



BY WILLIAM G. WILKOFF, M.D.

## LETTERS FROM MAINE

# Con-Templating

**D**o you use templates? If you haven't stepped over the threshold into the costly world of electronic health records, you may not understand the question.

In the old days, a template was a pattern or gauge for accurately creating a product. A stencil is a template. In addition to ensuring accuracy, a template allows its user to replicate the original product more efficiently.

Even if you haven't begun using electronic templates but practice in a group, you probably have adopted standard forms for a variety of patient

interactions—for example, ones for sick visits, which may be disease specific, or for well visits, which may be age specific. Obviously, standardization can make it easier for practicing physicians and their staffs to find information through documentation guided by templates. These forms can be bought off the shelf or developed internally by members of the group after what can be contentious ne-

gotiations between providers. Those of us who practiced by ourselves quickly became wedded to the formats we developed ourselves. When one joins a group, it can be difficult to leave our old favorite forms. And, when new editions are proposed, tugs-of-war can erupt over where to position, and how big to make, the boxes.

Some physicians prefer detailed and exhaustive checklists; others like myself prefer broad categories with plenty of elbow room to scribble and create anatomically incorrect drawings. We don't like being fenced in by a myriad of little boxes. Instead we crave the wide-open spaces to create and express our individuality.

Should a template dictate practice? Is it the purpose of the form to remind, coach, or arm twist the practitioner into asking certain questions or performing certain tests? There is certainly mounting evidence that checklists for procedures can improve outcomes. But when we are talking about an office visit encounter, one could ask, "Is the form the boss of me? Or is it merely a tool to guide my documentation so that my coworkers can find and understand what I have done?"

When templates become electronic, they can become tools for replicating documents of dubious quality. For example, when one clicks on a box that says "normal pharynx," the computer may spit out a stored bit of dialogue that includes "uvula midline, tonsils not enlarged." In reality the child may have a bifid uvula and his tonsils may have been surgically removed. Although these inaccuracies may be trivial, one can easily imagine others that are not so innocuous.

How many of us really carefully read the final documents generated by our clicks or wand taps? How many of us remember what the computer is going to say when we click "normal"? This kind of error by click is most obvious in emergency department records, which read like textbooks. Having spent more time in emergency departments than I care to remember, I know that the computer-generated record often bears little resemblance to what was actually examined.

Few of us intend to deceive when we document our findings, but a computerized template can make it easy to do so inadvertently.

Even more troubling is the phenomenon in which templates become too narrow and disease specific. All children with earaches are not made equal.

The diagnosis may not be otitis media but school avoidance or anxiety. If the office staff has already loaded in a template specific for otitis, the practitioner may be influenced away from other diagnoses.

A template that functions too much like a cookie cutter can discourage a broader assessment of the patient as a unique individual. ■

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Bausch & Lomb

**Besivance**  
besifloxacin ophthalmic  
suspension, 0.6%

**Brief Summary:** Based on full prescribing information revised April 2009.

To report SUSPECTED ADVERSE REACTIONS, contact Bausch & Lomb Incorporated at 1-800-323-0000 or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

#### INDICATIONS AND USAGE

Besivance™ (besifloxacin ophthalmic suspension) 0.6%, is indicated for the treatment of bacterial conjunctivitis caused by susceptible isolates of the following bacteria:

CDC coryneform group G  
*Corynebacterium pseudodiphtheriticum*\*  
*Corynebacterium striatum*\*  
*Haemophilus influenzae*  
*Moraxella lacunata*\*  
*Staphylococcus aureus*  
*Staphylococcus epidermidis*  
*Staphylococcus hominis*\*  
*Staphylococcus lugdunensis*\*  
*Streptococcus mitis* group  
*Streptococcus oralis*  
*Streptococcus pneumoniae*  
*Streptococcus salivarius*\*

\*Efficacy for this organism was studied in fewer than 10 infections.

#### DOSAGE AND ADMINISTRATION

Invert closed bottle and shake once before use. Instill one drop in the affected eye(s) 3 times a day, four to twelve hours apart for 7 days.

#### CONTRAINDICATIONS

None

#### WARNINGS AND PRECAUTIONS

##### Topical Ophthalmic Use Only

NOT FOR INJECTION INTO THE EYE.

Besivance™ is for topical ophthalmic use only, and should not be injected subconjunctivally, nor should it be introduced directly into the anterior chamber of the eye.

##### Growth of Resistant Organisms with Prolonged Use

As with other anti-infectives, prolonged use of Besivance™ (besifloxacin ophthalmic suspension) 0.6% may result in overgrowth of non-susceptible organisms, including fungi. If super-infection occurs, discontinue use and institute alternative therapy. Whenever clinical judgment dictates, the patient should be examined with the aid of magnification, such as slit-lamp biomicroscopy, and, where appropriate, fluorescein staining.

##### Avoidance of Contact Lenses

Patients should not wear contact lenses if they have signs or symptoms of bacterial conjunctivitis or during the course of therapy with Besivance™.

#### ADVERSE REACTIONS

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in one clinical trial of a drug cannot be directly compared with the rates in the clinical trials of the same or another drug and may not reflect the rates observed in practice.

The data described below reflect exposure to Besivance™ in approximately 1,000 patients between 1 and 98 years old with clinical signs and symptoms of bacterial conjunctivitis.

The most frequently reported ocular adverse event was conjunctival redness, reported in approximately 2% of patients.

Other adverse events reported in patients receiving Besivance™ occurring in approximately 1-2% of patients included: blurred vision, eye pain, eye irritation, eye pruritus and headache.

#### USE IN SPECIFIC POPULATIONS

##### Pregnancy

Pregnancy Category C. Oral doses of besifloxacin up to 1000 mg/kg/day were not associated with visceral or skeletal malformations in rat pups in a study of embryo-fetal development, although this dose was associated with maternal toxicity (reduced body weight gain and food consumption) and maternal mortality. Increased post-implantation loss, decreased fetal body weights, and decreased fetal ossification were also observed. At this dose, the mean  $C_{max}$  in the rat dams was approximately 20 mcg/mL, >45,000 times the mean plasma concentrations measured in humans. The No Observed Adverse Effect Level (NOAEL) for this embryo-fetal development study was 100 mg/kg/day ( $C_{max}$  5 mcg/mL, >11,000 times the mean plasma concentrations measured in humans).

In a prenatal and postnatal development study in rats, the NOAELs for both fetal and maternal toxicity were also 100 mg/kg/day. At 1000 mg/kg/day, the pups weighed significantly less than controls and had a reduced neonatal survival rate. Attainment of developmental landmarks and sexual maturation were delayed, although surviving pups from this dose group that were reared to maturity did not demonstrate deficits in behavior, including activity, learning and memory, and their reproductive capacity appeared normal.

Since there are no adequate and well-controlled studies in pregnant women, Besivance™ should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

##### Nursing Mothers

Besifloxacin has not been measured in human milk, although it can be presumed to be excreted in human milk. Caution should be exercised when Besivance™ is administered to a nursing mother.

##### Pediatric Use

The safety and effectiveness of Besivance™ in infants below one year of age have not been established. The efficacy of Besivance™ in treating bacterial conjunctivitis in pediatric patients one year or older has been demonstrated in controlled clinical trials [see 14 CLINICAL STUDIES].

There is no evidence that the ophthalmic administration of quinolones has any effect on weight bearing joints, even though systemic administration of some quinolones has been shown to cause arthropathy in immature animals.

##### Geriatric Use

No overall differences in safety and effectiveness have been observed between elderly and younger patients.

#### NONCLINICAL TOXICOLOGY

##### Carcinogenesis, Mutagenesis, Impairment Of Fertility

Long-term studies in animals to determine the carcinogenic potential of besifloxacin have not been performed.

No *in vitro* mutagenic activity of besifloxacin was observed in an Ames test (up to 3.33 mcg/plate) on bacterial tester strains *Salmonella typhimurium* TA98, TA100, TA1535, TA1537 and *Escherichia coli* WP2uvrA. However, it was mutagenic in *S. typhimurium* strain TA102 and *E. coli* strain WP2(pKM101). Positive responses in these strains have been observed with other quinolones and are likely related to topoisomerase inhibition.

Besifloxacin induced chromosomal aberrations in CHO cells *in vitro* and it was positive in an *in vivo* mouse micronucleus assay at oral doses  $\geq$  1500 mg/kg. Besifloxacin did not induce unscheduled DNA synthesis in hepatocytes cultured from rats given the test compound up to 2,000 mg/kg by the oral route. In a fertility and early embryonic development study in rats, besifloxacin did not impair the fertility of male or female rats at oral doses of up to 500 mg/kg/day. This is over 10,000 times higher than the recommended total daily human ophthalmic dose.

##### PATIENT COUNSELING INFORMATION

Patients should be advised to avoid contaminating the applicator tip with material from the eye, fingers or other source.

Although Besivance™ is not intended to be administered systemically, quinolones administered systemically have been associated with hypersensitivity reactions, even following a single dose. Patients should be advised to discontinue use immediately and contact their physician at the first sign of a rash or allergic reaction.

Patients should be told that although it is common to feel better early in the course of the therapy, the medication should be taken exactly as directed. Skipping doses or not completing the full course of therapy may (1) decrease the effectiveness of the immediate treatment and (2) increase the likelihood that bacteria will develop resistance and will not be treatable by Besivance™ or other antibacterial drugs in the future.

Patients should be advised not to wear contact lenses if they have signs or symptoms of bacterial conjunctivitis or during the course of therapy with Besivance™.

Patients should be advised to thoroughly wash hands prior to using Besivance™.

Patients should be instructed to invert closed bottle (upside down) and shake once before each use. Remove cap with bottle still in the inverted position. Tilt head back, and with bottle inverted, gently squeeze bottle to instill one drop into the affected eye(s).

Manufactured by: Bausch & Lomb Incorporated

Tampa, Florida 33637

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U.S. Patent No. 6,685,958

U.S. Patent No. 6,699,492

U.S. Patent No. 5,447,926

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