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INFECTION CONTROL AND HOSPITAL EPIDEMIOLOGY™

EDITORIAL

The Price of a Surgical-Site Infection: More Than Just Excess Length of Stay
EDWARD S. WONG, MD 722

ORIGINAL ARTICLES

The Impact of Surgical-Site Infections in the 1990s: Attributable Mortality, Excess Length of Hospitalization, and Extra Costs
KATHRYN B. KIRKLAND, MD; JANE P. BRIGGS, BSN; SHARON L. TRIVETTE, RN; WILLIAM E. WILKINSON, PHD; DANIEL J. SEXTON, MD 725

An Outbreak of Hospital-Acquired Hepatitis B Virus Infection Among Patients Receiving Chronic Hemodialysis
YVAN J.F. HUTIN, MD, MSC; SUSAN T. GOLDSTEIN, MD; JAY K. VARMA, MD; JOAN B. O'DAIR, RN, MPH; ERIC E. MAST, MD, MPH; CRAIG N. SHAPIRO, MD; MIRIAM J. ALTER, PHD 731

Safety of Peripheral Intravenous Catheters in Children
RUTH B. SHIMANDLE, RN, MPH; DANIEL JOHNSON, MD; MARK BAKER, MD; NAOMI STOTLAND, MD; THEODORE KARRISON, PHD; PAUL M. ARNOW, MD 736

"Pulse" Nasal Mupirocin Maintenance Regimen in Patients Undergoing Continuous Ambulatory Peritoneal Dialysis
JOSEPH M. MYLOTTE, MD, CIC; LUCINDA KAHLER, BS, MS; ELLEN JACKSON, RN 741

An Outbreak of Gram-Negative Bacteremia in Hemodialysis Patients Traced to Hemodialysis Machine Waste Drain Ports
SUSAN A. WANG, MD, MPH; RACHEL B. LEVINE, MD; LORETTA A. CARSON, MS; MATTHEW J. ARDUINO, DRPH; TERESA KILLAR, RN; F. GREGORY GRILLO, MD; MICHELE L. PEARSON, MD; WILLIAM R. JARVIS, MD 746

A Canadian Survey of Prophylactic Antibiotic Use Among Hip-Fracture Patients
DICK ZOUTMAN, MD; LAURENCE CHAU, MD; JAMES WATTERSON, MD; THOMAS MACKENZIE, MD; MARINA DJURFELDT, MSC 752

CONCISE COMMUNICATIONS

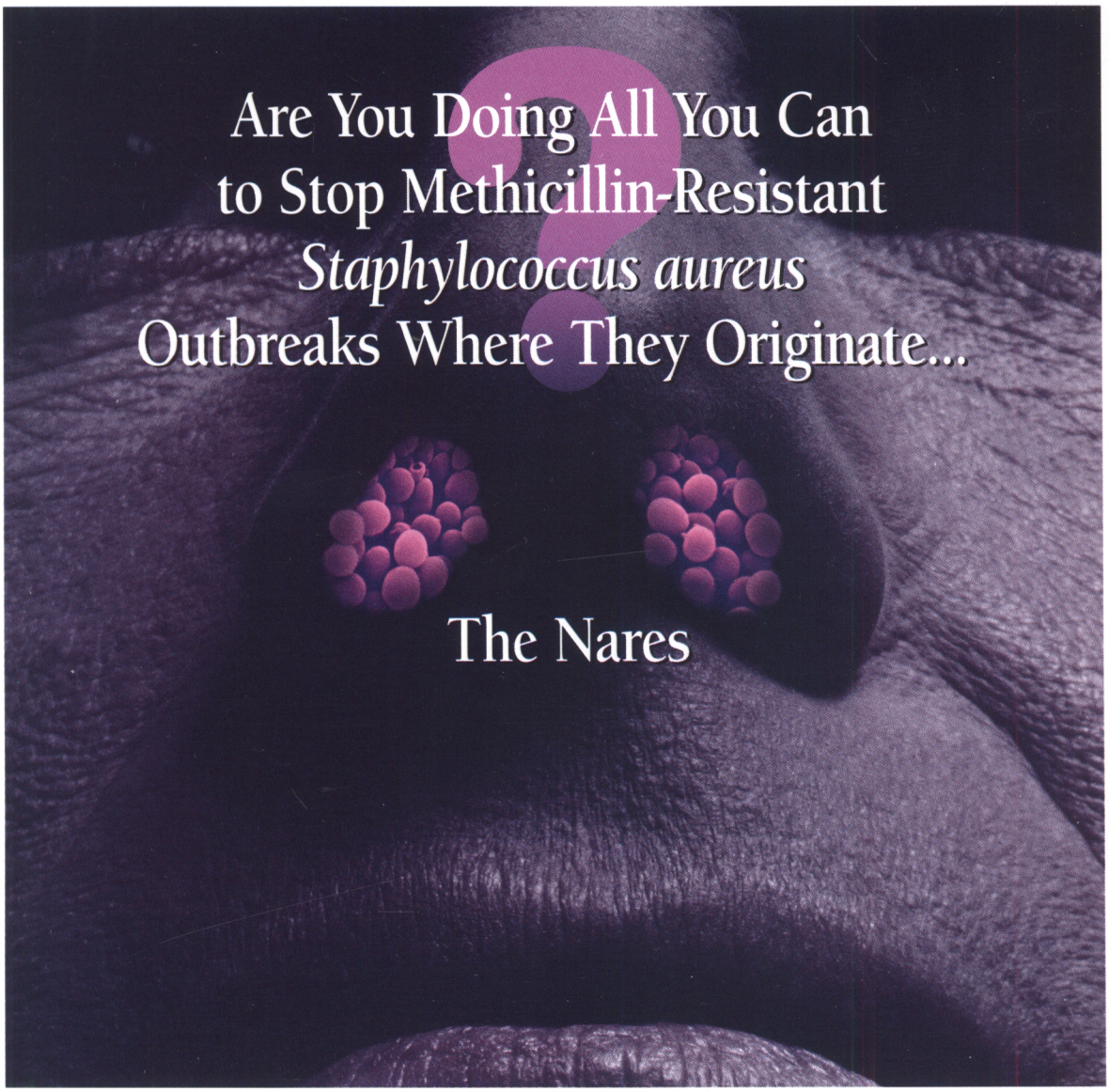
Outbreak of *Stenotrophomonas maltophilia* Bacteremia Among Patients Undergoing Bone Marrow Transplantation: Association With Faulty Replacement of Handwashing Soap
JEFFREY D. KLAUSNER, MD, MPH; CAROL ZUKERMAN, RN, CIC; AJIT P. LIMAYE, MD; LAWRENCE COREY, MD 756

Usefulness of Pulsed-Field Gel Electrophoresis in Assessing Nosocomial Transmission of Pertussis
MICHÈLE NOUVELLON, MD; JEAN-FRANÇOIS GEHANNO, MD; MARTINE PESTEL-CARON, PHD; CHRISTIAN WEBER; JEAN-FRANÇOIS LEMELAND, PHD; NICOLE GUISO, PHD 758

A Case-Control Study to Detect Modifiable Risk Factors for Colonization With Vancomycin-Resistant Enterococci
MARK LOEB, MD, MSC; SUZETTE SALAMA, PHD; MAXINE ARMSTRONG-EVANS, RN; GINA CAPRETTA; JAN OLDE, RN, CIC 760

Continued inside.

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- *Bactroban* Nasal is indicated for eradication of nasal colonization with methicillin-resistant *S. aureus* (MRSA) in adult patients and healthcare workers as part of a comprehensive infection control program to reduce the risk of infection among high-risk patients during MRSA outbreaks.[1]

Single-use tube (actual size)



- In a hospital study, *Bactroban* Nasal contributed to a dramatic reduction in MRSA infections and vancomycin costs during an outbreak.[2]
- Excellent safety profile[1]

The most frequently reported adverse events were headache (9%), rhinitis (6%), respiratory disorder (including upper respiratory tract congestion) (5%), pharyngitis (4%) and taste perversion (3%). Safety in children under 12 years of age has not been established in controlled clinical trials.

Contraindications … Do not use *Bactroban* Nasal in patients with known hypersensitivity to any of the constituents of the product.

Please see brief summary of prescribing information on adjacent page.

References: 1. Bactroban® Nasal prescribing information, 1995. **2.** Reagan DR, Dula RT, Palmer BH, et al. Control of MRSA in a VAMC with limited resources. Prog Abstr 31st Interscience Conference on Antimicrobial Agents and Chemotherapy, Chicago, U.S.A., Sept. 29-Oct. 2, 1991, p 104.

SB SmithKline Beecham Pharmaceuticals

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Bactroban® Nasal mupirocin calcium

2% ointment for intranasal use

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BACTROBAN® NASAL (mupirocin calcium ointment), 2%

Brief summary. For complete prescribing information, see package insert.

INDICATIONS AND USAGE

Bactroban Nasal is indicated for eradication of nasal colonization with methicillin-resistant *Staphylococcus aureus* in adult patients and health care workers as part of a comprehensive infection control program to reduce the risk of infection among patients at high risk of methicillin-resistant *S. aureus* infection during institutional outbreaks of infections with this pathogen.

NOTE:

(1) There are insufficient data at this time to establish that this product is safe and effective as part of an intervention program to prevent autoinfection of high-risk patients from their own nasal colonization with *S. aureus.*

(2) There are insufficient data at this time to recommend use of *Bactroban* Nasal for general prophylaxis of any infection in any patient population.

(3) Greater than 90% of subjects/patients in clinical trials had eradication of nasal colonization 2 to 4 days after therapy was completed. Approximately 30% recolonization was reported in one domestic study within 4 weeks after completion of therapy. These eradication rates were clinically and statistically superior to those reported in subjects/patients in the vehicle-treated arms of the adequate and well-controlled studies. Those treated with vehicle had eradication rates of 5% to 30% at 2 to 4 days post-therapy with 85% to 100% recolonization within 4 weeks.

CONTRAINDICATIONS

Bactroban Nasal is contraindicated in patients with known hypersensitivity to any of the constituents of the product.

WARNINGS

AVOID CONTACT WITH THE EYES. Application of *Bactroban* Nasal to the eye under testing conditions has caused severe symptoms such as burning and tearing. These symptoms resolved within days to weeks after discontinuation of the ointment.

In the event of a sensitization or severe local irritation from *Bactroban* Nasal, usage should be discontinued.

PRECAUTIONS

General: As with other antibacterial products, prolonged use may result in overgrowth of nonsusceptible microorganisms, including fungi. (See **DOSAGE AND ADMINISTRATION** in complete prescribing information.)

Information for Patients: Patients should: apply approximately one-half of the ointment from the single-use tube directly into one nostril and the other half into the other nostril; avoid contact of the medication with the eyes; discard the tube after using; press the sides of the nose together and gently massage after application to spread the ointment throughout the inside of the nostrils; and discontinue using *Bactroban* Nasal and call a health care practitioner if sensitization or severe local irritation occurs.

Drug Interactions: The effect of the concurrent application of intranasal mupirocin calcium and other intranasal products has not been studied. Do not apply mupirocin calcium ointment, 2% concurrently with any other intranasal products.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Long-term studies in animals to evaluate carcinogenic potential of mupirocin calcium have not been conducted. Results of the following studies performed with mupirocin calcium or mupirocin sodium *in vitro* and *in vivo* did not indicate a potential for mutagenicity: rat primary hepatocyte unscheduled DNA synthesis, sediment analysis for DNA strand breaks, *Salmonella* reversion test (Ames), *Escherichia coli* mutation assay, metaphase analysis of human lymphocytes, mouse lymphoma assay, and bone marrow micronuclei assay in mice. Reproduction studies were performed in rats with mupirocin administered subcutaneously at doses up to **40** times the human intranasal dose (approximately 20 mg mupirocin per day) on a mg/m^2 basis and revealed no evidence of impaired fertility from mupirocin sodium.

Pregnancy: Teratogenic Effects. Pregnancy Category B. Reproduction studies have been performed in rats and rabbits with mupirocin administered subcutaneously at doses up to 65 and 130 times, respectively, the human intranasal dose (approximately 20 mg mupirocin per day) on a mg/m^2 basis and revealed no evidence of harm to the fetus due to mupirocin. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Nursing Mothers: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, exercise caution when *Bactroban* Nasal is administered to a nursing woman.

Pediatric Use: Safety in children under the age of 12 years has not been established. (See **CLINICAL PHARMACOLOGY** in complete prescribing information.)

ADVERSE REACTIONS

Clinical Trials: In clinical trials, 210 domestic and 2,130 foreign adult subjects/patients received *Bactroban* Nasal ointment. Less than 1% of domestic or foreign subjects and patients in clinical trials were withdrawn due to adverse events. In domestic clinical trials, 17% (36/210) of adults treated with *Bactroban* Nasal ointment reported adverse events thought to be at least possibly drug-related. The incidence of adverse events that were reported in at least 1% of adults enrolled in domestic clinical trials were as follows: headache, 9%; rhinitis, 6%; respiratory disorder, including upper respiratory tract congestion, 5%; pharyngitis, 4%; taste perversion, 3%; burning/stinging, 2%; cough, 2%; and pruritus, 1%.

The following events thought possibly drug-related were reported in less than 1% of adults enrolled in domestic clinical trials: blepharitis, diarrhea, dry mouth, ear pain, epistaxis, nausea and rash. All adequate and well-controlled clinical trials have been performed using *Bactroban* Nasal ointment, 2% in one arm and the vehicle ointment in the other arm of the study.

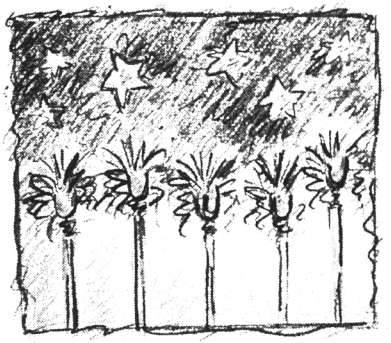
OVERDOSAGE

Following single or repeated intranasal applications of *Bactroban* Nasal to adults, no evidence for systemic absorption of mupirocin was obtained.

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St. Paul, Minnesota

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INFECTION CONTROL AND HOSPITAL EPIDEMIOLOGY™

CONTENTS

Continued from cover

TOPICS IN LONG-TERM CARE

Infection Control Programs in Long-Term–Care Facilities: Structure and Process
BARBARA A. GOLDRICK, RN, PHD 764

INFORMATION MANAGEMENT

***staffTRAK-TB:* Software for Surveillance of Tuberculosis Infection in Healthcare Workers**
DALE R. BURWEN, MD, MPH; M. FRANKLIN SEAWRIGHT, BS 770

Satellite Videoconferencing for Healthcare Workers: Audience Characteristics and the Importance of Continuing Education Credits
I-LUN CHEN, MD; JOSEPH N. ECKHARDT, MPH; RONDA L. SINKOWITZ-COCHRAN, MPH; WILLIAM R. JARVIS, MD 778

MEDICAL NEWS
GINA PUGLIESE, RN, MS; MARTIN S. FAVERO, PHD 781

SHEA NEWS
ANDREAS VOSS, MD, PHD 784

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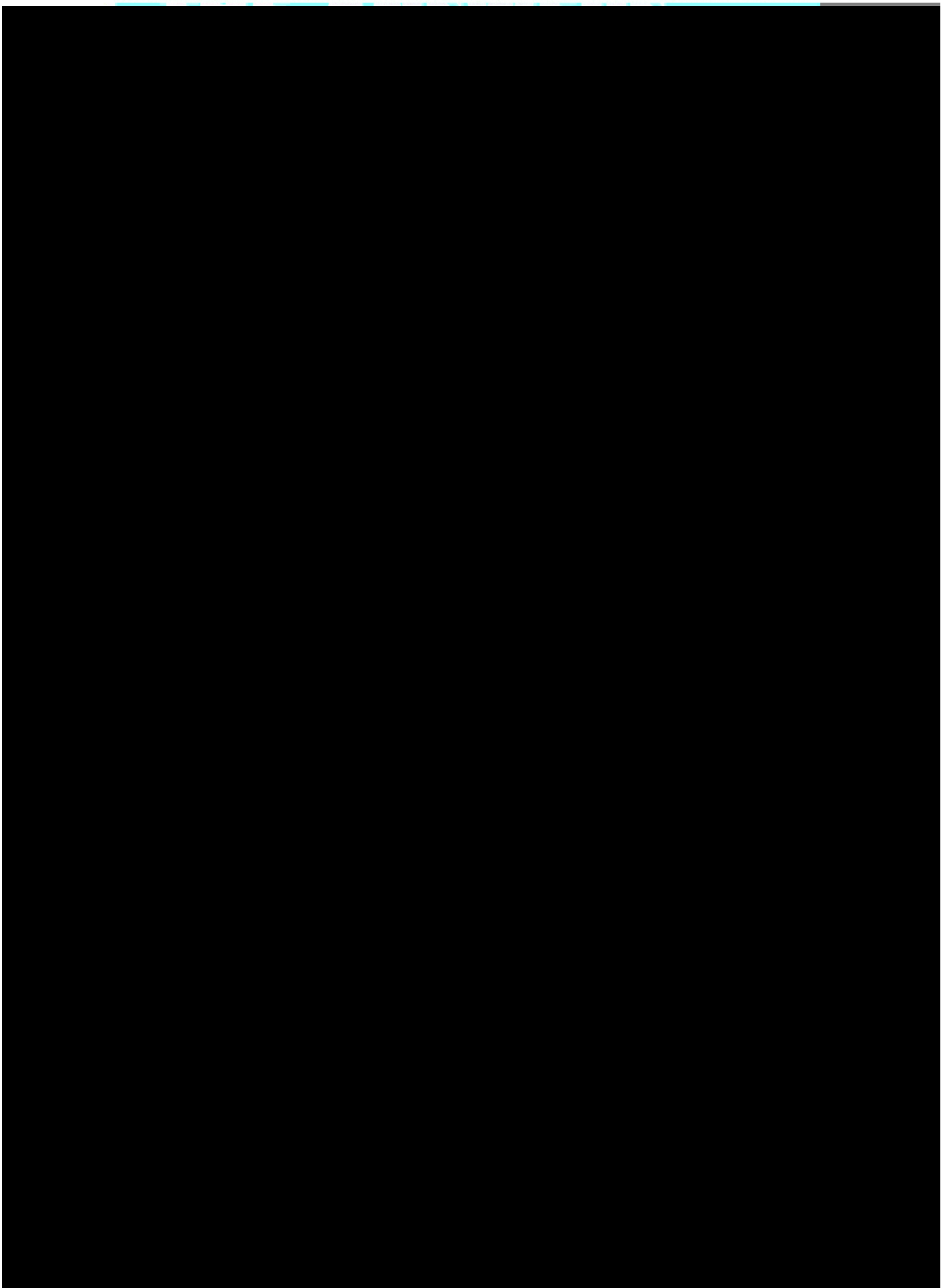
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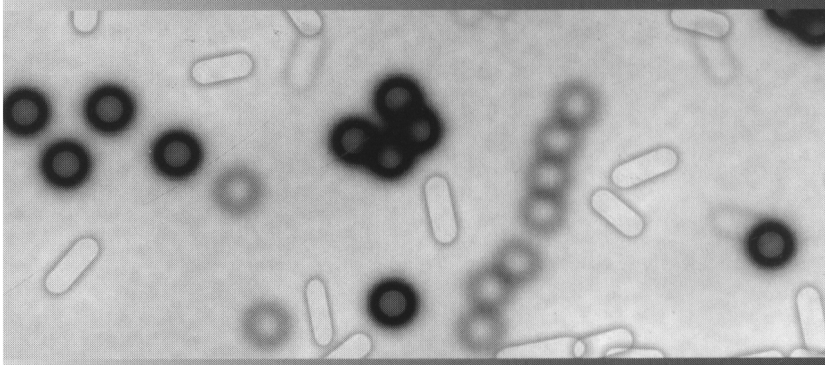
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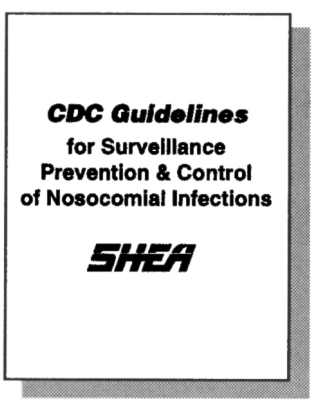
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