

HHS Seeking Electronic Biosurveillance System

BY MARY ELLEN SCHNEIDER
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WASHINGTON — Government officials and health information technology leaders plan to spend this year laying the groundwork for a system that would allow for the electronic transfer of ambulatory, emergency department, and laboratory data to public health agencies in less than a day.

Over time, officials would like to im-

plement a real-time nationwide public health monitoring system.

"The system we have is simply not adequate," Mike Leavitt, secretary of the Health and Human Services department, said at a meeting of the American Health Information Community. The United States faces the possibility of a bioterrorist attack and the threat of pandemic, he said.

Mr. Leavitt said he would like to get a "spotty net" of surveillance off the ground quickly by collecting a few key indicators

from as many electronic data sources as possible. Getting just 2-4 basic data points from all available sources would be a "quantum leap forward," he said.

Information from small and medium-sized primary care practices will be key to any electronic biosurveillance system, said Dr. David Kibbe, who represented the American Academy of Family Physicians at the meeting. The American Health Information Community is an advisory committee to the HHS department.

"There is widespread agreement that information technology can substantially improve surveillance both for ongoing public health and for health emergencies," said Dr. Thomas R. Frieden, commissioner of the New York City Department of Health and Mental Hygiene, who presented information on current electronic surveillance programs at the meeting.

There is a wide range of biosurveillance activities underway at the federal, state, and local levels, and in the private sector, Dr. Frieden said. For example, the Centers for Disease Control and Prevention operates the Public Health Information Network, which provides an architecture for public health information technology. Most recently, the agency established the BioSense program, which is aimed at supporting the connection of clinical care to public health and supporting "situational awareness" at the national level.

A number of state and local health departments have begun electronic reporting either from clinical laboratories or clinical information systems.

In New York City, the health department uses electronic reporting data on a daily basis. The system, which has been operating for more than 5 years, collects

information from ambulance dispatches, emergency department visits, pharmacy purchases, outpatient visits, and other sources. The system also collects free text, which allows officials to evaluate information they might not have thought about otherwise.

Currently, 50 hospitals—representing about 90% of emergency department visits in the city—report daily. The electronic reporting system has proved helpful in the early detection of pockets of influenza. The electronic syndromic system consistently picks up influenza activity 2-3 weeks before any other system.

New York City is not alone. North Carolina has a statewide, hospital-based clinical data monitoring system. It allows for monitoring of real-time inpatient, outpatient, and emergency department data.

But there are major needs that must be addressed to reach the goal of a nationwide system, said Dr. John Loonsk of the federal Office of the National Coordinator for Health Information Technology. For example, data need to be standardized so they can be compared across reporting organizations, privacy and confidentiality must be ensured, and improvements need to be made in the current patchwork of state and local health information technology capability, he said.

In the short term, one area that could be implemented rapidly is the electronic reporting of lab results. This has value both to public health and for the routine use of clinicians, Dr. Loonsk said. ■

BenzaClin^{topical gel} clindamycin 1% - benzoyl peroxide 5% gel

Brief summary. Please see full prescribing information for complete product information.

BenzaClin[®] Topical Gel (clindamycin - benzoyl peroxide gel)

Topical Gel: clindamycin (1%) as clindamycin phosphate, benzoyl peroxide (5%)

For Dermatological Use Only - Not for Ophthalmic Use

Reconstitute Before Dispensing

INDICATIONS AND USAGE

BenzaClin Topical Gel is indicated for the topical treatment of acne vulgaris.

CONTRAINDICATIONS

BenzaClin Topical Gel is contraindicated in those individuals who have shown hypersensitivity to any of its components or to lincomycin. It is also contraindicated in those having a history of regional enteritis, ulcerative colitis, or antibiotic-associated colitis.

WARNINGS

ORALLY AND PARENTERALLY ADMINISTERED CLINDAMYCIN HAS BEEN ASSOCIATED WITH SEVERE COLITIS WHICH MAY RESULT IN PATIENT DEATH. USE OF THE TOPICAL FORMULATION OF CLINDAMYCIN RESULTS IN ABSORPTION OF THE ANTIBIOTIC FROM THE SKIN SURFACE. DIARRHEA, BLOODY DIARRHEA, AND COLITIS (INCLUDING PSEUDOMEMBRANOUS COLITIS) HAVE BEEN REPORTED WITH THE USE OF TOPICAL AND SYSTEMIC CLINDAMYCIN. STUDIES INDICATE A TOXIN(S) PRODUCED BY CLOSTRIDIA IS ONE PRIMARY CAUSE OF ANTIBIOTIC-ASSOCIATED COLITIS. THE COLITIS IS USUALLY CHARACTERIZED BY SEVERE PERSISTENT DIARRHEA AND SEVERE ABDOMINAL CRAMPS AND MAY BE ASSOCIATED WITH THE PASSAGE OF BLOOD AND MUCUS. ENDOSCOPIC EXAMINATION MAY REVEAL PSEUDOMEMBRANOUS COLITIS. STOOL CULTURE FOR *Clostridium Difficile* AND STOOL ASSAY FOR *C. difficile* TOXIN MAY BE HELPFUL DIAGNOSTICALLY. WHEN SIGNIFICANT DIARRHEA OCCURS, THE DRUG SHOULD BE DISCONTINUED. LARGE BOWEL ENDOSCOPY SHOULD BE CONSIDERED TO ESTABLISH A DEFINITIVE DIAGNOSIS IN CASES OF SEVERE DIARRHEA. ANTIPERISTALTIC AGENTS SUCH AS OPIATES AND DIPHENOXYLATE WITH ATROPINE MAY PROLONG AND/OR WORSEN THE CONDITION. DIARRHEA, COLITIS, AND PSEUDOMEMBRANOUS COLITIS HAVE BEEN OBSERVED TO BEGIN UP TO SEVERAL WEEKS FOLLOWING CESSATION OF ORAL AND PARENTERAL THERAPY WITH CLINDAMYCIN.

Mild cases of pseudomembranous colitis usually respond to drug discontinuation alone. In moderate to severe cases, consideration should be given to management with fluids and electrolytes, protein supplementation and treatment with an antibacterial drug clinically effective against *C. difficile* colitis.

PRECAUTIONS

General: For dermatological use only; not for ophthalmic use. Concomitant topical acne therapy should be used with caution because a possible cumulative irritancy effect may occur, especially with the use of peeling, desquamating, or abrasive agents.

The use of antibiotic agents may be associated with the overgrowth of nonsusceptible organisms including fungi. If this occurs, discontinue use of this medication and take appropriate measures. Avoid contact with eyes and mucous membranes.

Clindamycin and erythromycin containing products should not be used in combination. *In vitro* studies have shown antagonism between these two antimicrobials. The clinical significance of this *in vitro* antagonism is not known.

Information for Patients: Patients using **BenzaClin Topical Gel** should receive the following information and instructions:

- BenzaClin Topical Gel** is to be used as directed by the physician. It is for external use only. Avoid contact with eyes, and inside the nose, mouth, and all mucous membranes, as this product may be irritating.
- This medication should not be used for any disorder other than that for which it was prescribed.
- Patients should not use any other topical acne preparation unless otherwise directed by physician.
- Patients should minimize or avoid exposure to natural or artificial sunlight (tanning beds or UVA/B treatment) while using **BenzaClin Topical Gel**. To minimize exposure to sunlight, a wide-brimmed hat or other protective clothing should be worn, and a sunscreen with SPF 15 rating or higher should be used.
- Patients should report any signs of local adverse reactions to their physician.
- BenzaClin Topical Gel** may bleach hair or colored fabric.
- BenzaClin Topical Gel** can be stored at room temperature up to 25°C (77°F) for 3 months. Do not freeze. Discard any unused product after 3 months.
- Before applying **BenzaClin Topical Gel** to affected areas wash the skin gently, then rinse with warm water and pat dry.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Benzoyl peroxide has been shown to be a tumor promoter and progression agent in a number of animal studies. The clinical significance of this is unknown.

Benzoyl peroxide in acetone at doses of 5 and 10 mg administered twice per week induced skin tumors in transgenic Tg.AC mice in a study using 20 weeks of topical treatment

In a 52 week dermal photocarcinogenicity study in hairless mice, the median time to onset of skin tumor formation was decreased and the number of tumors per mouse increased following chronic concurrent topical administration of **BenzaClin Topical Gel** with exposure to ultraviolet radiation (40 weeks of treatment followed by 12 weeks of observation).

Genotoxicity studies were not conducted with **BenzaClin Topical Gel**. Clindamycin phosphate was not genotoxic in *Salmonella typhimurium* or in a rat micronucleus test. Clindamycin phosphate sulfoxide, an oxidative degradation product of clindamycin phosphate and benzoyl peroxide, was not clastogenic in a mouse micronucleus test. Benzoyl peroxide has been found to cause DNA strand breaks in a variety of mammalian cell types, to be mutagenic in *S. typhimurium* tests by some but not all investigators, and to cause sister chromatid exchanges in Chinese hamster ovary cells. Studies have not been performed with **BenzaClin Topical Gel** or benzoyl peroxide to evaluate the effect on fertility. Fertility studies in rats treated orally with up to 300 mg/kg/day of

clindamycin (approximately 120 times the amount of clindamycin in the highest recommended adult human dose of 2.5 g **BenzaClin Topical Gel**, based on mg/m²) revealed no effects on fertility or mating ability.

Pregnancy: Teratogenic Effects: Pregnancy Category C:

Animal reproductive/developmental toxicity studies have not been conducted with **BenzaClin Topical Gel** or benzoyl peroxide. Developmental toxicity studies performed in rats and mice using oral doses of clindamycin up to 600 mg/kg/day (240 and 120 times amount of clindamycin in the highest recommended adult human dose based on mg/m², respectively) or subcutaneous doses of clindamycin up to 250 mg/kg/day (100 and 50 times the amount of clindamycin in the highest recommended adult human dose based on mg/m², respectively) revealed no evidence of teratogenicity. There are no well-controlled trials in pregnant women treated with **BenzaClin Topical Gel**. It also is not known whether **BenzaClin Topical Gel** can cause fetal harm when administered to a pregnant woman.

Nursing Women: It is not known whether **BenzaClin Topical Gel** is excreted in human milk after topical application. However, orally and parenterally administered clindamycin has been reported to appear in breast milk. Because of the potential for serious adverse reactions in nursing infants, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric Use: Safety and effectiveness of this product in pediatric patients below the age of 12 have not been established.

ADVERSE REACTIONS

During clinical trials, the most frequently reported adverse event in the **BenzaClin** treatment group was dry skin (12%). The Table below lists local adverse events reported by at least 1% of patients in the **BenzaClin** and vehicle groups.

	Local Adverse Events - all causalities in ≥1% of patients	
	BenzaClin n = 420	Vehicle n = 168
Application site reaction	13 (3%)	1 (<1%)
Dry skin	50 (12%)	10 (6%)
Pruritus	8 (2%)	1 (<1%)
Peeling	9 (2%)	-
Erythema	6 (1%)	1 (<1%)
Sunburn	5 (1%)	-

The actual incidence of dry skin might have been greater were it not for the use of a moisturizer in these studies.

DOSE AND ADMINISTRATION

BenzaClin Topical Gel should be applied twice daily, morning and evening, or as directed by a physician, to affected areas after the skin is gently washed, rinsed with warm water and patted dry.

HOW SUPPLIED AND COMPOUNDING INSTRUCTIONS

Size (Net Weight)	NDC 0066-	Benzoyl Peroxide Gel	Active Clindamycin Powder (In plastic vial)	Purified Water To Be Added to each vial
25 grams	0494-25	19.7g	0.3g	5 mL
50 grams	0494-50	41.4g	0.6g	10 mL

Prior to dispensing, tap the vial until powder flows freely. Add indicated amount of purified water to the vial (to the mark) and immediately shake to completely dissolve clindamycin. If needed, add additional purified water to bring level up to the mark. Add the solution in the vial to the gel and stir until homogenous in appearance (1 to 1½ minutes). **BenzaClin Topical Gel** (as reconstituted) can be stored at room temperature up to 25°C (77°F) for 3 months. Place a 3 month expiration date on the label immediately following mixing. Store at room temperature up to 25°C (77°F) (See USP).

Do not freeze. Keep tightly closed. Keep out of the reach of children.

US Patents 5,446,028; 5,767,098; 6,013,637

Prescribing Information as of May 2005.

Rx Only

Manufactured for

DERMIK LABORATORIES

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