hospital, it was estimated that implementation of just the preserved eye-drop section of the guidance for these two clinical areas alone would cost an extra £6,200 a year. This hospital had a POD policy on admission, and had adopted a 28-day maximum in-use expiry at discharge for preserved eye-drop supply. Where is the evidence base supporting such expensive changes to practice? Have studies identified increased eye infection rates or other risks to patients?

We propose that as a matter of urgency the Royal Pharmaceutical Society reviews the 2001 guidance in light of changing clinical practice and obtains sound microbiological advice on the relative risks in primary and secondary care settings. The guidance should cover the use of all ophthalmic topical preparations including preserved and unpreserved eye-drops in glass or polyethylene bottles with separate or integral dropper. It should also include eye ointments, oily eye-drops, ophthalmic CE-marked devices such as ocular lubricants, and contact lens solutions. In the meantime local clinical governance should determine procedures for the supply and administration of preserved multidose eye-drops relevant to the care setting in which they are to be used.

The microbiological evidence base to support the guidance is weak