What Can Public Health Learn from Model Interventions?

Resistance to antimicrobial drugs, a global threat that evolved in the 20th century, presents an ever-growing peril as we enter the 21st. Yet a dearth of information about strategies to contain the emergence and spread of antimicrobial resistance (AMR) has hampered public health’s counterattack. A number of interventions have been suggested as powerful strategies to limit AMR. Targeted at antimicrobial prescribers, patients, governments, hospitals, pharmaceutical companies, and/or agribusiness, such interventions can take the form of education, policymaking, legislative controls, economic incentives, and infection control programs. Among the successful interventions are WHO’s Integrated Management of Childhood Illness (IMCI) for acute respiratory infections, diarrheal diseases and malaria in children, and the Directly Observed Treatment Short-course strategy for tuberculosis. (See article, p 2.)

Assessing the utility and cost-effectiveness of AMR interventions has also hampered their implementation. Once an intervention’s success has been proven, the next necessary steps include generating publicity and initiating roll-out by nations and donors. APUA, together with chapters in more than 50 countries, is involved in the development and promotion of effective interventions to contain AMR. A cornerstone of such efforts is a full evaluation of their efficacy, cost-effectiveness, and generalizability.

This special issue of the *APUA Newsletter* describes a number of evidence-based interventions worthy of further evaluation and emulation.

References

Quality Control of Antibiotic Use:
Lessons from a Community Hospital in Brooklyn, New York

Jose P Aparicio, M.D., MPH; Ernest Visconti, M.D.; Margaret Kuhn-Basti, M.D.; Naser Yazigi, M.D.; Leon Rosenkranz, M.D.; Win Moe Aung, M.D.; Meharchand Oad, M.D.; Yin Thwe, M.D.; Lutheran Medical Center, Brooklyn, NY

Unnecessary and inappropriate antibiotic use are key factors in the emergence and dissemination of antimicrobial-resistant nosocomial pathogens and the consequent rise in health care costs. Patients who do not respond to first-line antibiotics often require newer generations of drugs that are typically more expensive. Patients infected with multidrug-resistant organisms are also more likely to respond poorly to treatment and to require longer hospital stays — factors that contribute to more costly patient management.

In Brooklyn, New York, multidrug-resistant gram-negative organisms have increased in recent years. Resistance rates among *Acinetobacter baumannii* to imipenem rose from 5% prior to 2001 to 14% in 2001. At Lutheran Medical Center (LMC), a 473-bed community hospital, resistance of *Pseudomonas aeruginosa* to amikacin increased from 3% in 1997 to 10% in 2002, while resistance to imipenem rose from 15% in 1997 to 29% in 2002.

APUA One-on-One

CDC Get Smart Campaign

Interview with Richard Besser, M.D., Medical Director, U.S. Centers for Disease Control and Prevention

If an anthrax epidemic struck the United States, Dr. Richard Besser would be manning the front lines of defense. As acting chief of the CDC’s Meningitis and Special Pathogens Branch, he focuses on combating bacterial diseases here and abroad. But before assuming this position in early 2003, Besser fought another urgent bacterial threat: drug-resistant infections spawned by inappropriate antibiotic use. As medical director of the agency’s *Get Smart: Know When Antibiotics Work* campaign, Besser shaped and directed a broad-scale model intervention aimed at curbing unnecessary antibiotic prescriptions for children’s upper respiratory infections.

Though a public health administrator, Besser also views the issue through the perspective of a physician. “I work in a free clinic in Atlanta half a day a week, which serves mainly Latino patients who don’t have insurance,” he says. “It allows

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DOTS: The Jewel of Global Public Health

Anibal Sosa, M.D., International Program Director, and Madeline Drexler, Associate Editor, APUA Newsletter

The MDR-TB Threat

One of the jewels of global public health is the DOTS program (directly observed treatment, short course) for tuberculosis patients. With two million deaths annually, tuberculosis remains a major public health peril. In the wake of the worldwide TB epidemic, MDR-TB has ominously spread to every reporting nation.

MDR-TB is resistant to isoniazid and rifampicin, two of the most reliable front-line drugs. Worldwide, 79% of MDR-TB cases are “super strains,” resistant to at least three of the four main drugs used to cure the disease. According to a 2004 report from the World Health Organization, 300,000 new cases of MDR-TB are diagnosed each year. MDR-TB has grown at an especially alarming rate in the former Soviet Union, where the public health system collapsed in the wake of political and economic changes. Regions with the highest prevalence of MDR-TB are those with the world’s fastest-growing HIV infection rates: Eastern Europe and Central Asia.

MDR-TB strains seriously impair TB control and prevention efforts, because second-line drugs are less potent and not well-tolerated, and may require regimens lasting two years. The inability to detect resistance early is one of the main factors involved in the genesis and control of MDR-TB, because it results in prolonged exposure to ineffective drugs. In resource-poor areas, inconsistent drug supply and weak TB-control infrastructure can lead to a vicious cycle of inadequate treatment, the generation of drug resistance, and transmission of resistant strains.

The emergence of drug-resistant TB has been linked to lack of standardized therapeutic regimens; poor implementation compounded by frequent or prolonged shortages of drugs in areas with inadequate public health infrastructure or political instability; and use of anti-TB drugs that are of unproven quality or that are sold over-the-counter or on the black market.

TB strains have shown the capacity to develop resistance to every known treatment drug. Resistance is most likely to evolve in cavitary lesions, where high-volume replication spawns mutations. Multiple drug therapy, which suppresses the evolution of such drug-resistant strains, is the backbone of treatment.

In the case of the TB bacillus, drug-resistance arises primarily from the accumulation of mutations in individual drug target genes. Drug resistance also apparently springs from treatment problems — including noncompliance and inadequate treatment regimens — and not from the emergence of novel resistance mechanisms. This biological fact should reassure health officials that DOTS will continue to be an effective way to reduce primary resistance, acquired resistance, and relapses.

The DOTS Strategy

DOTS, introduced on a global scale in 1995, is founded on five principles: government commitment to TB control; case detection by sputum smear microscopy; effective DOTS programs will continue to be the main weapons against the emergence of drug-resistant TB. Effective DOTS programs will continue to be the main weapons against the emergence of drug-resistant TB.
scopy; a standardized six-to-eight-month treatment using a combination of drugs; a regular and uninterrupted supply of essential drugs; and standardized recording and reporting. Under the DOTS program, a six-month supply of drugs can cost as little as $10 per patient. In areas where MDR-TB is minimal or nonexistent, DOTS achieves cure rates of up to 95% — high enough to dramatically reduce the TB burden while preventing the emergence of drug resistance. Various studies have documented that an effective DOTS program can decrease rates of MDR-TB, which is 100 times more expensive to treat.

The short-course chemotherapy on which DOTS is based, however, usually fails to cure MDR-TB. DOTS-Plus is a comprehensive management approach undertaken in areas where there is high prevalence of MDR-TB. In DOTS-Plus, second-line antituberculosis drugs are administered, along with monitoring by sputum culture, drug-susceptibility testing, and directly observed individualized therapy.

The Future of DOTS

It is easier to prevent MDR-TB from arising than to rein in an established epidemic. Thus, effective DOTS programs will continue to be the main weapons against the emergence of drug-resistant TB. In addressing the global dangers of drug-resistant TB, the recent WHO report calls for expansion of the DOTS program, increased funding for DOTS-Plus, and more investment in disease surveillance and laboratory research.

Scientists estimate that it will take 20 to 30 years to finally eliminate the ancient scourge of tuberculosis. Currently, DOTS is our best option to reverse the course of this deadly pandemic and to prevent the terrifying rise of its drug-resistant strains.

Q: You've published papers demonstrating that antibiotic prescribing declined in the U.S. from 1992 to 2000. Although you didn't state the specific reasons behind that decline, what's your hunch?
A: Where defensive medicine used to mean prescribing an antibiotic, it may now mean improving communication with your patients. By understanding patient concerns and letting patients know the natural history of many non-bacterial infectious diseases, patients are more willing to leave the office without a prescription.

Q: In your published studies, you were unable to ascertain whether antibiotics were being appropriately or inappropriately prescribed, because prescriptions weren't linked to diagnoses. Is that information crucial in any broad-based intervention?
A: Yes. Health plans that have targeted the appropriateness of drug selection have had an impact. Through physician profiling and physician feedback, doctors can see how their drug selection compares with national recommendations and with other providers in their groups. Those kinds of interventions improve drug selection.

The next area where we would like to focus is the appropriateness of drug selection. Here we run directly into the marketing arm of the pharmaceutical industry. Direct-to-consumer promotion of antibiotics and the use of free antibiotic samples in physician offices are just two factors that may lead to increased prescribing of drugs that are not recommended for first-line treatment of many infections.

Q: What specific measurable interventions do you foresee?
A: We would encourage health plans to look at use of targeted therapy for acute otitis media and for sinusitis. The American Academy of Pediatrics and the American Academy of Family Physicians recently released guidelines for the management of these infections that reaffirm the role of amoxicillin as first-line therapy when antibiotics are indicated. A number of health plans...
have implemented quality improvement programs directed at these conditions and have seen improvements in antibiotic selection. A health plan’s goal could be that, for a given clinician, 60% of his or her patients suffering from acute otitis media, for example, are treated with a first-line agent. While these interventions can cut drug costs, they can also be seen as quality improvements, because they minimize dangerous side effects.

Q: How should policy makers evaluate the success of an appropriate antibiotic use program?
A: What should be measured is the improvement in antibiotic prescribing. I don’t think you can evaluate an appropriate antibiotic use campaign based on whether rates of resistance go down—because these programs may not, in and of themselves, lead to a decrease in resistance, at least in the community. It’s different if we’re talking about a health care setting.

Q: Could the Get Smart campaign be replicated in developing nations?
A: Our materials and messages cannot simply be translated into other languages and distributed. In each setting the resistance problem and antibiotic use factors leading to the problem will be different. In some countries, an appropriate antibiotic use program means improving antibiotic distribution, and improving access to medical care so that children who need antibiotics are getting them at appropriate doses and for the appropriate length of time. It clearly is a more complex problem in countries where there’s a wider gap between the “haves” and “have-nots.”

Dr. Besser spoke with Associate Editor Madeline Drexler.

Community hospitals — which struggle with limited budgets and frequent policy shifts both from private insurance organizations and from Medicare/Medicaid — face particular challenges in providing proper infection management. It is therefore especially important that these institutions identify strategies that provide optimal treatment choice without incurring unnecessary expenses.

A continuous quality improvement program that identifies problems, develops corrective measures, and provides follow-up is essential to such an intervention. At Lutheran Medical Center, such a quality control intervention was instituted in October 2002 with the goal of promoting the appropriate prescription of antibiotic regimens by the medical staff; promoting the use of cultures when indicated; decreasing the rate of inappropriate antibiotic regimens; and decreasing hospital costs for antibiotics. The intervention was evaluated between October 2002 and December 2003. The hospital population covered by this intervention included inpatients in the departments of medicine, surgery, obstetrics and gynecology, and pediatrics.

The intervention began with an assessment of LMC prescription practices. Case discussions and prescription reviews by the hospital’s infectious disease physician team revealed that antibiotics were administered for longer periods than needed; patients often did not receive the drug of first choice; patients were receiving inappropriate antibiotic combinations; and laboratory cultures were not being ordered where indicated. Moreover, the physician team found that, in many cases, medical staff did not comply with appropriate protocols for antibiotic use. Nor was there a permanent program overseeing antibiotic prescription, or a continuous quality improvement program.

In planning this intervention, team members were mindful of potential risks. If solutions were implemented too quickly, it could hurt the team’s ability to demonstrate measurable improvements. If volunteers were not fully trained and prepared, it could impede the quick and accurate collection of data. If data collection and research methodology were not carefully defined, the study could exceed its original time frame. And if the coordinator and volunteers did not develop an initial relationship with the medical staff, data collection could be difficult and incomplete.

Intervention participants came from various departments in the hospital: infectious disease, pharmacy, research, and administration. In planning a quality control intervention, the team identified the following goals: (1) Ensure that appropriate antibiotic prescription practices would endure after the intervention was complete. (2) Ensure the continued use of cultures, where indicated. (3) Identify and verify a decrease in...
QUALITY CONTROL continued from page 4

The project was implemented in four phases (see Table 1). Phase I, the restricted antibiotic control phase, was introduced from October 2002 to December 2003. Twelve antibiotics were selected for restriction based on cost, associated resistance rates, and overuse (see Table 2). The restricted drugs were: vancomycin, ciprofloxacin, meropenem, imipenem/cilastatin, dalfopristin/quinupristin, amikacin, cefepime, linezolid, piperacillin/tazobactam, caspofungin, amphotericin B liposomal, gatifloxacin. These antibiotics required an infectious disease physician’s approval before pharmacy staff dispensing. Prescriptions were reviewed daily with the prescribing physician, and inappropriate regimens were discussed along with alternative recommendations.

In Phase II, physicians’ order forms were redesigned to include laboratory and clinical information. This phase was introduced from April 2003 to December 2003. Laboratory information included whether a particular antibiotic, and whether the drug was being ordered for empiric, prophylactic, or therapeutic purposes.

In Phase III, also introduced from April 2003 to December 2003, a medication management report listed all patients on antibiotics. The project team especially focused on patients taking ciprofloxacin and levofloxacin intravenous (IV). During this phase, the antibiotic project team contacted prescribers to explore the possibility of shifting from IV to PO.

In Phase IV, introduced from June 2003 to December 2003, laboratory reports were reviewed every other day. The project team singled out cases of resistance to the antibiotics prescribed. Clinicians were made aware of the findings as soon as possible, and potential treatment alternatives were discussed. All information was entered into a database in order to determine resistance trends.

LMC’s four-phase intervention brought successful results. The use of restricted antibiotics — particularly ciprofloxacin, meropenem, gatifloxacin, and dalfopristin/quinupristin — was reduced. In addition, more prescribers now consulted with an infectious disease physician for approval of restricted antibiotics. The number of prescribers who filled in information forms about their reasons for ordering a particular drug increased dramatically from April 2003 to December 2003. During this time period, more physicians also accepted recommendations to change from IV to PO. Between June and December 2003, antibiotic treatment regimens were changed in 153 patients after the prescriber was informed by the antibiotic team that infections were resistant to the antibiotics patients were receiving.

Cost savings were significant. In 2003, after adjustments were made for drug inflation, changes in hospital days, and loss of certain generic drugs, the intervention achieved a savings of $432,613 — a 19% decrease in antibiotic purchases compared with original 2003 projections without the project. Future steps to continue the improved use of antibiotics include tracking expenses by diagnosis at discharge; developing a more effective data entry system; reviewing the impact of other factors such as the admission of nursing home patients; reviewing the use of antibiotic prophylaxis in surgery; and further evaluation of vancomycin use.

References:

Select Model Interventions in Two Sites
San Jose, Costa Rica: An Antibiotic Management Program at Hospital Nacional de Ninos

Carla M. Odio, M.D.
APUA-Costa Rica Chapter Coordinator

Problem: Overall in Costa Rica, neonatal intensive care units account for the largest intrahospital consumption of antibiotics. Between 70% and 90% of all neonates in the NICU are administered these drugs. Infection accounts for 30% of all deaths in the NICU.

Methods: An infectious disease specialist makes daily rounds. Three times a week, the ID specialist notes the number of patients on antibiotics; patients on antibiotics who have documented infections; patients with documented infections for whom the antibiotics are tailored to the susceptibility pattern of the offending pathogen; and type of antibiotics being prescribed.

Results: From March 2000 to April 2004, there was a 20-84% reduction in use of various antibiotics: 33% for vancomycin; 52% for carbapenems; and 37% for third generation cephalosporins. In addition, the hospital has seen a 30% reduction in the number of multidrug-resistant gram-negative coliform bacilli infections. During the 12-month intervention period, NICU prevalence of nosocomial bacterial infections dropped from 28% to 13%; prevalence of fungal infections dropped from 18% to 7%.

Since 2002, all enterococci have been susceptible to penicillin and aminoglycosides. Since 2002, no outbreaks have been due to multidrug-resistant Klebsiella pneumoniae. The NICU prevalence of nosocomial infections has dropped from 40-45% before 2000 to 410% in the last two years, a decline that we attribute to more rational antibiotic use.

Next Steps/Lessons Learned: Most cases of suspected sepsis, even if nosoco-

Table 2. Antibiotics selected for restriction in Phase 1

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<th>Generic Name</th>
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<tr>
<td>Amphotericin B lipid complex</td>
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<td>Amikacin</td>
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<td>Caspofungin</td>
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<td>Ciprofloxacin</td>
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<td>Dalfopristin/Quinupristin</td>
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<td>Piperacillin/Tazobactam</td>
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<td>Vancomycin</td>
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MODEL INTERVENTIONS continued on page 6
APUA Roundtable Proposes New UTI Guidelines

APUA’s June 2003 scientific roundtable on treatment trends for urinary tract infections has produced a report that will be published in Clinical Infectious Diseases. The article, “Acute Uncomplicated Cystitis in an Era of Increasing Antibiotic Resistance: A Proposed Approach to Empiric Therapy,” addresses the threat of growing fluoroquinolone resistance. The roundtable, which included national experts on UTIs, was chaired by Thomas Hooton, M.D., Professor in the Division of Allergy and Infectious Diseases, University of Washington School of Medicine. The CID article is expected to be published this summer.

ROAR Awards Second Subgrant Study

APUA has awarded its second subgrant under The Reservoirs of Antibiotic Resistance (ROAR) Project, a five-year initiative funded by the National Institute of Allergy and Infectious Diseases and coordinated by APUA. The ROAR Project’s goal is to define the role of commensal organisms as reservoirs of antibiotic resistance that may be transferred to pathogenic organisms.

Under a ROAR subcontract, Dr. James Tiedje, of Michigan State University’s Center for Microbial Ecology, will conduct research on antibiotic resistance genes residing in soil. This study was chosen by an APUA-organized expert review committee, which considered over 40 applications. To become involved in the ROAR Project or to join the ROAR email list, please visit our website at www.ROARProject.org, or contact carol.cogliani@tufts.edu.

GAARD


This year the GAARD Network, in collaboration with the world’s foremost experts on global health, will produce its first “Report on the Global Status of Antimicrobial Resistance: Implications for Public Health Policy and Practice.” The Report will raise awareness about the importance of appropriate antimicrobial treatment and surveillance as a tool for monitoring and evaluation, and for providing evidence-based information to guide antimicrobial policies and practices.

The GAARD Network will hold its next formal meeting at this year’s Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC). As part of the formal ICAAC program, an APUA-coordinated Focus Session on Antimicrobial Resistance Information Systems will discuss the benefits of coordinated global information on antimicrobial resistance, based on the GAARD experience. APUA convened the first GAARD meeting in 1998. Since then, the group has held regular meetings and has combined data for special studies.

Judge Rules in Baytril Hearings

On March 19, an administrative law judge ruled in favor of the U.S. Food and Drug Administration’s proposal to withdraw approval for use of the fluoroquinolone antimicrobial Baytril in poultry, because of concerns about increasing resistance in human Campylobacter infections. Closely related to Cipro, Baytril was approved by FDA in 1995 and is currently marketed by the Bayer Corporation. Abbott Labs, which formerly manufactured a similar drug, voluntarily withdrew its product in compliance with FDA’s initial request in 2000. APUA is pleased to report that the normal, can be initially treated with drugs such as methicillin or oxacillin, plus an aminoglycoside. In more than 80% of cases, treatment can be discontinued after 48 hours. Third-generation cephalosporins and carbapenems are rarely needed, especially once the outbreaks due to multidrug-resistant gram-negative coliform bacilli have been controlled. By reducing the number of patients on antibiotics, we have a higher yield of etiologic agents on those who do become infected, thus increasing overall rational antibiotic use. As a result of the intervention, hospital administrators developed formal protocols and algorithms for antibiotic use.

MODEL INTERVENTIONS continued from page 5

APUA “FAAIR Report” was entered as evidence in the proceedings by CVM.

VRSA Found in New York

In March 2004, vancomycin-resistant Staphylococcus aureus was isolated from a urine culture obtained from a resident of a long-term care facility. This finding represents the third documented clinical isolate of VRSA from a patient in the United States. According to the Centers for Disease Control and Prevention, two commonly used automated antimicrobial susceptibility testing panels failed to detect vancomycin resistance in the isolate. (MMWR, April 23, 2004/53(15); 322-323)
APUA-Nepal Publishes Antibiotic Treatment Guidelines

In April 2004, APUA-Nepal published the nation’s first National Antibiotic Treatment Guidelines, produced with the counsel of physicians, veterinarians, pharmacists, and APUA headquarters staff. The guidelines address antibiotic use in pregnancy, surgery, pediatrics, ophthalmology, obstetrics and gynecology, general medicine, tuberculosis treatment, and other medical realms.

Second International Conference on Improving Use of Medicines (ICIUM)

Dr. Anibal Sosa, Director of the International Program, exhibited a poster and gave a presentation about the use of surveillance data in the development of standard treatment guidelines (STGs) in developing countries. Dr. Sosa noted that the incorporation of surveillance data into STGs allows for better resource allocation of drugs. The conference was held in Chiang Mai, Thailand, March 30-April 2, 2004.

APUA-Georgia

The chapter is planning its first conference on AMR and the appropriate use of antimicrobials, scheduled for fall 2004. For more information, see our chapter events page at: http://www.tufts.edu/med/apua/intl/events.html

APUA-India

The chapter held a National Symposium on the Use of Antibiotics on February 29, 2004, in Jaipur, India. In collaboration with the Indian Society for Antimicrobial Chemotherapy and the National Academy of Medical Sciences, the chapter co-sponsored a course on promoting rational drug use in the community.

APUA-Croatia

The chapter held a workshop on antimicrobial susceptibility testing in March 2004, in Zagreb, Croatia. The workshop, attended by microbiologists, discussed antibiotic sensitivity tests and interpretative reading; mechanisms of drug resistance; quality assurance; and resistance patterns and antibiotic consumption in Croatia.

Cincinnati Pediatric Research Program

Robert M. Siegel, M.D.

Problem: Acute otitis media (AOM) is the most commonly treated bacterial infection in children. Studies have demonstrated that AOM in children can be managed without antibiotics. In England, studies have shown that antibiotic use for AOM could be decreased by prescribing a safety-net antibiotic prescription (SNAP) to be filled if symptoms do not resolve with observation after 48 hours. Most parents in the United States, however, believe that antibiotics are necessary to treat AOM. In addition, many physicians believe that parents want antibiotics for their sick children, a fact that is reflected in antibiotic prescribing habits.

The objective of this study was to determine whether parents in the U.S. find a SNAP for AOM acceptable and whether antibiotic consumption could be cut by its use.

Methods: Children between 1 and 12 years of age with uncomplicated AOM were eligible for the study. Excluded were those with a temperature >101.5 degrees F; ear infection in the past three months; signs of another bacterial infection, or toxic appearance. Families were given acetaminophen, ibuprofen, or topical otic anesthetic drops for pain control. They were also given a prescription for an antibiotic and told not to fill it unless symptoms either increased or did not resolve after 48 hours.

Results: Only 55 (31%) of the 175 who were contacted for follow-up had filled their safety net antibiotic prescription; 78% of parents reported that pain medication was effective; 63% of parents reported that they would be willing to treat future AOM episodes without antibiotics and with pain medication alone. In a follow-up study, review of the charts of study patients for 60 days post-enrollment showed that the complication rate was typical. The relapse reinfection rate was higher in those children under 2 years of age.

Lessons Learned: When patients are educated about an illness and empowered by being brought into the decision-making process, they are powerful partners. A follow-up study one year after the original study showed that all participants were using SNAP to some degree, and that both study participants and community pediatric groups lowered their antibiotic use. The decline was more significant in the study group. The Cincinnati Pediatric Research Group is currently revising its otitis media guidelines to include SNAP as an option.

Though most clinical innovations are met with caution, this innovation seems quite acceptable to the target population and takes relatively little effort.

MODEL INTERVENTIONS continued from page 6

Cincinnati, Ohio, USA:
A Quality Improvement Program for AOM

Cincinnati Pediatric Research Group
Robert M. Siegel, M.D.

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Alliance for the Prudent Use of Antibiotics
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