Special Communication

# Using Multidose Eyedrops in a Health Care Setting
## A Policy and Procedural Approach to Safe and Effective Treatment of Patients

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**IMPORTANCE** Quality and safety of eyedrop use for patients treated in a health care setting play a vital role in the delivery of health care.

**OBJECTIVE** To describe the development of a policy and procedural approach to the use of multidose eyedrops in multiple patients, approved and accepted by The Joint Commission in compliance with preferred practice standards in ophthalmology, the safe handling and administration of multidose eyedrops, and cost benefits of a multidose eyedrop approach.

**DESIGN, SETTING, AND PATIENTS** Using a policy and procedural approach, we petitioned The Joint Commission for approval and evaluated the cost benefits of implementation of a multidose process for eyedrop administration in patients undergoing surgery and treatment at the Utah Valley Regional Medical Center, Provo.

**RESULTS** The Joint Commission approved our policy and procedural approach, implemented in April 2012. Cost savings to both patients and the facility were significant. Costs to patients undergoing a single cataract operation were decreased as much as $283.85. Costs to the facility were decreased by $330.91 per cataract case.

**CONCLUSIONS AND RELEVANCE** Approval of our policy and processes indicates that The Joint Commission validates our policy and its adherence to accepted preferred practice guidelines of safe handling and administration of multidose eyedrops and establishes precedence that may be followed by other eye care facilities and health care organizations in the future. Our policy provides a safe and effective process for administering eyedrop medications to patients as well as controlling excessive health care costs to both patients and health care facilities.

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The use of preservative-containing multidose eyedrops in multiple patients has historically been an accepted standard of practice by eye care facilities and eye care practitioners. Multidose eyedrops used in these settings include those used for examination purposes, treatment, and surgical prophylaxis. Recently, during the accreditation process by The Joint Commission (TJC) at our facility at the Utah Valley Regional Medical Center, Provo, a commission finding resulted in a directive to our pharmacy department and facility for single bottle, single use only per patient of multidose eyedrops. In response to the directive and based on accepted standards of practice and evidence-based reports, a detailed policy and procedure were written for the safe handling and control of these products. We appealed to TJC to reverse the commission's finding and allow us to continue the use of these products in multiple patients. This article describes TJC's decision on our appeal, discusses the use of multidose eyedrops in multiple patients and established standards of practice for their use in a health care setting, evaluates cost considerations and advantages of their use, and provides guidance in establishing policies and procedures for safety and quality control in administering multidose products to patients.

## Methods

Prior to January 2011, there was no formal directive or policy governing the use of multidose eyedrops in multiple patients at the Utah Valley Regional Medical Center. In January 2011, a pharmacist (M.K.J.) specialized in ophthalmic pharmacy practice was recruited to establish an operating room pharmacy at the Utah Valley Regional Medical Center. As one of the priorities of the new pharmacy, the pharmacist wrote, proposed for approval by the hospital's Pharmacy and Therapeutic Committee, and established a policy and procedure for the safe handling and use of multidose eyedrops in mul-

Table 1. Cost Comparison for Single vs Multidose Use of Eye Medications

| Drug | AWP, $[a] | Patient Charge, $ | |
|---|---|---|---|
| | | Single Use Only | Multidose Policy[b] |
| Flurbiprofen sodium, 0.03%, 2.5 mL | 31.33 | 31.33 | 3.13 |
| Ketorolac tromethamine, 0.4%, 5 mL | 106.87 | 106.87 | 10.69 |
| Tropicamide, 1%, 3 mL | 14.00 | 14.00 | 1.40 |
| Cyclopentolate hydrochloride, 1%, 2 mL | 16.80 | 16.80 | 1.68 |
| Phenylephrine hydrochloride, 2.5%, 2.5 mL | 27.49 | 27.49 | 2.75 |
| Gatifloxacin[c] | 123.86 | 123.86 | 12.39 |
| Prednisolone acetate, 1.0%, 5 mL | 55.67 | 55.67 | 5.57 |
| Betaxolol hydrochloride, 0.5%, 5 mL | 63.41 | 63.14 | 6.34 |
| Timolol maleate, 0.5%, 5 mL | 17.00 | 17.00 | 1.70 |
| Brinzolamide, 1%, 10 mL | 145.26 | 145.26 | 14.53 |
| Brimonidine tartrate, 0.1%, 5 mL | 97.10 | 97.10 | 9.71 |

Abbreviation: AWP, average wholesale price.

[a] With no price markup.

[b] Assumes average use in 10 patients without discarding owing to contamination. Patient charge is based on 10 doses.

[c] Comparative fourth-generation moxifloxacin hydrochloride is not included owing to its nonpreservative formulation.

tiple patients undergoing ocular surgery. The policy was submitted to the hospital's local Infectious Disease Committee and was approved prior to the opening of the new pharmacy. Additionally, the policy was submitted to corporate headquarters for review and was formally approved systemwide in August 2012.

To collect and analyze data to determine cost-effectiveness of a multiuse policy, cost to facility, and cost to patients, an operating room pharmacy–specific billing code was created. This code was then tagged electronically onto all patient billing records to identify patients who were billed for the use of eyedrops associated with a surgical event. At the end of 1 year, a report was generated and analyzed. Cost to patient, cost to facility, and the specific eye medications used per surgery type were then determined. Average costs for patients and the facility were determined for all medications used. Additionally, for purposes of this article, costs for single cataract operations are presented as an example of cost comparison per surgery type.

Medication costs were determined using the average wholesale price for each eye medication.[1] Acquisition costs for medications reported are based on pricing at the time of our article being submitted for publication and may vary with time.

## Results

The Utah Valley Regional Medical Center, Provo, is part of Intermountain Healthcare and serves as the regional trauma and medical center for Intermountain's Urban South Region. Patients undergoing ocular surgery receive a variety of surgical procedures, including anterior segment, retinal and posterior segment, corneal, and oculoplastic procedures. Each patient undergoing surgery receives a variety of multidose eyedrop preparations preoperatively, intraoperatively, and postoperatively during the course of treatment.

During TJC review at our facility in February 2012 and contrary to the process we were using at the time, TJC issued a finding that was to require only single-patient use of all multidose dropper bottles, after which all bottles were to be discarded and wasted. We disagreed with the initial finding and filed an appeal for consideration by TJC to reverse the finding. A formal appeal to TJC was submitted for review along with evidence-based reports,[2,3] current standards of practice for governing bodies in ophthalmology, and a copy of the detailed policy and procedure for safe handling and administration of multidose eyedrops that we had written for use at our facility. The evidence-based reports submitted demonstrated that postoperative infection rates in patients following cataract surgery at an eye care hospital were significantly controlled and dramatically decreased by the antibiotic selection for patients undergoing cataract surgery while using the same kind of policy for multidose eyedrops that we describe herein. In our appeal we concluded, and TJC agreed, that concerns regarding infections observed in these studies were affected by antibiotic susceptibility and antibiotic use, not by the use of a multidose eyedrop policy. In April 2012, TJC reviewed our appeal and supporting documentation and reversed its previous finding, allowing our facility to implement our policy and procedure for safely using multidose eyedrops in multiple patients.

Cost advantages to a multidose eyedrop policy were significant for both the patient and the facility. This is because with a multidose policy, medication costs can be spread over multiple patients rather than entire bottles being charged to single patients. Additionally, the expense of maintaining large medication stock can be significantly decreased for the facility. These cost and expense savings can then be factored into the overall expense for eye care procedures, helping to decrease and control overall health care costs to patients and to facilities in providing care (**Table 1**). An example of these cost savings to both the patient and the facility are illustrated by analyzing medication costs for a single cataract operation (**Table 2**). For the use of preoperative eyedrops (administered on admission and on call to surgery), intraoperative eyedrops (administered on arrival to the operating room and during surgery), and postoperative eyedrops (administered at the conclusion of surgery and during the recovery process), costs to patients under a multidose policy can be decreased by $283.85 compared with the cost to the patient without the policy. (Cost estimates do not include any price markup to patients and are based on average wholesale pricing). Additionally, medication costs to the facility were decreased by $330.91 per cataract case.

## Discussion

The use of preservative-containing multidose eyedrops in multiple patients is common practice among physicians in an eye care setting. Foremost consideration in such a practice must be given to pre-

Table 2. Medication Cost Comparison for Cataract in a Single Case[a]

| Drug | Cost, $ | | | |
|---|---|---|---|---|
| | Patient | | Facility | |
| | SDV | MDV | SDV | MDV |
| Preoperative use | | | | |
| Tropicamide, 1%, 2 doses | 14.00 | 2.80 | 14.00 | 1.40 |
| Phenylephrine hydrochloride, 2.5%, 2 doses | 27.49 | 5.50 | 27.50 | 2.75 |
| Cyclopentolate hydrochloride, 1%, 2 doses | 16.80 | 3.36 | 16.80 | 1.68 |
| Ketorolac tromethamine, 0.4%, 2 doses | 106.87 | 21.38 | 106.87 | 10.69 |
| Gatifloxacin, 2 doses | 202.51 | 40.50 | 202.51 | 20.25 |
| Intraoperative use | | | | |
| Tropicamide, 1%, 1 dose | | 1.40 | | |
| Phenylephrine hydrochloride, 2.5%, 1 dose | | 2.25 | | |
| Cyclopentolate hydrochloride, 1%, 1 dose | | 1.68 | | |
| Postoperative use | | | | |
| Timolol maleate, 0.5%, 1 dose | 17.00 | 1.70 | | |
| Gatifloxacin, 1 dose | | 20.25 | | |
| **Total** | **384.67** | **100.82** | **367.68** | **36.77** |

Abbreviations: MDV, multidose vial; SDV, single-dose vial.

[a] The MDV use is when the multidose use policy was in effect; the SDV use is when no multidose policy was in effect. Prices reflect only average wholesale pricing, with no markup added. Values assume average use in 10 patients without discarding owing to contamination, and patient charges are based on 10 doses.

ventive measures for contamination (eAppendix 1 in the Supplement) and potential infection.

There are a variety of standards and techniques established by organizations for managing infection control with the use of multidose containers of medications. The US Pharmacopeia 797 (USP 797) provides guidelines governing pharmacies for the use of sterile preparations and multidose vials in an effort to ensure quality, safety, and benefit of medication use in patients. The Joint Commission has adopted these guidelines for accrediting health care organizations and their use of multidose vials. The USP 797 states that "multiple-dose containers (eg, vials) are formulated for removal of portions on multiple occasions because they contain antimicrobial preservatives. The beyond-use date after initially entering or opening (eg, needle-punctured) multiple-dose containers is 28 days unless otherwise specified by the manufacturer. If the vial is labeled as a multi-dose vial or container, then the dating should not exceed 28 days UNLESS the manufacturer has data to support longer dating."[4]

The American Academy of Ophthalmology is one of the largest membership associations of ophthalmologists in the United States. It establishes standards of care and practice considered to be preferred and best practice for ophthalmic specialists in providing comprehensive eye care to patients. Among its publications of preferred practice guidelines are standards for "Infection Prevention in Eye Care Services and Operating Areas and Operating Rooms."[5] As its standard for multidose containers (eg, eyedrops), the American Academy of Ophthalmology has adopted USP 797's standard for multidose medications. Additionally, the American Academy of Ophthalmology provides safety measures for handling and maintaining quality of the container throughout multipatient use.

Keys to the use of multidose eyedrops in multiple patients are a detailed and rigorously applied policy and procedure. The procedure must take into account, first and foremost, patient safety and quality of care. It must provide standards and directions for the safe handling and administration of eyedrops by hospital staff providing care, which ensures infectious disease control and accuracy of drug and dose administration. Important elements pertaining to a successful policy and procedure are shown in eAppendix 1 and eAppendix 2 in the Supplement. Some of these elements include guidelines for handling the dropper bottle, expiration dating, training of medical staff administering eyedrops, conditions of contamination for discarding dropper bottles, and pharmacy involvement in maintaining patient safety and quality throughout the course of treatment.

While we chose to follow established standards for use of multidose eyedrops, including 28-day expiration dating from the initial use of the eyedrops, it is the option of any organization to follow these standards and adopt different expiration dating so long as it does not exceed the 28-day expiration dating recognized by TJC. For example, if an organization determines it would be better to use 24-hour expiration dating, with new bottles opened each day and then discarded at the conclusion of the day, it may do so. Whatever dating is determined by the organization, we believe the adherence to a rigorously applied policy and procedure for safe handling and administration must still be followed, and we are confident TJC would also require such adherence. Our decision to follow the established standard of 28-day expiration dating with the use of a detailed policy and procedure has allowed us to maintain quality of care and safety with the use of multidose eyedrops in patients. It has also allowed us to maximize eyedrop supply use among our processes, leading to cost savings that we have been able to pass along to our patients.

The regular training of staff regarding the policy and administration of eyedrops is a vital part of a successful policy. New and existing staff should be educated and trained regularly in the proper technique of administering eyedrops. Documentation verifying this education and training should be maintained for review, if necessary, during TJC accreditation. Staff must understand the definition of what contamination of an eyedrop is and, under the policy, be allowed full discretion to discard any eyedrops they feel are contaminated without any hesitation or reservation.

For the proper administration of eyedrops, we suggest following the step-by-step guidelines outlined in the American Pharmacists Association's textbook *Handbook of Nonprescription Drugs: An Interactive Approach to Self-care*[6] (**Box**). As with any process involving treatment of patients, staff should wash their hands before and after using eyedrops in patient eyes. The tamper-proof seal on un-

opened eyedrops should be removed completely before using the eyedrops, and when the dropper bottle cap is removed for use of the eyedrops, it should be placed on a clean surface inside up to avoid contamination inside the cap. When the staff finishes using the eyedrops, the cap should be replaced in a sterile manner and screwed down tightly to avoid leaking and contamination.

As a guide for staff, our policy defines clearly what constitutes eyedrop contamination, requiring immediate discarding of the eyedrops and not using them on another patient. Under our policy, a dropper bottle has been contaminated when the following occur: (1) the dropper tip is touched in any manner to any part of the eye structure or surface (eyeball, eyelids, eyelashes); (2) the dropper tip is touched in any way by the administering staff member; (3) an open dropper is found with no expiration date on it; (4) an open dropper contains an expiration date longer than 28 days; or (5) an opened bottle (dated or not dated with an expiration) is found uncapped. Additionally, our policy indicates that eyedrops used for treating patients considered infectious or immunocompromised are to be new, unopened bottles and are to be discarded immediately once treatment is finished, not to be used on another patient. Finally, any staff member may determine at his or her discretion whether a dropper bottle is contaminated. We educate all staff that when in doubt, they should throw it out.

Our approach to multidose use of eyedrops in patients applies to all areas of our organization, including all surgical, inpatient, and clinic areas of patient care. The Joint Commission does not separate the perioperative arena from the clinic arena for its accreditation processes. It looks for consistency throughout an organization in policy and procedure as well as carrying out such policy and procedure. Because of that, we make no distinction between perioperative or clinic settings with our policy and procedure for multidose eyedrops, and we feel strongly that this approach should be used by all ophthalmic care practitioners in whatever setting they may be.

**Box. Administration Guidelines for Eyedrops**

1. Wash hands well before administering eyedrops to patients.
2. Tilt the patient's head back slightly.
3. Gently grasp the lower outer eyelid below the eyelashes, and pull the eyelid away from the eye to create a pouch.
4. Place the dropper directly over the eye. Avoid touching the dropper tip to any portion of the eyelid, eyelashes, or eye itself.
5. Just before instilling the eyedrop, instruct the patient to look up.
6. As soon as the eyedrop is instilled, gently release the eyelid and instruct the patient to gently close the eye for 3 minutes, minimizing blinking and squeezing of the eye.
7. Use a finger to put gentle pressure over the opening of the tear duct.
8. If multiple eyedrops are to be administered, wait at least 5 minutes between eyedrops. This helps ensure that the first eyedrop is not flushed away by the second and that the second eyedrop is not diluted by the first.
9. If using a suspension eyedrop, shake well before instilling. If using a solution eyedrop with a suspension eyedrop, always use the solution eyedrop first, followed 5 minutes later by the suspension eyedrop, to prolong retention time of the suspension in the tear film.
10. If both eyedrops and ointment are to be administered together, instill eyedrops at least 10 minutes prior to using the ointment preparation to prevent the ointment from creating a barrier to the eyedrops' penetration of the tear film and cornea.

## Conclusions

While TJC does not provide any formal direction for the use of multidose eyedrops in multiple patients, the acceptance of our appeal and subsequent reversal of the initial finding indicates that TJC validates our policy and its adherence to accepted preferred practice guidelines of safe handling and administration of multidose eyedrops established by the American Academy of Ophthalmology for eye care practitioners. We believe the approval of our policy governing multidose eyedropper use establishes precedence for TJC that may be followed by other eye care facilities and health care organizations in the safe use of multidose eyedrop medications in multiple patients. The use of a multidose policy for preserved eyedrop preparations provides a safe and effective process for administering eyedrop medications to patients as well as controlling excessive health care costs to both patients and health care facilities.

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