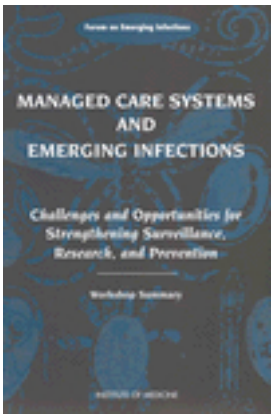

Managed Care Systems and Emerging Infections: Challenges and Opportunities for Strengthening Surveillance, Research, and Prevention, Workshop Summary

Jonathan R. Davis, Editor; Based on a Workshop of the Forum on Emerging Infections, Institute of Medicine

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Managed Care Systems and Emerging Infections

Challenges and Opportunities for Strengthening Surveillance, Research, and Prevention
Workshop Summary

Jonathan R. Davis, *Editor*

Based on a Workshop of the Forum on Emerging Infections
Division of Health Sciences Policy
INSTITUTE OF MEDICINE

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All presenters at the workshop have reviewed and approved their respective sections of this workshop summary for accuracy, and Forum on Emerging Infections members who were present at the workshop have reviewed the document to ensure that it accurately reflects the workshop discussions. In addition, this workshop summary has been reviewed in draft form by independent reviewers chosen for their diverse perspectives and technical expertise, in accordance with procedures approved by the National Research Council's Report Review Committee. The purpose of this independent review is to provide candid and critical comments that will assist the Institute of Medicine (IOM) in making the published document as sound as possible and to ensure that the document meets institutional standards. The review comments and draft manuscript remain confidential to protect the integrity of the deliberative process.

Although the independent reviewers have provided many constructive comments and suggestions, responsibility for the final content of this document rests solely with the Forum and IOM. The Forum and IOM thank the following individuals for their participation in the review process: Daniel L. Azarnoff, D.L. Azarnoff Associates; William Baine, Center for Outcomes and Effectiveness Research; Richard Dixon, The Lewin Group; Laura Efros, Office of Science and Technology Policy; Adel A.F. Mahmoud, Merck & Co., Inc.; and Theodore E. Woodward, University of Maryland School of Medicine.

Preface

The Forum on Emerging Infections was created in 1996 in response to a request from the Centers for Disease Control and Prevention and the National Institute of Allergy and Infectious Diseases. Its goal is to provide structured opportunities for representatives from academia, industry, professional and interest groups, and government [*] to examine and discuss scientific and policy issues of shared interest that are specifically related to research and prevention, detection, and management of emerging infectious diseases. In accomplishing this task, the Forum provides the opportunity to foster the exchange of information and ideas, identify areas in need of greater attention, clarify policy issues by enhancing knowledge and identifying points of agreement, and inform decision makers about science and policy issues. Although the Forum seeks to illuminate issues rather than resolve them directly, it does not provide advice or recommendations on any policy pending before any agency or organization. Its strengths are the diversity of its membership and the commitment of individual members expressed throughout the activities of the Forum.

A critical part of the work of the Forum is a series of workshops. The first of these, held in February 1997, addressed the theme of public-and private-sector collaboration (IOM, 1997b). The second workshop took place in July 1997 and explored aspects of antimicrobial resistance (IOM, 1998). The third workshop, on which this document reports, was held in March 1998 and examined the implications of managed care systems and the ability of those systems to address emerging infectious diseases in the age of managed care. Subsequent workshops

[*] Representatives of federal agencies serve in an *ex officio* capacity. An *ex officio* member of a group is one who is a member automatically by virtue of holding a particular office or membership in another body.

have addressed the core capacity of the public and private health sectors in emerging infectious disease surveillance and response (November 1998 workshop) and the international aspects of emerging infections (October 1999). Workshop summaries based on those workshops are in production.

The restructuring of health care systems will have a major impact on the public health enterprise, including the prevention, monitoring, and treatment of infectious diseases. It is unrealistic to consider that managed care by itself will subsume all of the traditional public health functions, such as observation of compliance treatment regime for patients with tuberculosis or partner notification and contact investigation for patients with sexually transmitted diseases or for other disease outbreaks. Managed care needs to be integrated with a strong, functional public health system, and that integration requires partnership and appropriate incentives. For these reasons, the Forum convened a workshop to assess the opportunities and challenges confronting infectious disease surveillance, research, and prevention posed by changes in the health care environment. After a highly successful workshop characterized by discussion that was as rich and wide-ranging as would be expected of a diverse and knowledgeable assembly, a summation of the presentations and discussions were integrated into this workshop summary.

The workshop summary is organized as topic-by-topic descriptions of the presentations and discussions that occurred during the workshop. Its purpose is to present lessons from relevant experience, delineate a range of pivotal issues and their respective problems, and describe some potential responses described by the workshop participants. All information reported in the text emerged from the presentations made at the workshop and the subsequent, relevant discussions. Thus, the workshop summary is not a comprehensive or exhaustive exploration of the issues involved, nor does it represent a consensus of views or opinions. Rather, it summarizes a dialogue among representatives from different sectors and their thoughts on which research may merit further attention. The names of the presenters are identified at the beginning of each section. The summary descriptive material provides context and overview of the identified presentations and was prepared by the editor.

The Forum and the Institute of Medicine express their warmest appreciation to the individuals and organizations that gave valuable time to provide information and advice to the Forum through participation in the workshop. Each of the following contributed greatly: William Baine, Agency for Health Care Policy and Research; René Bowser, Georgetown University Law Center; John Burke, School of Medicine, University of Utah; Laurie Burke, U.S. Food and Drug Administration; Douglas Cocks, Eli Lilly & Company; Thomas Davies, GTE Corporation; Frank DeStefano, Centers for Disease Control and Prevention (CDC); Richard Dixon, National Independent Practice Association Coalition; Margaret Hamburg, U.S. Department of Health and Human Services; Susan Horn, Institute for Clinical Outcomes Research, Research for International Severity Information Systems, University of Utah School of Medicine; Denise Koo, CDC; David Korn, Biomedical and Health Sciences Research, Association of American Medical Colleges; Nora Morris, Healthcare Education and Research Foundation, Inc.; Richard Platt,

Harvard Pilgrim Health Care; Robert Rubin, The Lewin Group; Jerome Schentag, Millard Fillmore Health System; Anne Schuchat, CDC; Benjamin Schwartz, CDC; Lana Skirboll, Office of Science Policy, National Institutes of Health (NIH); Walter Stamm, Division of Allergy and Infectious Diseases, University of Washington School of Medicine; and Karl Western, NIH.

The Forum is indebted to the IOM staff who contributed during the course of the workshop and the production of this workshop summary. On behalf of the Forum, I gratefully acknowledge the efforts led by Jonathan Davis, study director for the Forum and editor of this report, for his thoughtful and insightful approach and skill in the translating the workshop proceedings and discussion into this workshop summary. I would also like to thank the following IOM staff for their valuable contributions to this activity: Christina Thacker and Gretchen Kidder assisted with the workshop planning and logistics; Nicole Amado developed the Glossary and Acronyms list; Vivian Nolan drafted and revised various sections of the workshop summary and provided detailed support to facilitate its development; Robert Levy, a medical summer intern, drafted the appendix on the Veterans Affairs health care system; and Sarah Pitluck, Alden Chang, Thelma Cox, and Hallie Wilfert provided expert support at various developmental stages of the workshop summary.

I want to especially thank Polly Harrison, who directed the Forum from its inception through two workshops, and who also dedicated much effort and time to developing this workshop's agenda. Other professional staff also provided invaluable help. Consultant and technical writer Kathi Hanna contributed significantly to the revision of the manuscript during the report review process. Paul Phelps, an independent writer, incorporated into the first draft the many pieces of written material presented during the workshop. The extensive commentary and suggestions made by the copy editor, Michael Hayes, are gratefully acknowledged.

The Forum and myself also greatly appreciate the time and expertise contributed by Kenneth W. Kizer, Gary Roselle, and Larry J. Strausbaugh, all from the Veterans Health Administration, U.S. Department of Veterans Affairs, for their consultation and review of the Appendix on the Veterans Affairs health care system.

Finally, the Forum and the IOM also wish to thank its sponsors, which supported this activity. Financial support for this project was provided by the U.S. Department of Health and Human Services, National Institutes of Health, Centers for Disease Control and Prevention, and U.S. Food and Drug Administration; U.S. Department of State, Bureau of Oceans and International Environmental and Scientific Affairs; U.S. Department of Veterans Affairs; Abbott Laboratories; American Society for Microbiology; Applied Microbiology, Inc.; Bristol-Myers Squibb Company; Burroughs Wellcome Fund; Eli Lilly & Company; Glaxo Wellcome; Hoffmann-La Roche; Merck; Pfizer; SmithKline Beecham; and Wyeth-Ayerst Laboratories.

Joshua Lederberg
Chair

Contents

Summary

Joshua Lederberg, Ph.D.

Over the past 20 years, managed care has risen to dominate health care delivery in the United States. In a managed care system, health plans attempt to coordinate and control the use of medical health care-related services by limiting reimbursement. Purchasers of health plans (employers) contract with managed care organizations, which then select providers or groups of providers (primary care physicians) to care for an enrolled patient population. After a patient either selects or is assigned a provider, these primary care physicians generally act as gatekeepers for access to specialty or emergency services, with the goal of reducing the level of unnecessary health care services provided, thereby promoting reductions in overall costs. Generally, managed care is considered more cost-effective than the third-party fee-for-service system because of the potential for more stringent control over expenditures and use of services (Kizer, 1999).

The development of managed care systems for the financing and delivery of health care in the United States has created both opportunities and challenges for both providers and patients. As dramatic restructuring of the nation's health care system evolves, managed care will likely have a major effect not only on health care delivery but on many aspects of the public health enterprise as well. The fight against infectious diseases—through prevention, surveillance, treatment, and research—represents one of many areas in which managed care organizations have the potential to make marked improvements in a community's health. To make such a contribution, however, controls on reimbursements for health care expenditures must be reevaluated, as they can pose an impediment to effective collaboration among managed care organizations and the public health community.

Trends indicate that some managed care organizations are making progress in the fight against infectious diseases, but they also indicate potential problems. The emphasis on controlling costs, the move toward management of infectious

diseases by nonspecialists, and the shift from inpatient to outpatient treatment all raise concerns in terms of infectious disease prevention, control, and reporting. Additionally, managed care practices may increase the complexity of an infectious disease outbreak investigation and subsequent public health response. If such trends continue, the result may be lost opportunities to mitigate the impacts of infectious diseases. However, collaborations between the public health community and managed care industry can ensure that the public's health is protected and that the health care environment is increasingly managed with cost containment as a goal.

To help inform the debate about the consequences of health care restructuring on infectious disease control and to identify model systems that illustrate best practices, the Forum on Emerging Infections convened a workshop—the subject of this workshop summary—to identify, clarify, and solidify some of the current and potential best practices in managed care with respect to identifying and treating emerging infections. The workshop focused on five major areas of importance to infectious disease control that both shape and are shaped by the changing health care environment: (1) basic and clinical research, (2) clinical practice guidelines, (3) surveillance and monitoring, (4) education and outreach, and (5) drug formularies. Workshop participants outlined many of the challenges to be overcome and identified possible opportunities for addressing obstacles. A summary of these challenges and opportunities listed in the following sections were addressed and discussed by workshop participants. These challenges and opportunities, however, do not necessarily represent the views of either the Forum on Emerging infections or the Institute of Medicine.

BASIC AND CLINICAL RESEARCH

Health care reform has changed the financial base upon which the modern academic medical center is structured. The cost-containment efforts of managed care organizations have reduced the institutions' net revenues from the provision of clinical care that have traditionally been used to support research and training. Concomitantly, the amount of time that faculty can spend conducting research and training future scientists and physicians has also been reduced, as the managed care system encourages physicians to treat more patients on a daily basis. Yet, in light of these changes, managed care can work with academic health centers to strengthen the foundation on which they conduct clinical investigations. Armed with large patient populations and centralized information systems, managed care organizations are uniquely positioned to partner their resources with the research infrastructure and culture offered by academic health centers. The following objectives related to conducting basic and clinical research in a managed care setting emerged during the workshop presentations and discussions and are described in greater detail in the workshop summary:

- supporting the functions of academic health centers,

- ensuring adequate databases for clinical research,
- exploiting the unique advantages of managed care for surveillance and research, and
- promoting collaboration.

CLINICAL PRACTICE GUIDELINES

One hallmark of successful clinical practice is the adherence to preestablished guidelines. However, the adoption of standard guidelines among managed care organizations has been slow, as competing managed care organizations are often unwilling to share the data necessary to construct the guidelines. Even when the data are available, moreover, standardized clinical practice guidelines often have not been validated under sustained use in clinical settings. Furnishing managed care organizations with opportunities to implement and evaluate clinical practice guidelines will entail the involvement of providers and purchasers of health care to overcome both organizational and psychosocial barriers. The following challenges to and opportunities for the development of clinical practice guidelines in managed care organizations emerged during the presentations and discussions and are discussed in greater detail in this workshop summary:

- developing clinical practice guidelines,
- promoting adoption and use of guidelines in managed care organizations, and
- involving clinicians in guideline development and implementation.

SURVEILLANCE AND MONITORING

The surveillance and monitoring of emerging infections, including microbial resistance, in the managed care environment demand an effective partnership among health care providers, academic health centers, commercial laboratories, and the traditional public health system. Professional roles and responsibilities across the spectrum of infectious disease surveillance activities must be clearly understood and supported by all parties involved. The capabilities of public and private microbiology laboratories cannot be overlooked (and therein may lie a role for the Centers for Disease Control and Prevention in providing training for state laboratory personnel in the use of new molecular tests). Sharing data on rapid and accurate diagnosis and disease reporting will be at the heart of an effective partnership with managed care and public health systems to combat emerging infections. The following challenges and opportunities to disease surveillance and monitoring in the managed care setting are discussed in the text of this workshop summary:

- understanding professional roles in surveillance and monitoring,
- ensuring availability of data,
- promoting sharing of data,
- tracking nosocomial infections,
- accurate reporting of encounter-level data, and
- overcoming structural barriers.

EDUCATION AND OUTREACH

Managed care organizations are interested in improving the health of the entire community, not just their own members. However, infectious diseases may not be as high a priority as other diseases to health maintenance organizations, and consequently fewer resources are committed to any systematic, large-scale education or outreach initiatives. Although this direction may not seem beneficial to patients, it is driven by the purchasers of managed care who give a lesser priority to infectious diseases. Opportunities do exist, however, for educational institutions or pharmaceutical manufacturers to play a larger role in health education, both to providers and to purchasers of health care. The hope is that such efforts will then spread throughout the managed care industry. The following challenges to and opportunities for the development of education and outreach programs in the managed care setting are discussed in this workshop summary:

- promote professional education efforts,
- encourage judicious antibiotic use, and
- invest in educational programs.

DRUG FORMULARIES

Drug formularies were originally intended to help reduce prescription drug costs while maintaining good health care. Recent evidence suggests that formulary policies concerning antibiotics may have contributed to the rise in the rate of antibiotic resistance by microorganisms even while the expected goals of cost containment have not been realized. To examine these concerns, this session was organized around three basic issues: (1) how managed care makes formulary decisions, (2) the relationship between pharmaceutical companies (manufacturers and distributors) and managed care, and (3) the impacts of these formulary decisions on the discovery and development of new antimicrobial agents. Although further studies are needed to address the increasing costs associated with formularies, some practices that could provide quality health care without adverse repercussions were identified. The following challenges and opportunities to the development of drug formularies in managed care organizations are discussed in this workshop summary:

- ensuring availability of current information on new drugs,
- managing antibiotic selective pressure,
- need for new management strategies for cost reduction, and
- achieving quality care and cost containment.

1

Introduction

BACKGROUND*

As dramatic restructuring of the nation's health care system evolves, managed care organizations will likely have a major effect not only on health care delivery but on many other aspects of the public health enterprise as well. Specifically, the fight against infectious diseases—through prevention, surveillance, treatment, and research—represents one of many areas in which managed care organizations have the potential to make marked improvements to a community's health. To make such a contribution, however, controls on reimbursements for health care expenditures must be carefully considered as they may pose an impediment to effective collaboration among managed care organizations and the public health community,

Over the last 20 years, managed care has come to dominate health care delivery in the United States; more than 150 million Americans participate in health insurance arrangements that fall under the diverse umbrella of "managed care" (Miller and Luft, 1994). This development illustrates a trend from an alliance between providers of care and insurers under the traditional fee-for-service indemnity arrangements to the current systems in which insurers work more closely with large, group payers—primarily employers and government agencies (Rosenbaum et al., 1997). The term *managed care* encompasses a broad variety of arrangements, many of which continue to evolve as they adjust to market pressures.

Generally, in a managed care system, health plans attempt to coordinate and thereby control the use of medical health care-related services (specialty visits or emergency care) by restricting reimbursement for services. Purchasers of health

* This evaluation is based on the opening remarks of Margaret Hamburg, M.D.. Assistant Secretary for Planning and Education, U.S. Department of Health and Human Services; additional sources are listed in the references section.

care services contract with managed care organizations, which then select providers or groups of providers to care for an enrolled patient population. A patient either selects or is assigned a provider, typically a primary care physician who may have received special training in managing care and who may also have financial incentives to manage that care effectively. Such physicians often act as gatekeepers for access to additional specialty services because of the restrictions placed on reimbursements for specialty service provisions. Ideally, the system operates to reduce unnecessary services for health care, allowing managed care organizations to decrease their overall costs.

Theoretically, purchasers enter into contracts with managed care organizations largely on the basis of cost, the benefits package, and quality, thus creating the incentive for these organizations to offer superior services and consumer-oriented benefits. A competitive environment has produced variations in organizational structures as managed care groups attempt to balance the financial risks of cost-control measures with the provision of quality health care (Association of State and Territorial Health Officials, 1995). Managed care thus has evolved into several types of health plan structures, including health maintenance organizations (HMOs); the staff model, group model, and network model HMOs; individual practice association model and mixed model HMOs; preferred provider organizations; point-of-service plans; physician-hospital organizations; and management services organizations. Table 1-1 describes the types of managed care organizations. Appendix B is a glossary of terms and acronyms commonly used in the managed care industry and encountered throughout this workshop summary.

An effective health care delivery system depends on the availability of a continuum of different types of services, ranging from research to clinical services to public health programs. As it has evolved, managed care has influenced each of these elements of the continuum, creating new pressures, as well as providing novel opportunities. Although several areas of health care in the present system are encountering difficulties, certain aspects of managed care, primarily its emphasis on prevention, should give the public health community reasons for optimism. Some of the benefits from an emphasis on prevention include the following:

- the ability to deliver a range of clinical preventive services such as immunizations and screening for infectious diseases;
- the increase in incentives to link clinical preventive services with community-based prevention through educational outreach and behavior modification efforts;
- the data collection systems that may complement public health efforts aimed at communicable disease monitoring and quality assurance; and
- the organizational structures of managed care entities, particularly those that use selected providers and that have explicit expectations or requirements for certain clinical practices, which may prove valuable in enhancing disease reporting, disease management, and quality assurance.

TABLE 1-1 Types of Managed Care Organizations

Type of Organization	Description
HMO	Organized system of health care that arranges a comprehensive range of health care services to a voluntarily enrolled population in a geographic area on a primarily prepaid and fixed periodic basis.
Staff model HMO	HMO in which practitioners are salaried employees of the HMO. The practitioners may also receive a bonus or other incentive income.
Group model HMO	HMO in which an organized group of practitioners contract with an HMO to provide services, often on a mutually exclusive basis. The provider organization receives a negotiated, per capita payment, which may be distributed to individual clinicians by salary, capitation payments, fee-for-service reimbursements, or incentive payments.
Network model HMO	HMO which contracts with individual clinicians, groups or IPAs, and hospitals to provide care. The contracts are usually not exclusive, and providers may be paid by capitation, fee-for-service, or other mechanisms. Clinicians may contract with the HMO directly or through an intermediary organization such as a medical group or IPA.
Individual practice association model	A model in which an HMO contracts with independent practice associations (IPAs) to provide care. The IPAs are generally directed and often owned by member providers who retain their independent practices but use the IPAs to obtain managed care contracts and, on occasion, to administer care-related services.
Mixed model	Combination of two or more of the above.
Preferred provider organization (PPO)	Network discount, fee-for-service provider arrangement in which patients are given incentives to stay inside the network; receipt of services outside of the PPO network are allowed with an increased copayment or deductible; a PPO has some structured quality and utilization management.
Point-of-service plan	Organized system of health care provided by an HMO model with the option of the delivery of services outside of the network with a higher copayment or deductible.
Physician-hospital organization (PHO)	Legal entity formed or owned by hospitals and physicians to obtain payer contracts; physicians may retain ownership of their practices but agree to accept managed care patients under terms negotiated by the PHO.
Management services organization	Organization that provides practice management, administration, and support services to individual physicians or group practices.

SOURCE: Adapted from IOM, 1997a.

In the clinical setting, because managed care organizations provide health care services to an enrolled population, they have the capacity to provide patient follow-up, as well as to monitor treatments and outcomes across a range of important clinical research areas, including patterns of antibiotic use and resistance, control of nosocomial infections, and investigation and evaluation of new screening strategies or diagnostic methods. These capabilities are particularly important in the monitoring and control of emerging infections.

In many ways, managed care organizations also may have an advantage over other systems of health care in providing increased accountability for the appropriateness and quality of clinical care. Many managed care organizations have the infrastructure to improve surveillance through (1) systematic collection of relevant data from the health care provider's first encounter with a patient, including all information important to communicable disease reporting; (2) standardization of computerized systems that can monitor health data; and (3) education of providers regarding the importance of their role in accurate disease reporting. The Health Plan Employer Data and Information System (HEDIS), which was developed by a coalition of health plans, employer purchasers, and the National Committee for Quality Assurance, uses standardized measures to evaluate performance in quality of care, access and satisfaction, membership and utilization, finance, and health plan management. The current HEDIS structure serves as an important first step in gathering standardized data for evaluation of managed care systems, but until there is more widespread adoption of uniform standards across managed care plans, its value will be less than optimal.

Although trends indicate that managed care is making some progress in the fight against infectious diseases, they also indicate potential problems for both health care providers and consumers. The emphasis on controlling the costs of reimbursement for health care services can lead to an incorrect or missing diagnosis, underreporting of some infectious disease conditions, and inadequate follow-up. Moreover, the move within managed care toward treatment of infectious diseases by general practitioners rather than specialists—perhaps beneficial in terms of cost control and of broader attention to a patient's complaints—may weaken infectious disease control. The complexities of today's emerging pathogens require more multifaceted regimens for the appropriate management of patients and tracing of the source of exposure. Human immunodeficiency virus infection-AIDS presents a good example: the knowledge base is evolving so rapidly and some of the treatment regimens require such sophisticated knowledge of the disease, its progression, and available therapy that the best treatment often lies outside the realm of primary care. Thus, to achieve appropriate management of complex infectious diseases, managed care organizations might have to implement guidelines and oversight that reflect the expertise of infectious disease specialists or ensure the excellent integration of specialty care expertise into clinical services.

The shift from inpatient to outpatient treatment, which is more pronounced in managed care organizations, has also raised challenges for infectious disease reporting. The outpatient care setting is not likely to have the necessary infrastructure for disease reporting commonly found in the inpatient care setting. This includes a dedicated hospital epidemiologist or infectious disease specialist who understands the reporting rules and requirements, who is responsible for reviewing cases and reporting diseases, and who has an established and effective relationship with the state or local health department. An emphasis on outpatient treatment could encourage less reliance on laboratory testing and subtyping of isolates, with subsequent deficiencies resulting in the typing of the infecting pathogen. Insufficient disease reporting through these traditional mechanisms could impair disease control efforts, as well as the identification and tracking of potential outbreaks. Additionally, the various laboratory and treatment practices of managed care organizations, including contracting with laboratories remote from the origin of the specimen, can make the recognition of, reporting, and response to an outbreak less reliable.

Yet managed care organizations cannot be expected to assume all of the traditional functions of the public health systems, especially when deficiencies already exist outside of managed care. For example, the observation of compliance with the treatment regimen for patients with tuberculosis or panner notification and contact investigation for patients with sexually transmitted diseases are generally beyond the capacities of managed care systems. Moreover, managed care systems have neither the resources and expertise nor the mandate and authority to replace public health programs designed specifically to protect the community's health. Thus, partnerships between managed care and the public health community are required to shield already strained public health infrastructure from further stresses.

The need for collaboration is even more important in light of the reality that managed care organizations increasingly are becoming the major mode of health care delivery and financing for publicly funded care and the Medicaid and Medicare programs (CDC, 1995). Many state governments have chosen managed care to provide health care services for individuals enrolled in state Medicaid programs, creating the "managed Medicaid" model. Local decision makers have redirected significant resources from public health system programs to managed care systems, believing that managed care systems are an alternative source for the provision of services. However, managed care does not always fully integrate public health system programs.

An additional concern for the public health community is the effect of the increasingly competitive nature of the health care market on publicly supported services, including clinical services and broader public health programs that require effective linkage with clinical services. An unintended consequence of market competition on clinical services and public health programs may be a reduced capacity over time of academic health centers to support both research and training, activities that have traditionally relied on a healthy combination of service-related revenues and public financing. The responsibilities of basic and

clinical research and training may disproportionately fall on public-sector institutions, such as the U.S. Department of Veterans Affairs (VA), the largest provider of health care training in the United States and one of the largest research organizations in the world (Appendix A).

The transformation of the U.S. health care system to one of managed care may be the single most important development in health care delivery since the rise of modern medicine and the advent of health insurance. Because managed care organizations now claim enrollment of more than 150 million Americans, this transformation has not only altered the relationships between patients and independent providers but has also changed Medicaid from a fee-for-service government health insurer into a large-scale purchaser of private insurance. To improve health outcomes, public and private purchasers of health care—particularly large employers, the Health Care Financing Administration, and state Medicaid agencies—should form partnerships with public health agencies (CDC, 1995). These new arrangements, combined with collaborative efforts with managed care organizations, could greatly improve community health while containing health care costs.

Clearly, assessment of the impact of managed care on the control of emerging infectious diseases is complicated by the rapidly changing environment of the U.S. health care system. Managed care is changing the type and quality of health care that many Americans receive. By promoting the integration of health care services, including public health, managed care could enhance not only the continuity of care but its quality as well.

ABOUT THE WORKSHOP AND ORGANIZATION OF THE WORKSHOP SUMMARY

Jonathan R. Davis, Ph.D., *Editor*

In the rapidly changing environment of health care delivery and financing, the impact of managed care on infectious disease surveillance, research, and prevention impelled this workshop on the part of the Institute of Medicine (IOM) Forum on Emerging Infections to assess the opportunities and challenges posed by changes in this environment. In developing the workshop agenda, Forum members identified five key areas for discussion: (1) basic and clinical infectious disease research, (2) clinical practice guidelines, (3) emerging infections surveillance and monitoring, (4) education and outreach, and (5) drug formularies and product development. This workshop summary is organized according to these five key areas (Chapters 2 to 6, respectively), followed by concluding remarks (Chapter 7), references, and a series of appendixes (Appendix A, the Veterans Health Administration and Infectious Disease; Appendix B, Glossary and Acronyms; Appendix C, Workshop Agenda; and Appendix D, Forum Member and Staff Biographies).

The managed care environment is diverse, and for the purposes of this workshop summary, only for-profit types of managed care organizations are considered in detail. However, in addition to non-profit and for-profit organizations, other significant players are governmental, including the VA and the U.S. Department of Defense. Of particular note, the VA has the largest fully integrated health care system in the world and is the only national safety net for many highly vulnerable patients. Appendix A presents an overview of VA health care systems with regard to emerging infections and managed care.

Representatives from managed care organizations, hospitals, government agencies, pharmaceutical companies, and academia were invited to give panel presentations moderated by Forum members. Each panelist was asked to highlight important issues, suggest possible practical solutions, and recognize impediments that must be overcome. By the end of the workshop discussions, participants noted that no two managed care organizations are identical. Moreover, the Forum members and participants recognized that the information cited may be unrepresentative of managed care organizations and that additional presentations from managed care organizations were needed for a greater exploration of the subject, Thus, by default, the workshop focused on a few model systems to stimulate discussion and to provide examples of successful programs.

In identifying organizations that could serve as examples of organizations whose practices effectively fight infectious diseases, the Forum recognized the Group Health Cooperative of Puget Sound for its leadership in research, the National Independent Practice Association Coalition and the Healthcare Education and Research Foundation for examples of clinical practice guidelines, the Harvard Pilgrim and Latter-Day Saints Hospital as models of effective surveillance and monitoring systems, and the Group Health Association of America for its guidance in educational and outreach programs. Through the workshop the Forum has identified some examples of best practices in managed care and infectious disease control, and through this workshop summary it hopes to disseminate information on why certain programs are effective, as well as provide for others guidance on how to achieve positive results in a variety of settings.

This report of the Forum-sponsored workshop is prepared in the form of a workshop summary by and in the name of the editor with the assistance of staff and consultants, as an individually authored document. Sections of the workshop summary not specifically attributed to an individual reflect the views of the editor and not those of the Forum on Emerging Infections. The content of those sections is based on the presentations and the discussions that took place during the workshop. Accordingly, each of the next five chapters begins with an opening statement of context and background authored by the editor, followed by descriptions of the presentations that were made by invited participants. At the end of each of these chapters is a summary by the editor of the issues and themes that emerged from the presentations and during the discussions. The last chapter contains concluding remarks authored by the Chair of the Forum.

2

Conducting Basic and Clinical Research in the Managed Care Setting

Health care systems worldwide are being dramatically restructured to control costs through improved efficiency and coordination of services, reduce the level of utilization of unnecessary or inappropriate services and resources, increase the provision of preventive care, and maintain or improve the quality of care. Specifically, in the United States, the impact of health care reform on academic health centers has reduced physicians' incomes from the provision of clinical care and limited the amount of time that faculty can spend conducting research and training future scientists and physicians. In recent years, academic health centers have felt the fiscal pressure of health care restructuring as managed care organizations negotiate discounted fees with the faculty practice plans and teaching hospitals that support medical schools. The presentations described below examine the opportunities and challenges for academic health centers and managed care organizations to work together in the fields of basic and clinical research in addressing issues related to emerging infections.

PERSPECTIVE OF ASSOCIATION OF AMERICAN MEDICAL COLLEGES ON BASIC AND CLINICAL RESEARCH

Presented by David Korn, M.D.

Senior Vice President for Biomedical and Health Sciences Research, Association of American Medical Colleges

Medical schools are the intellectual hub of academic health centers (AHCs). They train physicians (M.D.s) and biomedical research scientists (Ph.D.s). They also perform a great deal of research, presently receiving just over 50 percent of the extramural research budget of the National Institutes of Health (NIH). In ad

dition to conducting research and training, academic health centers provide health care services to a large number of medically underserved populations, often indigent patients, as well as provide the bulk of specialized care. The continued provision of these important public services may be threatened by the growing dominance of managed care and cost-focused health care delivery markets.

Medical schools are heavily dependent on two primary sources of funds: clinical revenues (from the provision of patient care) and research revenues (from grants and contracts) (Figure 2-1). In private, research-intensive medical schools, the relative dependence on grants (which are mostly from federal government sources, but which also include nonfederal funds) and clinical revenues from hospitals and practice plans become proportionately larger in the absence of state and local support. These revenue sources support a wide array of education, research, and clinical care programs. In private, research-intensive medical schools, the proportion of total expenditures that come from tuition and fees, endowment earnings, and state support averages only 10 percent, whereas the proportion for public, research-intensive medical schools is about 18 percent. Thus, both private and public medical schools rely heavily on the clinical revenues generated by faculty.

The 35-year trend in the source of revenues within academic health centers is shown in Figure 2-2. In fiscal year 1961, the United States had 85 medical schools with aggregate expenditures of $430 million (current dollars), of which 40 percent was raised from federal (NIH) research funds. By 1996, there were 125 medical schools with total expenditures of over $32 billion, but only 19 percent came from federal research funds. In contrast to money from federal funding, clinical revenues rose from less than 5 percent to well over 50 percent (Figure 2-2). Some of these revenues provided cross-subsidies for academic objectives; in fiscal year 1993, for example, about 10 percent of revenues from faculty practice plans were estimated to support biomedical research.

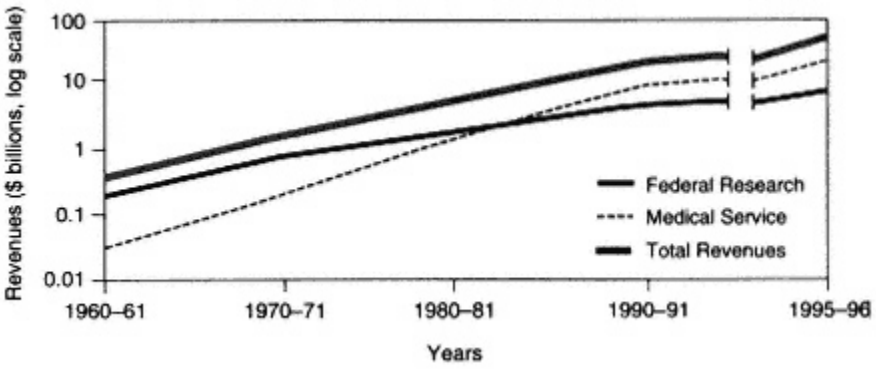

Figure 2-1 Growth in medical education in the United States from 1960 to 1996, as measured by revenues (in log billions of dollars). Source: AAMC, 1998.

Revenues derived from the provision of clinical medical services have also helped support core academic programs and undergraduate and graduate medical education and have built what are now called AHCs. in fact, the revenues from the provision of clinical services generated at AHCs over the past four decades have contributed significantly to excellent clinical care and to outstanding basic and clinical research. AHCs have also fostered the U.S. biotechnology industry and have served as an important safety net for health care delivery, particularly for those who are disadvantaged and most in need.

However, the market-driven shift away from cost reimbursement and fee-for-service revenue sources has eroded the clinical revenue margins that previously provided AHCs with substantial discretionary funds to support basic and clinical research. In addition, the ongoing transformation of health care delivery under managed care has resulted in a migration of care out of the hospital and into ambulatory-care settings. Moreover, managed care tends to emphasize general medicine as opposed to specialized care. These changes not only have affected the ability of AHCs to conduct clinical research, which is closely tied to specialty training, but also may have narrowed the scope of the research agenda. For the period from 1986 to 1995, data suggest that for the 13 medical schools in regions where managed care has achieved a high level of penetration (over 40 percent) there has been a slower rate of growth in NIH funding—and, consequently, a declining share of and rank in the proportion of NIH funding—relative to that for medical schools in markets where managed care has achieved low (under 20 percent) or medium (20 to 40 percent) levels of penetration (Figure 2-3).

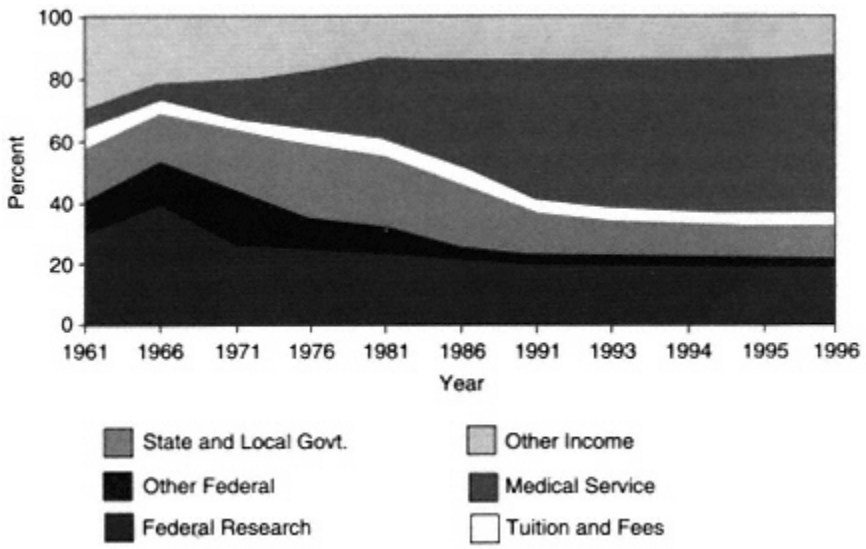

Figure 2-2 U.S. medical school revenues as a percentage of total revenues. Source: AAMC, 1998.

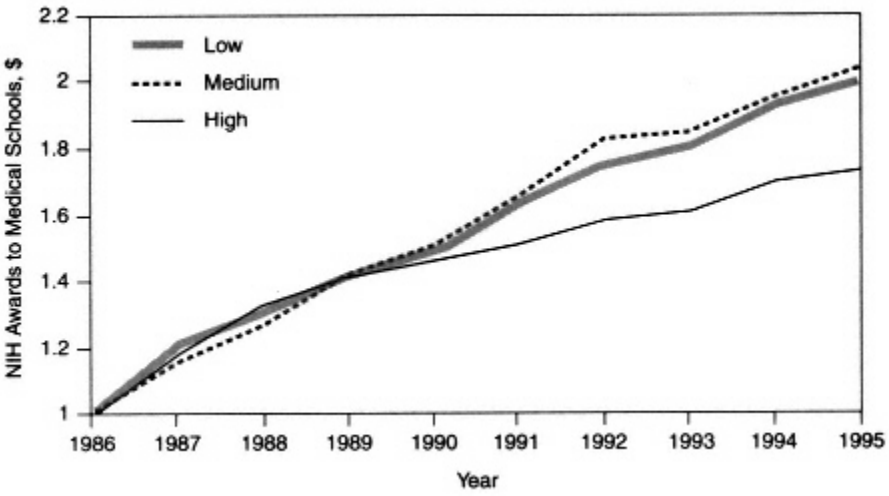

Figure 2-3 NIH awards to U.S. medical schools in different managed care markets, 1986 to 1995. Dollar amounts are relative. For instance, in 1995, markets with low levels of managed care penetration received 1.99 times more funding, markets with medium levels of managed care penetration received 2.03 times more funding, and markets with high levels of managed care penetration received 1.75 times more funding than they received in 1986. Source: Moy et al., 1997.

The modern-day structure of medical schools has evolved over time. In recent decades AHCs have provided medical education and research training, a research infrastructure, and care for the underserved. Today, however, AHCs are increasingly pressed to continue these obligations while assuming a greater proportion of their costs. As such, it has become harder to perform the type of large-scale, population-based research commonly required to control emerging infections. Managed care organizations, however, have the potential to assist in these efforts with their integrated, computerized database capabilities. These capabilities are discussed in the next section.

OPPORTUNITIES FOR POPULATION-BASED CLINICAL RESEARCH USING DATA FROM MANAGED CARE ORGANIZATIONS

Presented by Frank DeStefano, M.D., M.P.H.

Medical Epidemiologist, Vaccine Safety and Development Activity, Centers for Disease Control and Prevention

Stimulated by the shift toward managed care, health care organizations in the United States are increasingly consolidating into integrated systems that

cover large populations. Integrated systems provide data on all levels of inpatient and outpatient care, from primary care through highly specialized tertiary care. In such systems, computerized information systems are extensively used for a variety of patient care and administrative functions. The availability of computerized information covering the entire spectrum of medical care for large populations provides opportunities for many types of health research, including public health surveillance, epidemiological studies, and health services research.

The continued growth of computerized medical information systems in managed care organizations should improve the efficiency with which such studies can be conducted. At present, however, computerized databases are not sufficiently evolved to negate the need to obtain additional confirmatory or supplemental information from hard-copy records or interviews with patients. The key elements of medical information systems for use in population-based health research include (1) mechanisms for the identification and progressive tracking of individuals in a defined population, (2) procedures that ensure the accuracy of the diagnostic and other clinical data entered into an electronic database, and (3) development of uniform data sets with information on demographic variables (e.g., race and ethnicity) and other risk factors, in addition to diagnostic and treatment information.

The Centers for Disease Control and Prevention (CDC) effort to study rare adverse events that occur after the receipt of vaccines serves as an example of how computerized databases of various large health maintenance organizations (HMOs) can be linked into a single research database. The Vaccine Safety Data Link (VSD) is a project of CDC's National Immunization Program, which began in 1991 as a collaboration between four federal agencies and four long-established staff model HMOs. VSD links together the computerized databases of the four HMOs to provide primary information for research on vaccine safety and other health issues. The data fields include population and vaccination status, as well as health outcomes (diagnostic codes from hospital discharges, emergency room visits, and clinic outpatient visits), laboratory test results, and pharmacy records.

Staff model HMOs are good partners for this project because they provide and maintain detailed records on all levels of patient care, including cost data. They also have a stable, identifiable patient population from which subjects can be selected, and they are able to implement interventions (and ensure follow-up) on a systemwide basis. One of the HMO partners, for example, is conducting a systemwide study of pneumococcal polysaccharide vaccine in which revaccinated patients are compared with patients being vaccinated for the first time for immunogenicity and reactogenicity.

The databases of managed care organizations, however, also pose challenges to clinical research because of a lack of uniformity and their orientation toward administrative and management purposes rather than clinical or research purposes. Thus, adaptation of these databases for use in research can be expensive and time-consuming. In addition, many HMOs do not routinely record data on important variables, such as race or ethnicity, consanguinity, socioeconomic

status, or risk factors such as cigarette smoking. Furthermore, databases lack information on medical conditions for which the patient does not seek treatment and may not list information on deaths that occur outside the hospital (although this can be overcome by use of links to diverse local vital records offices).

Clinical researchers may also find problems with these types of integrated databases when changes in HMO policies and procedures occur, which might affect patient care, outcomes, data collection, selection bias in the patient population (because of the nature of the HMO membership), disenrollment (which complicates long-term follow-up), and the lack of research infrastructures in HMOs. For example, a proposed research project on a rotavirus vaccine would require laboratory tests that the HMOs themselves would be unlikely to conduct. Other limitations might be posed by the nature of services provided by the HMO; that is, if its emphasis is on primary care, the patient population might be skewed away from those in need of specialty care, thereby limiting the types of data collected on the enrollee population. These limitations might have implications for the development of evidence-based research or guidelines. Concerns about the privacy of the medical record may also pose an impediment to the clinical researcher (although this is not restricted to managed care organizations). For example, the Mayo Clinic reports that privacy laws in Minnesota may prevent managed health care systems from conducting medical record reviews, and laws in other states may erect barriers that would prevent the use of patient records for research. The issue of medical privacy is complex and is being examined and considered by the U.S. Congress and the Secretary of the U.S. Department of Health and Human Services.

CONDUCTING CLINICAL RESEARCH WITHIN MANAGED CARE ORGANIZATIONS

Presented by Walter Stature, M.D.

Head, Division of Allergy and Infectious Diseases, University of Washington School of Medicine

The trend toward managed care is often viewed as antithetical to research since managed care priorities often emphasize rapid patient throughput, low-cost care, limited laboratory testing, quotas for numbers of patient consults per physician, and lack of reimbursement for costly procedures. In reality, the managed care environment may be uniquely well suited for patient-oriented clinical research as well as for epidemiological and health services research. Unique advantages provided by large managed care organizations include well-defined, representative, and stable patient populations; the integration of inpatient and outpatient services within one system; centralized pharmacy services; centralized laboratory services; computerized and uniform databases, including databases containing medical, pharmacy, and laboratory records; and control of approaches to the delivery of health care at the individual practitioner level. These

characteristics can facilitate patient recruitment into large, population-based studies, patient retention, and implementation of randomized intervention trials. Elements integral to the success of clinical research conducted in the managed care setting include selection of research projects of importance to the managed care organization, participation of relevant managed care providers who are interested in a particular research topic, collaboration between academic investigators and the managed care organization, external funding of the research, publication of results in peer-reviewed publications, and incorporation of research results into the clinical practice of the managed care organization. Given these and other factors, the managed care environment can provide unique research opportunities.

Group Health Cooperative of Puget Sound (which is now merged with Kaiser-Permanente) is a large staff model HMO that has more than 500,000 enrollees and the experience and infrastructure needed to conduct research. It has collaborated with the University of Washington on numerous major research projects over the past 15 years. However, less than 25 such managed care organizations exist in the United States.

The principal advantage of working with a research-savvy managed care organization is its ability to provide a large, well-defined, and relatively stable patient population that has uniform access to care, thereby minimizing selection bias and facilitating retention and follow-up in studies. Inpatient and outpatient services are integrated, and support services such as laboratory and pharmacy services are centralized, uniform, and computerized. Moreover, standardization at the physician and clinic levels makes randomization easier. In the case of Group Health Cooperative of Puget Sound, there is also an affiliated research center with experience in supporting the infrastructure for population-based research.

An example of a collaboration between the University of Washington and Group Health Cooperative is a randomized intervention trial to screen women for cervical *Chlamydia trachomatis* infection for the prevention of pelvic inflammatory disease. Chlamydial infection is the most common bacterial sexually transmitted disease in the United States. The main clinical sequelae are upper genital tract infection and pelvic inflammatory disease. The first step in this project was a cross-sectional study to define the prevalence and risk factors for chlamydial infection among 1,800 female enrollees, which provided a representative demographic profile of women in the Puget Sound region. This cross-sectional study identified a subpopulation in which the disease is prevalent. The second phase of the study involved an intervention trial in which a *Chlamydia* screening test was randomly administered to women from the high-risk group. All women were then monitored for 12-months. The results showed that screening reduced the incidence of pelvic inflammatory disease by 60 percent.

The collaboration between the University of Washington and a large HMO was the key to success in this clinical research project. The relevance of the study to Group Health Cooperative was vital for the success of the project, as was the inclusion of Group Health Cooperative clinicians during the planning and execution stages. However, external funding was also necessary, because

the research units of managed care organizations must frequently be self-supporting. In this study, most of the funding came from NIH, which provided the financial means to pay for salaries, testing, and the collection of additional information. In this example, the results were published in a peer-reviewed journal and were subsequently incorporated into the clinical practice of Group Health Cooperative.

NIH ACTIVITIES RELATED TO CLINICAL RESEARCH AND MANAGED CARE

Presented by Lana Skirboll, Ph.D.

Associate Director for Science Policy, National Institutes of Health

In 1995, NIH convened the Clinical Research Panel, which subsequently created a subpanel to consider additional potential sources of clinical research funding, including managed care organizations. Although the panel members had received anecdotal data from academic health centers that clinical research was suffering under the current managed care system, it was difficult to obtain reliable data that addressed the magnitude of the problem or even the costs associated with conducting clinical research. To date, the effort to collect such data continues; a collaboration between the National Cancer Institute (NCI) and the RAND Corporation is attempting to provide this type of information. In addition, NCI is collaborating with the CHAMPUS program of the U.S. Department of Defense and with the Health Care Financing Administration (HCFA) to develop estimates of the patient care costs of clinical research.

Historically, there have been tensions between academic clinical researchers and HMOs. Managed care organizations complain that academics want to pursue research that is not relevant to their clinical needs, that investigators fail to consult with them early in the process of designing clinical trials, that the only concern of academic scientists is access to patients, and that these researchers do not follow through clinically with the results of their studies but merely publish them in peer-reviewed journals. On the other hand, academic clinical researchers complain that HMOs are reluctant to refer patients to academic health centers because it is perceived that care is too expensive; they demand discount rates from academic health centers, which results in lost subsidies to clinical research; and in some cases, they are reluctant to pay the costs for the routine care provided in the research context.

To bridge this gap, NIH sponsored a series of meetings to broaden the dialogue on clinical research. Participants included the Association of American Medical Colleges, the American Association of Health Plans (AAHP), and payers or purchasers of health care, including large corporations that are interested in good health care for their employees but that are not necessarily interested in clinical research. Some participants representing the corporate purchasers of

services from health care plans suggested that academic health centers need to further downsize and streamline their activities to reduce costs.

NIH has institutionalized its commitment to forging research relationships with managed care organizations by creating a Managed Care Fellowship and a Trans-NIH Managed Care Working Group. NIH has also appointed a liaison to help AAHP members better understand NIH and clinical research. The goal of these and other initiatives is to formulate a set of core principles on the nature and value of clinical research, to determine the actual costs of research, and to establish who should pay for the various costs of clinical research. In addition, a demonstration project has been proposed to HCFA. That project will study how the public sector might pay for the patient care costs of clinical investigations, an important first step in the formation of a partnership between clinical researchers and managed care organizations.

SUMMARY OF CHALLENGES AND OPPORTUNITIES

Jonathan R. Davis, Ph.D., *Editor*

The presentations described above and the discussion that followed during the workshop highlight several challenges and opportunities related to conducting basic and clinical research in a managed care setting. These are summarized below in the sections Supporting the Functions of Academic Health Centers, Ensuring Adequate Databases for Clinical Research, Exploiting the Unique Advantages of Managed Care for Surveillance and Research, and Promoting Collaboration.

Supporting the Functions of Academic Health Centers

The clinical revenues generated at AHCs have greatly contributed to the growth and excellence of medicine in the United States, produced outstanding basic and clinical research, promoted the training of physicians and scientists, facilitated the growth of the nation's biotechnology industry, and provided a health care safety net for those most in need. As discussed at the workshop, however, the continued provision of these important services is challenged by the growing dominance of managed care and other market forces in the health care system, in which the primary focus on cost containment can be at odds with these critically important but expensive endeavors. To address this challenge, many workshop participants emphasized the importance of involving all the various stakeholders in ensuring the continuation and support of AHCs in conducting research, training physicians and scientists, and providing access to health care.

Ensuring Adequate Databases for Clinical Research

Health care organizations are increasingly consolidating into integrated systems that provide care at all levels and that cover large populations. The computerized information systems used in these settings serve a variety of patient care and administrative functions. However, because of wide variability in these systems, their adaptation to uniformity and consistency for use in clinical research can be expensive and time-consuming. In addition, as discussed by the workshop participants, the use of integrated databases in clinical research can be compromised by policy and procedural changes adopted by managed care organizations, which can make it difficult to track trends; selection bias caused by the characteristics of the enrollee populations; and the lack of a research infrastructure within managed care organizations to collect, process, and analyze research data. An additional challenge is posed by the current trend toward less integrated models of managed care, which results in the provision of a narrower range of services and therefore the availability of a correspondingly narrower set of databases for evidence-based medicine. Use of the data in these databases by clinicians and researchers may also pose privacy concerns, and such concerns may be obstacles to investigators who rely on medical records to conduct research.

If infectious disease studies are to be conducted in the managed care setting, it was suggested that their efficiencies could be improved by using standardized, computerized medical information systems and by incorporating key elements into the development of these systems for use in population-based health research. These include mechanisms that identify and progressively track individuals in a defined population, procedures that ensure the accuracy of the diagnostic and other clinical data, and the development of uniform data sets.

Exploiting the Unique Advantages of Managed Care for Surveillance and Research

Some view managed care as antithetical to clinical research because priorities often emphasize rapid patient throughput, low-cost care, limited laboratory testing, quotas for numbers of patient consults per physician, and lack of reimbursement for costly procedures. The possibility that managed care organizations could improve surveillance and treatment of emerging infections was discussed at some length. This could be accomplished through the (1) systematic collection of relevant data, (2) standardization of computerized systems that can monitor health data, and (3) education of providers regarding their importance in accurate disease reporting.

Moreover, the managed care environment was described by many as being uniquely well suited for patient-oriented clinical research, as well as for epidemiological and health services research, because of the following characteristics: (1) a large, well-defined, and relatively stable patient population that has uniform access to care; (2) integrated inpatient and outpatient services within one

system; (3) centralized support services such as pharmacy and laboratory services; (4) uniform and computerized databases; and (5) standardized delivery of health care at the individual practitioner and clinic levels.

Promoting Collaboration

Close collaboration between academic health centers and managed care organizations is critical to the success of clinical research. As discussed in the workshop, however, managed care organizations perceive some clinical research as irrelevant to their patient needs and are not routinely consulted early in the experimental design of clinical trials. Conversely, clinical researchers at academic health centers find that some managed care organizations are reluctant to refer patients to clinical trials and are unwilling to pay for the routine patient care provided in the research context.

Close collaborations between academic health centers and managed care organizations can be achieved by (1) selecting research projects of importance to managed care, (2) seeking the active participation of relevant and interested providers, (3) identifying external funding for research protocols, (4) collaboration between academic investigators and the managed care organization, (5) facilitating publication of results in peer-reviewed publications, and (6) ensuring that the results are incorporated into managed care practice.

Summary

Although academic health centers have become dependent on clinical revenues to support a portion of their research activities, pressure from managed care is reducing both the profit margins and the faculty time that are available to support research and training. At the same time, managed care organizations have large patient populations and centralized information systems that create opportunities for epidemiological and clinical trials research. In the past 10 years, a few large and stable managed care organizations have developed the infrastructure and culture to collaborate with academic and government researchers. The creation of stronger partnerships between managed care organizations and academic health centers is one way to meet the public health need to combat emerging infections.

The system of managed care, however, is undergoing a rapid evolution that may threaten the stability and survival of these partnerships. NIH is working with the managed care industry to develop mechanisms that would continue to support clinical research in a managed care environment. Whether increases in the NIH budget or research funds from the pharmaceutical industry will replace

cutbacks from Medicaid educational opportunities or from clinical funds that formerly supported research faculty salaries remains to be determined.*

In addition, some of the discussions focused on the fact that research on emerging and reemerging infections is threatened by the decline of microbiology laboratories in academic health centers. For example, CDC has noted a decline in the quality of testing that has been performed on the samples that it receives, and this decline in quality may weaken the public health system's ability to recognize an emerging pathogen or disease outbreak. A possible solution that was discussed at the workshop and that may combat the decline would be the creation of centers of excellence in microbiology with links to the large populations in stable, research-oriented HMOs. Consequently, there is an immediate need to gauge the health of the nation's public health laboratories, a topic that will be addressed in an upcoming workshop of the Institute of Medicine Forum on Emerging Infections.

* After this workshop was held, a new report from the Institute of Medicine examined both the evidence for extending coverage for routine care during clinical trials and the cost to Medicare of doing so. The report, *Extending Medicare Reimbursement in Clinical Trials* (IOM, 1999), recommends that Medicare should pay for routine care of beneficiaries enrolled in clinical trials in the same way it pays for this care outside of clinical trials. The report urges HCFA to issue unambiguous rules to end widespread uncertainties about what should or should not be reimbursed. The authoring committee noted that since Medicare has a stake in ensuring that the medical interventions it pays for are effective, it would be sound policy to remove any disincentives to the participation of Medicare recipients in clinical trials. However, Medicare should not pay for unapproved drugs and devices, or radical new procedures, unless reimbursement is already allowed under a prior agreement with the federal government. All data-collection costs should remain the responsibility of the researchers or their sponsors.—*Ed.*

3

Clinical Practice Guidelines

As managed care matures and as competing plans become willing to accept a greater degree of uniformity in standards of care, the question of who will set those standards remains. New standards are easier to implement when they fill a gap than when they change existing behavior or when they call for more care. In turn, asking for less care may be a difficult proposition, particularly when patient satisfaction is an important issue for the purchaser of care. In some instances, patient satisfaction may be contingent upon receipt of a prescribed medication, such as an antibiotic. On the other hand, some plans implement telephone management of certain infections, which also receives high marks in terms of patient satisfaction.

Changes to existing clinical practice guidelines or implementation of new rules is most effective when these efforts are initiated from the ground up, overcoming both psychosocial and organizational barriers. The presentations described below examine the challenges and opportunities related to clinical practice guidelines, managed care, and emerging infections.

CLINICAL PRACTICE GUIDELINES FOR EMERGING INFECTIONS AND MANAGED CARE

Presented by Anne Schuchat, M.D.

Chief, Respiratory Diseases Branch, Centers for Disease Control and Prevention

The time interval between the emergence of new infectious agents and the formulation and implementation of clinical practice guidelines for their control is shrinking. An example of this is the emergence of the hanta pulmonary syn

drome. The cause of the syndrome, the hanta virus, was quickly identified, followed by the rapid development and implementation of prevention guidelines. This development has encouraging implications for the prevention of emerging infections. Technological advances and greater community activism have contributed to this trend, as have improvements in behavioral science and medical communications. Managed care may also be a contributing factor, particularly as more of the at-risk populations for new and reemerging infections are included under managed Medicaid contracts.

The example of Group B streptococcal infection provides an illustration of ways in which managed care can provide new opportunities to implement and evaluate clinical practice guidelines for controlling infectious diseases. Twenty-five years ago, Group B streptococcus emerged as the principal cause of sepsis and meningitis among newborns in the United States, resulting in treatment costs of approximately $300 million per year. Clinical trials during the 1980s demonstrated that the use of antibiotics in high-risk mothers during labor was successful in preventing transmission of the streptococcus to neonates. However, this strategy was not implemented. Both logistical concerns and lack of public pressure accounted for this absence of a response. Cost-effectiveness studies conducted in the early 1990s provided further support for this approach. The formation of a parents' organization, the Group B Strep Association, placed pressure on the medical community to develop a new standard of care. In 1996, the Centers for Disease Control and Prevention collaborated with the American College of Obstetricians and Gynecologists and the American Academy of Pediatrics to issue consensus guidelines for the prevention of neonatal Group B streptococcal infection. Evaluation of these new guidelines at the Group Health Cooperative of Puget Sound showed that changing the timing of prenatal screening and offering treatment to all carriers (i.e., the screening-based approach included in the consensus recommendations) was feasible and could be efficiently implemented. This approach significantly increased the proportion of women who received antibiotics during labor (Anne Schuchat, Chief, Respiratory Diseases Branch, CDC, personal communication, January 8, 1999). Adoption of Group B streptococcal prevention policies by hospitals throughout the United States has been accompanied by a significant decline in Group B streptococcal disease (CDC, 1998; Schuchat, 1999).

As managed care evolves it offers increased advantages for implementation and evaluation of clinical practice guidelines. Patient recruitment, systemwide implementation, and the surveillance and monitoring of infectious diseases with computerized databases are some of the tools available to managed care systems to help combat emerging infections. Information can be readily accessed when systems are well designed and integrated, allowing quicker responses to new recommendations. On the other hand, the challenges to be overcome are subscriber turnover, proprietary restrictions on access to data from managed care organizations, and the adoption of different guidelines across organizations. Until these challenges have been addressed for clinicians, patients, laboratory personnel, and public health officials, the systemwide implementation of standard

ized clinical practice guidelines may not be successful in addressing the threats of emerging infections.

REALITIES OF IMPLEMENTING GUIDELINES

Presented by Nora Morris, M.A.

Assistant Director/Senior Analyst, Healthcare Education and Research Foundation, Inc.

The implementation of standardized clinical practice guidelines in managed care systems is a difficult process that requires communitywide efforts, including participation from the purchasers of health care plans. Development and adoption of clinical practice guidelines will involve changes in the individual and organizational behaviors of physicians, nurses, health care administrators, patients, and individual health care facilities. Health care providers presented with clinical practice guidelines must consider them in light of the financial incentives of the managed care organization, professional incentives and culture, personal and professional beliefs and experiences, and what they consider to be in the best interest of the patient. Patients on the receiving end also bring to their treatment a health history, and personal beliefs and experiences. Broad participation in the development of guidelines will ensure that barriers to adoption are identified early.

An example of the successful implementation of clinical practice guidelines can be found in the managed care systems in the St. Paul-Minneapolis area. Since the early 1990s, managed care organizations in that region have worked together to institute standardized clinical practice guidelines. To accomplish this goal, participating organizations first targeted the audiences for such guidelines: physicians, nurses, health care administrators, and patients. Second, potential barriers to implementation were identified: knowledge and skills deficits and resource and organizational shortfalls. It was not until these issues were addressed that efforts were made to complete and implement the guidelines.

The barriers to implementation of standardized clinical practice guidelines may be found at many levels within a managed care setting. Knowledge and skills deficits have the ability to affect the decisions of all participants. For example, primary care physicians treating a patient with AIDS and lacking access to the most current data about courses of therapy may be daunted by sophisticated treatment guidelines. At the patient level, the degree of family support that a patient receives is a contributing factor to the acceptance or rejection of standardized guidelines, as is the degree of community and financial support available. These factors combine to influence a patient's decision about seeking and adhering to therapy. At the organizational level, ongoing conflicts within an organization may prevent members from learning about and adhering to proposed guidelines. This type of barrier can be more difficult to address since it involves changing the behaviors of many people simultaneously. Full imple

mentation of guidelines requires the cooperation of clinicians, health care administrators, public and private payers, patients, and patients' families.

MAKING GUIDELINES INSTRUMENTAL: THEORY VERSUS PRACTICE

Presented by Richard Dixon, M.D., FACP
Medical Director, National Independent Practice Association Coalition

The foundation of *managed care* is care management. Better outcomes and lower costs could materialize if the care for individual patients and populations is systematically organized. This can be accomplished by ensuring the use of available evidence-based best clinical practices and the implementation of reasonable standards, even when best practices have not been defined. Better care management, which has resulted from the spread of managed care nationwide, is expected to reduce the enormous variations in practices and outcomes that have been documented whenever patterns of practice and outcomes have been evaluated.

The promise of managed care to the better management of care has not yet been successfully fulfilled. With only a few exceptions, studies have shown that the outcomes achieved under managed care systems are at least as good as those achieved under the old, unmanaged fee-for-service systems. Although managed care has undoubtedly achieved actual improvements in the quality of care, those improvements appear to have been modest.

There are several reasons why managed care has not fulfilled its promise to standardize care, make care more cost-effective, and produce better outcomes. In large part, failure has occurred because it has been exceedingly difficult to change physicians' practice patterns. Clinical practice guidelines can influence a physician's decisions and actions. To affect clinicians' behaviors and decisions, clinical practice guidelines should satisfy five criteria. First, they must be clinically credible to clinicians and must be viewed as important. Unfortunately, patterns of practice vary considerably by geography, specialty, and practice setting, reflecting the likelihood that there is no common consensus about the best—or even the proper—clinical steps to be taken in the same clinical situation. The guidelines themselves contribute to this variation since many different guidelines that address the same conditions are available, and guidelines are occasionally contradictory. Many clinicians do not consider published guidelines to be applicable to their patients because those guidelines often come from research settings and academic centers, which are believed to be different from typical community settings. Additionally, some guidelines are not documented to be safe or effective, so clinicians are reluctant to accept them on faith.

Second, guidelines must provide clinicians with a single, coherent message. Clinicians are often under contract with many health plans and work in several

hospitals. If these plans and hospitals promote the use of different guidelines, clinicians are likely to reject all of them since it is difficult, if not impossible, to use different standards of care based on the hospital or insurance company responsible for the patient.

Third, most experts who have attempted to deploy clinical practice guidelines agree that physicians must "buy into" the guidelines. This usually requires that the affected clinicians be involved in the construction of guideline elements. Although guidelines imposed from the top are typically poorly received, it is difficult to develop local guidelines. Because clinicians are busy and are increasingly required to meet productivity targets, they are reluctant to devote time to guideline development. Other resources are also scarce: good guidelines require systematic research, local assessments of variations in practice, considerable meeting time to develop consensus, and ongoing processes to monitor guideline effectiveness and to educate the clinicians.

Fourth, guidelines must be living documents. Best practices evolve over time, and a guideline that represented the evidence-based best practice several years ago may not be appropriate now. Therefore, guideline maintenance requires long-term investments.

Finally, and perhaps most importantly, physicians need incentives to change practices and adopt clinical practice guidelines. Financial incentives may not be the most important, but they cannot be ignored. If a physician is paid more not to follow a guideline, the guideline is unlikely to be adopted. In addition, if a guideline reduces a physician's efficiency and productivity, it will be resented. Positive financial rewards for compliance with guidelines hasten their adoption. Nonfinancial incentives must also be considered. Clinicians must be assured that by following the guideline they are providing care at least as good as that provided without following the guideline.

These five challenges are compelling and can be realized. Major purchasers of health care must recognize improvements occur when clinicians make decisions about patients. Those purchasers are in a good position to require health plans and hospitals to standardize the required guidelines and to reward those who comply with the guidelines. Hospitals and plans should also recognize that guidelines will make care more effective and more cost-effective, so they should provide resources to help with the development of local guidelines. Additionally, informed patients can pressure and encourage their doctors to use evidencebased best practices, which in turn can have a positive effect on clinicians. For example, an educated patient population that is knowledgeable about childhood immunization issues would most likely have improved rates of compliance with immunization guidelines. Finally, if quality of care is truly believed to be an important national value, society must begin to pay for quality. Higher-quality providers must be paid more than providers who provide lower-quality care, and the latter motivated to sharpen their expertise.

SUMMARY OF CHALLENGES AND OPPORTUNITIES

Jonathan R. Davis, Ph.D., *Editor*

The presentations described above and the discussion that followed during the workshop highlighted several challenges and opportunities related to clinical practice guidelines in a managed care setting. These are summarized below as Promoting Adoption and Use of Guidelines in Managed Care Organizations and Involving Clinicians in Guideline Development and Implementation.

Promoting Adoption and Use of Guidelines in Managed Care Organizations

Providing managed care organizations with opportunities to implement and evaluate clinical practice guidelines can control new and reemerging infectious diseases. This is especially important as more members of the populations at risk for these diseases are included in managed care plans. Systemwide clinical practice guidelines that address the various audiences likely to use them and that anticipate barriers to their implementation can be adopted. Each of the targeted audiences—clinicians, patients, laboratory personnel, administrators, and consumer groups—has an important role to play if communitywide efforts are to be successful. These efforts would likely involve changes to human and organizational behaviors, including not only the behaviors of the medical community but also those of patients and the individual health care facilities.

Many workshop participants discussed the fact that managed care is focused on prevention, populations, standardization, cost containment, and quality and is thus uniquely positioned to promote and use clinical practice guidelines. As discussed earlier in this chapter, however, some of the existing guidelines have not been validated, and others do not address the needs of clinicians, many of whom contract with multiple plans that have different and often contradictory guidelines. In addition, it is sometimes difficult to gather the data necessary to construct the guidelines, as competing managed care organizations are often unwilling to share proprietary data. Despite these obstacles, the adoption of clinical practice guidelines may be more easily accomplished for the treatment of emerging infectious diseases than for other subspecialties, in part because the label "emerging" conveys a need for the development and adoption of new guidelines.

The development of guidelines is challenged further by patterns of practice that vary considerably by geography, specialty, and practice setting, reflecting the likelihood that there is no common consensus about the best—or even the proper—clinical steps to be taken in the same clinical situation. Moreover, the guidelines themselves contribute to variations in patterns of practice since many different guidelines that address the same conditions are available and guidelines are occasionally contradictory.

Involving Clinicians in Guideline Development and Implementation

As discussed by the workshop participants, many clinicians do not view published guidelines as being applicable to their patients because those guidelines often come from research settings and academic centers believed to be different from typical community settings. Moreover, some clinical practice guidelines are not documented to be safe or effective, so clinicians are reluctant to accept them on faith. Because clinicians are busy and are increasingly required to meet productivity targets, they are reluctant to devote time to clinical practice guideline development.

Protected time and resources were discussed as essential needs of members of the medical community to become more knowledgeable on the latest medical advances in disease pathogenesis and current diagnosis and therapy, an important and integral component of maintaining high-quality medical care and adherence to guidelines. When hospitals and plans recognize that clinical practice guidelines will help make clinical care more effective and more cost-effective, they will be more likely to provide resources to help with the development of local guidelines.

The Need for Systemwide, Standardized Guidelines

Subscriber turnover and proprietary restrictions on access to managed care data, combined with the adoption of different clinical practice guidelines across managed care organizations, may compromise efforts to implement systemwide, standardized clinical practice guidelines. However, health care plan purchasers are in a good position to require health plans and hospitals to standardize the required guidelines and to reward those who comply with them.

Promoting Professional and Public Education

In addition to members of the health care profession, the public must also be better educated and informed about current information on disease states and treatments. Informed patients can encourage their doctors to use evidence-based best practices, which in turn can have a positive effect on clinicians.

Summary

A common thread throughout the discussion of clinical practice guidelines revolved around the extent to which managed care organizations should promote clinical practice guidelines. A common perception is that managed care fails to adhere to standardized clinical practice guidelines because many of these guidelines have not been validated under sustained clinical settings. Furthermore, it is

argued that the guidelines in use do not adequately address the needs of clinicians, many of whom contract with multiple plans that have different and often contradictory guidelines. Consequently, it was recognized that it may be difficult to change guidelines or implement new ones because effective change comes from the ground up and would need to overcome both psychosocial and organizational barriers. Nevertheless, initiatives to standardize clinical practice guidelines have involved successful collaborations among providers, mechanisms to standardize guidelines across plans, involvement and comments from physicians, and financial and other incentives from major purchasers. Opinion leaders and administrative champions play vital roles in implementing new guidelines.

Guidelines may be less of a problem in infectious diseases than in other subspecialties, as shown by the success of one health maintenance organization in achieving a 40 percent reduction in neonatal Group B streptococcus infections. Managed care organizations offer a number of advantages for evaluating this kind of initiative, including patient recruitment, systemwide implementation and monitoring, and a computerized database. Industry and professional organizations can also play an important role in developing and disseminating new guidelines.

The adoption of clinical practice guidelines may be more easily accomplished for the treatment of emerging infectious diseases than for other subspecialties, in part because the label "emerging" conveys a need for the development and adoption of new guidelines. Even here, however, guidelines should be flexible and dynamic, allowing treatment to change in response to comments on compliance and results. In addition, there may be a need to reassess these data on a regular basis and revise the guidelines as required.

4

Surveillance and Monitoring

A well-coordinated public health system for the detection and control of emerging infections and antimicrobial resistance requires an effective partnership among health care providers, academic health centers, and the traditional public health system. Effective infectious disease surveillance necessitates that physicians send samples to competent laboratories for confirmation of their diagnoses and that they report the findings through the public health system. Yet, each aspect of infectious disease surveillance is evolving independently and rapidly.

Cost-reduction and reimbursement efforts through managed care emphasize the heavy reliance on empiric care rather than laboratory data. This reduces the use of diagnostic tests, discourages visits to specialists, and shifts care to ambulatory settings, where the capabilities for diagnosis and care are less than those found at inpatient facilities. Yet, standard types of managed care organizations, such as the staff model and preferred provider health maintenance organizations (HMOs), are being bypassed by some large payers in favor of the direct purchase of services from individual physicians and small laboratories. For example, in Minnesota, a state that has been a leader in setting trends in managed care, large buyers of health care (employers, primarily corporations) are dictating coverage. The factors that determine coverage often differ between such groups and the individual consumer or public health groups. One-third of Minnesotans are forced to change health plans on an annual basis, based on their employers' financial situation (Michael Osterholm, State Epidemiologist and Chief, Acute Disease Epidemiology Section, Minnesota Department of Health, Minneapolis, personal communication, March 23, 1998). This situation may signal the end of large, centralized laboratories, a change that could have major implications for disease surveillance as outcome measurement and population-based studies become more difficult. Consequently, there is a particular concern that managed care systems may reduce their levels of compliance in infectious

disease reporting and inadvertently circumvent the requisite comprehensive analysis of pathogenic isolates needed for disease tracking.

Laboratory practices are also changing because fewer tests are conducted to determine new pathogens and levels of susceptibility to antimicrobial agents. Moreover, since large laboratories that are not likely to be in the same state as a patient's HMO conduct much of the laboratory testing, a widespread outbreak might not be detected through reporting by a single HMO. This situation is problematic because HMO patient databases are often uncoordinated and poorly networked, consequently making disease tracking even more complex and difficult.

The uniqueness of each managed care organization and the essential capabilities of private and public microbiological laboratories underscore the importance of working together. The challenge that lies ahead is how to plan a comprehensive infectious disease surveillance system that allows maximum coordination and flexibility for change. The opportunities are many for all parties to become involved in negotiating how the evolving health care system can improve public health.

The presentations described below examine the opportunities and challenges for academic health centers and managed care organizations to work together in the fields of basic and clinical research in addressing issues related to emerging infections.

AN EMPLOYER'S PERSPECTIVE

Presented by Thomas J. Davies, M.P.A., J.D.
Manager of Managed Care, GTE Corporation

Integrated health care delivery systems offer the greatest hope for improving quality while managing costs, including the quality and costs of infectious disease control. Employers as purchasers of health care can play an important role in determining the extent and quality of care for their employees. They can also be instrumental in helping determine how care is administered and used. Many believe that consumers, not employers, have largely driven the growth toward managed care because of their preference for the greater benefits and lower costs of HMOs. Subsequently, employers have responded in a number of ways depending on their size and their perceptions about how they can influence the delivery of health care. Small and midsize companies largely regard their role as helping to pay premiums, that is, to alleviate some of the costs of health care for the employee by arranging and paying for health insurance. Large companies, on the other hand, have unique opportunities to make more of an investment and move toward value-driven purchasing strategies, whereas smaller and midsized firms tend to choose health plans on the basis of cost. Many employers see managed care as their best hope for containing costs while maintaining

quality. Such employers believe that quality health care represents a better value and costs less.

In recent years, 33 large companies on the West Coast of the United States have formed the Pacific Business Group on Health (PBGH) to provide leadership to steer the health care market toward increased quality and accountability. This coalition of businesses strives to improve quality through the administration of their health care programs. The strategy includes encouraging employees to select certain systems of care voluntarily and ensuring that those decisions are based on value. However, employers tend to regard health care in terms of prevention, acute care, and chronic care, not in terms of specific infections, emerging or otherwise. From the point of view of PBGH, too many managed care organizations are only managing costs and are not paying attention to accountability. A larger problem is the lack of timely, accurate, and complete information about employee's health care encounters that can be used appropriately by health plans, individual practitioners, and payers. These data were previously available through the claims information routinely collected by fee-for-service, indemnity-based plans.

MANAGED CARE AND INFECTIOUS DISEASE SURVEILLANCE: OPPORTUNITIES FOR COLLABORATION

Presented by Denise Koo, M.D., M.P.H.

Director, Division of Public Health Surveillance and Informatics, Centers for Disease Control and Prevention

Public health surveillance and monitoring activities are a cornerstone of public health practice, providing information essential for assessing public health status, monitoring trends, suggesting public health priorities, and evaluating the effectiveness of public health programs. In one of these monitoring functions, the Centers for Disease Control and Prevention (CDC) manages a system of national surveillance of notifiable diseases in coordination with state health departments and publishes data on a weekly basis.

When considering how public health surveillance may be conducted through managed care organizations, there is great potential for many benefits and opportunities to be gained through partnerships with managed care. Because the improved health of a population is a primary goal of managed care organizations and public health agencies, both will benefit by sharing data and working together. There are, however, several impediments to conducting surveillance through managed care organizations.

First, there is a lack of understanding on the part of health care providers about the roles of state and local public health departments in infectious disease surveillance. In general, few health care providers understand the importance of public health surveillance, the role of the provider as a source of data, and the role of the health department in response to infectious diseases. Some of this

lack of understanding stems from the fact that public health agencies may not always provide feedback to providers on how the data are used and may not make the data available to the public (or at least to providers or potential users of the data). For example, public health systems can provide surveillance data about the incidence of a particular disease in the community at large. These data can help raise or lower the threshold of clinical suspicion for that condition and encourage early detection and appropriate treatment of that infectious disease. Public health systems, as part of the response to cases of infectious disease, can also facilitate the tracking of contacts who have been exposed to a disease and subsequent administration of prophylactic treatment of contacts, regardless of whether the original case patient is enrolled in the same HMO. in general, managed care systems provide an excellent opportunity for public health agencies to clarify their role in infectious disease surveillance and response and to build partnerships to ensure communication concerning cases of disease and opportunities for prevention of the spread of disease. Public health officials need to disseminate infectious disease surveillance data and reports to health care providers in a timely, readily accessible, and useful manner. One available mechanism for the expeditious dissemination of this information is the Internet.

An additional impediment to public health surveillance is proprietary concerns about patient data. Many managed care organizations regard their consumer data as proprietary. They fear that their data will be used to measure their performance against the performances of other managed care organizations, particularly concerning items not entirely under their control (such as disease incidence). Public health agencies need to reassure managed care organizations that public health surveillance is not a regulatory function and that the purpose of conducting disease surveillance is to monitor the status of the public's health and to identify opportunities for improving community health status.

A disincentive to managed care organizations is duplication of data entry. To make the best use of the potential wealth of data in managed care information systems, public health agencies need to work with managed care organizations to ensure efficient, direct, and confidential reporting of data from managed care laboratory data systems to public health agencies for surveillance purposes. Additionally, public health agencies need to devise mechanisms to obtain for surveillance purposes other relevant data from managed care inpatient and outpatient information systems, such as enrollment and encounter records. Some states are already conducting pilot studies precisely directed to the achievement of such goals.

Some public health officials worry that fewer diagnostic tests will be performed in the managed care setting because of cost-cutting requirements (for example, tests for self-limited illnesses like diarrhea) leading to the decreased availability of information about emerging infectious diseases. There is concern not only about whether diseases or conditions will be detected, but there is also concern that the data captured in managed care information systems for such patients either will be insufficient for determination of the etiology of a disease or will be inaccurate. Some public health officials are concerned that the data

gathered by managed care organizations are weighted toward economic considerations (i.e., for reimbursement purposes) and might not contain medical information necessary for surveillance purposes. Some pilot studies conducted by managed care organizations and public health agencies are trying to determine the quality, accuracy, and availability of data regarding infectious diseases. These studies are showing that diagnostic testing may actually be no less prevalent among providers associated with managed care organizations than among other providers. If it is determined that diagnostic testing is not used because of cost considerations, partnerships between public health laboratories and managed care organizations could be negotiated to ensure that the testing needed for public health purposes is completed. To achieve this goal, public health agencies and managed care organizations need to work with medical information specialists as well as others to develop standards for computer-based patient records to ensure that such records will be useful for population-based health.

Finally, apprehension about the sharing of electronic data records with outsiders, including public health officials, is widespread among health care providers inside and outside of managed care. However, to accomplish their jobs effectively, public health agencies routinely have access to sensitive personal data, such as sexually transmitted disease contacts or sexual or other risk factors for disease. To date, public health agencies have an excellent record of accomplishment in safeguarding patient confidentiality and using these data only for public health purposes. However, fears about confidentiality have been used as an argument against the sharing of electronic medical data even for public health purposes. These concerns underscore the importance of privacy legislation pending before the U.S. Congress.

The field of public health is increasingly interested in expanding the amount and type of data used for surveillance to monitor old, new, or emerging public health problems. Public health officials often struggle to reconcile data about cases of infectious diseases reported by distinct sources and are seeking means of obtaining and linking the data already available electronically. The administrative simplification portion of the 1996 Health Insurance Portability and Accountability Act, which requires the potential use of standards developed by industry, provides additional incentives to work toward these solutions. Public health agencies must include managed care organizations as partners in this effort.

COLLABORATIVE SURVEILLANCE EFFORTS AND MONITORING OF DATA

Presented by Richard Platt, M.D.

Director of Research, Harvard Pilgrim Health Care

HMOs and public health agencies are natural partners in the development of community-based surveillance systems. Harvard Pilgrim Health Care, a mixed

model HMO with a membership of approximately 1.4 million people, has four ongoing collaborations with CDC, and two of these include the Massachusetts Department of Public Health. The first three partnerships involve antibiotic use, sexually transmitted disease surveillance, and tuberculosis surveillance, respectively. The fourth partnership, described below, focuses on the epidemiology of nosocomial infections. Its goal is to create a population-based, integrated program that addresses the major problems of these infections in whole populations.

TABLE 4-1 New Problems and New Solutions

Problems	Solutions
• Increased risk because of involvement of acutely ill patients and riskier interventions • Examples of factors that result in increased risk include: placement in an intensive care unit, immunosuppression, receipt of implanted prosthetic material, and extensive surgery • More antibiotic-resistant pathogens • Receipt of care outside of acute-care hospitals • Resource constraints	• Information systems provide better data more efficiently • Integrated delivery systems and HMOs have data on delivery of care and outcomes in multiple locations

SOURCE: Table compiled from presentation by Richard Platt at workshop.

Nosocomial infections are a growing concern because they involve more acutely ill patients and riskier interventions and are caused by a growing number of antibiotic-resistant pathogens. Moreover, they are increasingly likely to be initiated in the outpatient setting, which constrains control and prevention efforts. For example, many surgical operations are performed in an ambulatory-care setting, and a larger fraction of postoperative care for all patients is administered outside of acute care hospitals. In addition, resources available for traditional infection surveillance are increasingly constrained. At the same time, HMOs use information systems that provide better data more efficiently than was previously possible. Furthermore, integrated delivery systems contain data on the delivery and outcomes of care in several locations within the system, allowing analysis of care across the continuum (Table 4-1).

Recently, Harvard Pilgrim Health Care used the information from its staff model program to study surgical site infections (SSIs). Analysis of data from 5,572 surgical procedures showed that less than half a percent of these patients developed infections before discharge (Figure 4-1). About 84 percent of infections that occurred became patent after discharge from the hospital. However, most procedures involved no postoperative stay, and few of the patients who

developed infections returned to the hospital where the surgery was performed for treatment. Comparisons of different postdischarge surveillance systems, primarily surgeons' and patients' questionnaires, illustrate that both questionnaires missed most infections. More surprising, the majority of infections reported by surgeons were not due to postoperative SSIs. Infections were detected through automated HMO records, and these records detected 75 percent of infections with a predictive value of 50 percent. The HMO's record linkage capabilities, including records from the hospital, ambulatory-care data, and pharmacy dispensing data, substantially outperformed both of the measures (surgeons' and patients' questionnaires) described above. Automated HMO data records supplemented by a limited record review (6 percent of records) resulted in a sensitivity of detection of 90 percent of infections and a predictive value of 100 percent (Figure 4-2).

On the basis of these findings and under a cooperative agreement with CDC's Hospital Infections Program, Harvard Pilgrim Health Care is collaborating with 11 hospitals and the three largest HMOs in eastern Massachusetts to assess the broader applicability of these methods. All of these participants realize the need to serve the public's health. The members of these HMOs (a total of 2.8 million members) account for 90 percent of the managed care enrollees in the region, which amounts to 36 percent of the region's residents. Together, they perform 70 percent of the coronary bypass surgeries and 40 to 50 percent of the breast surgeries and cesarean deliveries, the procedures on which this effort focuses.

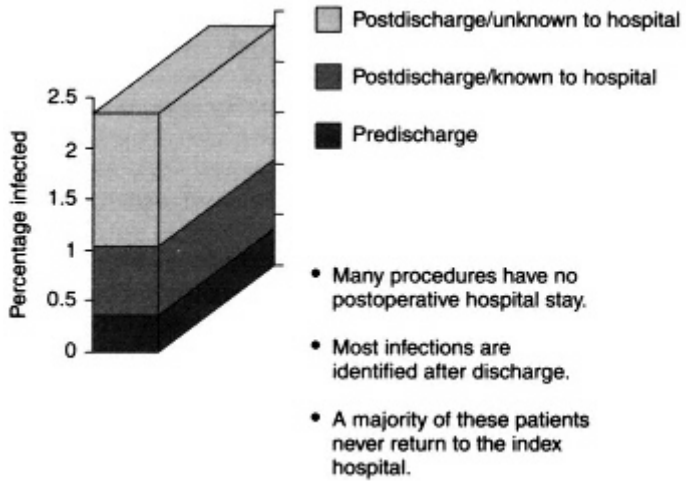

Figure 4-1 Limits of hospital-based SSI surveillance.
Data are for 5,572 procedures. Source: Sands et al., 1996.

- Surgeons' questionnaires miss most infections.
- Most infections reported by surgeons are *not* postoperative surgical site infections.
- Patients' questionaires also miss most infections.
- Automated HMO data are much more accurate.

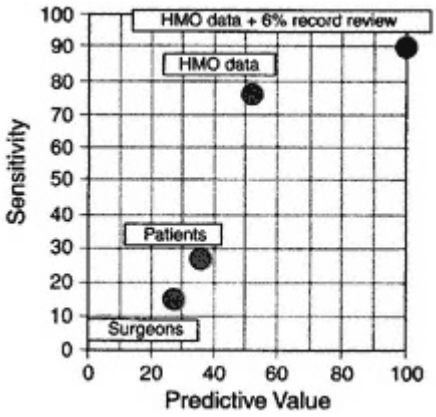

Figure 4-2 Postdischarge SSI surveillance. Source: Sands et al., 1996, 1999.

The goal of such collaboration is to identify SSIs by using automated inpatient and population-based ambulatory-care data, to characterize antibiotic-resistant pathogens, and to relate the rates of infection and antibiotic resistance to the appropriateness of preoperative antibiotic prophylaxis. A secondary goal is to assess and control other types of infection and, to the extent possible, extend this collaborative model to other types of problems. Although this approach was developed in a research-oriented HMO, it should be widely applicable in other settings and useful for a variety of other surveillance problems. Future activities under this agreement may include monitoring of other nosocomial infections, including neonatal infections and implanted central venous catheter infections.

Ultimately, these and similar collaborative efforts should serve as models for surveillance systems that work best when public health agencies and all of the participants involved in the care of individuals work together. These Harvard Pilgrim Health Care studies have proven that HMO data can help solve an existing problem—in this case, the inability to perform effective postdischarge surveillance for nosocomial infections—and can thereby reduce unnecessary efforts by hospital personnel.

LATTER DAY SAINTS HOSPITAL'S SYSTEM

Presented by John P. Burke, M.D.

Chief, Department of Clinical Epidemiology, Latter Day Saints Hospital, and Professor of Medicine, University of Utah School of Medicine

Experiences from the Latter Day Saints (LDS) Hospital in Salt Lake City, Utah, suggest that the best surveillance system operates in real time, providing

immediate responses that guide providers in performing interventions that are based on practice guidelines. The LDS Hospital has a highly advanced information system that maintains each patient's medication records and warns the pharmacy of potential drug interactions or allergic reactions. It also suggests medications for specific patients on the basis of prescription guidelines and current indicators such as white cell count, fever, and results of microbiological cultures and roentgenograms. In the case of emerging infections, the system also alerts the physician to infections caused by multiple-drug-resistant organisms or to a prescription that is at odds with what would normally be prescribed.

The goal of the system is flexible, informed decision making. The system includes bedside monitors that provide monographs on formulary antibiotics, as well as each nursing unit's history of nosocomial infections and the susceptibility patterns of the strains that caused those infections. An outpatient model provides guidance for the treatment of otitis media, pharyngitis, and urinary tract infections based on the cost of antimicrobial agents adjusted for patient-specific factors such as height, weight, and renal function. All of this is designed to make the system easy to use and thus promote its use; physicians, for example, find that it has greatly simplified the task of prescribing antibiotics.

Analysis of practice over the past 11 years at LDS Hospital indicates that the proportion of patients receiving antibiotics has increased from 32 to 54 percent, which may represent LDS Hospital's rising role as the main referral center for a 23-hospital system. However, the number of patients receiving antibiotics does not adequately reflect the antibiotic exposure of this population. Further analysis shows that the number of defined daily doses per 1,000 patient-days has decreased by 40 percent and that the cost of medication declined from $122 to $52 per antibiotic-treated patient over the same period. In addition, the incidence of adverse drug events due to antibiotics has declined by 60 to 70 percent, and there has been little change in the levels of antibiotic resistance. The research question being pursued is whether surveillance and monitoring have affected antibiotic resistance. The hope is that patient-specific use of information will stabilize antibiotic resistance and lead to a more sophisticated type of informed decision making, one that will control costs as well as prevent the emergence or reemergence of antibiotic resistance.

LABORATORY-BASED REPORTING AND MANAGING ENCOUNTER-LEVEL DATA

Presented by Richard Dixon, M.D., FACP

Medical Director, National Independent Practice Association Coalition

If surveillance for emerging and changing infection trends is to be effective, diagnoses must be accurate, reported in a standardized manner, and monitored. Sources of information on infections include voluntary reports of clinical diag

noses by clinicians, reports of laboratory results, and diagnoses recorded in administrative data sets. Diagnoses recorded in administrative data sets include descriptions of diagnoses and procedures performed during individual patient encounters that are usually submitted to obtain payment for the services rendered. However, none of these sources is complete or accurate. Physicians are notoriously lax in reporting even those conditions required by law or regulation. Because administrative data sets primarily involve financial transactions, they commonly fail to capture critical features of illnesses. Fortunately, not every infection needs to be reported; common infections require that only a small but consistent portion of cases be recognized and reported for surveillance to be effective. On the other hand, conditions that occur infrequently require highly efficient capture of diagnoses if changes in their patterns are to be recognized. For each monitored condition, there is a threshold of accuracy and completeness of reporting. Surveillance and monitoring will fail if that threshold is not met.

The efficiency of infectious disease surveillance will likely be affected by the dramatic changes that are occurring in the U.S. health care system. Efforts both to reduce costs and to stay within predetermined budgets are having the greatest effects. Care that was formerly provided within or by hospitals and other institutions is being shifted to ambulatory-care sites where administrative data are of lower quality. Patients with complex cases of disease, who were formerly treated in university and other referral centers, are increasingly being treated in community-based facilities where laboratories are likely to have fewer resources and lower capacities. Visits to highly trained specialists are being discouraged. Empirical treatment based on symptoms is being promoted to reduce the use of costly diagnostic procedures, especially when treatments can be prescribed without precise diagnoses, such as the use of broad-spectrum antimicrobial agents to cover a broad range of potential pathogens.

These changes are often blamed on managed care. It must be recognized, however, that these changes are likely to occur under any model of care delivery in which cost containment is emphasized and that they do not simply reflect the policies of managed care organizations. In fact, many of the gaps in diagnostic information antedated managed care. Since administrative data have mainly been used to reimburse clinicians and hospitals, there has been no incentive to report observations unrelated to reimbursements. In the past decade, hospitals have been forced to document the accuracies of their submitted claims, but the focus has been on the detection of excessive or fraudulent billings, not on the identification of underreported diseases.

Even less attention has been paid to the accuracy or completeness of ambulatory-care data other than to uncover fraud or other inappropriate billing practices. An extensive effort is being conducted in California to improve the completeness, accuracy, and availability of clinical information so that outcomes and accountability can be better assessed. This involves the California Information

Exchange (CALINX) project, a joint effort of California's purchasers (led by the Pacific Business Group on Health), hospitals and provider organizations (led by the National Independent Practice Association Coalition), and health plans (led by the California Association of Health Plans).* As part of CALINX, the Completeness and Accuracy of Managed-Care Administrative Data Sets (CAMAS) project is being conducted. The CAMAS project will assess the accuracy and completeness of the information reported to managed care organizations by physicians under contract to those organizations. It is suspected that only a small portion of important information about clinical encounters is actually ever reported to HMOs, and if those suspicions were true, it would be unrealistic to expect HMOs to provide data that they themselves do not have.

In theory, managed care organizations should place more value on the data used to make diagnoses. A principal tool used to reduce costs is effective management of care and the provision of the right treatment, at the right time, to the right people. Thus, better diagnostic information should reduce the use of expensive treatments or at least permit more focused and, often, less expensive therapy. Moreover, the National Committee for Quality Assurance (NCQA) is placing a greater emphasis on outcomes in making accreditation decisions about managed care organizations and will likely begin to accredit provider organizations. Both of these NCQA initiatives should improve the quality of diagnoses on which surveillance is based. The Health Insurance Portability and Accountability Act of 1996 requires the federal government to set data standards, which will affect both laboratory and clinical data. Some believe, however, that the absence of standards is not the major impediment to obtaining good public health data. Increasing concerns about privacy are an important obstacle. An even greater obstacle may be the absence of a "business case" for reporting surveillance data. For example, to report more complete and accurate diagnostic codes, providers will need improved information systems. They also need to change their patterns of work to improve the amount and precision of information collected and reported. These changes are costly, but providers do not believe that they will be rewarded for their investments in terms of increased revenues, improved efficiency, or a better ability to manage patients.

Effective surveillance will entail more than regulations requiring reporting of recognized infections and more than standards for the ways in which those infections are diagnosed and reported. It will require good data to populate those reports. Better information systems are important, but the greatest need entails substantial changes in provider incentives to work up cases of disease and report on them. At present, those incentives call for doing less; the incentives should reward better diagnoses and reports.

* Additional information about CALINX may be obtained from its web site: www.calinx.org.

LABORATORY-BASED REPORTING ISSUES

Presented by Robert Rubin, M.D.

President and Chief Operating Officer, The Lewin Group

There may be a structural barrier between infectious disease surveillance and managed care organizations. In theory, private-sector laboratories report unusual infections and forward the isolates responsible for those infections to public health officials, who then verify the diagnosis and perform special studies of esoteric or low-volume infections. A study conducted by the Lewin Group, public health laboratories, and Health System Change on behalf of the U.S. Department of Health and Human Services evaluated public health laboratories in light of the changes in the health care system. Survey results from that study counter the commonly held belief that managed care has worsened the infrastructure of public health and microbiology laboratories. Only 43 percent of public health laboratory directors agreed with this widely held opinion, whereas 47 percent thought that managed care has no impact on public health efforts and 10 percent pointed to positive effects from managed care.

Under managed care, however, there is a tendency to treat patients empirically on the basis of symptoms rather than to perform laboratory tests and use the results of those tests as a basis for specific diagnoses. The emphasis on cost-efficiency may also be a disincentive to submission of reports and isolates. In addition, many HMOs have comprehensive contracts with large, national laboratories, with the Laboratory Corporation of America, Quest Diagnostics, and SmithKline Beecham Clinical Laboratories controlling 43 percent of the clinical testing in the United States (Sachs, 1997). Because of the interstate nature of their business, those laboratory personnel may not always be aware of state and local reporting requirements.

Several initiatives are under way to address these issues. The state of Washington's public health laboratory has entered into an agreement with Group Health Cooperative of Puget Sound to create the Clinical Laboratory Advisory Council to improve the laboratory delivery system and to open communications with all stakeholders. Representatives from public and private laboratories work through advisory groups that develop recommendations on a range of laboratory issues, from integration to practice guidelines to licensure. CDC has funded a few inventive pilot projects, including a study of the transmission of laboratory test results between managed care and the state public health laboratory in Washington State.

Public health laboratories, however, have not made the best use of the potential advantages of working with managed care. With limited resources being the obvious deterrent, many public health laboratories view managed care as a potential competitor. In addition, surveillance and monitoring issues, as well as the general topic of emerging infections, are seldom on the table when states seek to contract out services for their Medicaid populations. This may be shortsighted,

because good-quality surveillance and care may reduce long-term costs for all stakeholders. Such efforts at dialogue may facilitate improvements in public health laboratories' attempts to preserve vital elements of their infrastructures.

LEGAL CONCERNS

Presented by René Bowser, J.D.

Fellow, Georgetown University Law Center

Federal and state government responsibility for public health is certainly a necessity but is not a sufficient condition for maximization of public health. Indeed, unilateral actions by governments in fully promoting and protecting the health of the community are limited. For example, governments are not nearly as closely associated with individuals and their health care as managed care organizations are. From this perspective, managed care is better positioned to observe personal choices, obtain information on rates of illness and injury from specific causes, and identify health risks in the community. Furthermore, these organizations generally possess greater expertise in providing cost-effective personal medical services and clinical preventive services than government and are likely to be more flexible in their approaches to solving public health problems. Yet, despite the advantages that managed care organizations bring to public health, few incentives exist for them to provide communitywide public health services.

A deliberative effort should be made to secure managed care's cooperation in expanding public health activities, including surveillance and monitoring. This can be accomplished through well-considered delegations of public health activities, incentives, and regulations. Most local health departments lack the personnel, laboratories, and information systems need to identify and effectively respond to the great variety of health risks facing populations. At the same time, many managed care organizations are developing the capacity to identify clusters of diseases and injuries within the enrolled population and, through investigation, determine their causes. This information is critical for public health policy development and community health assessment. Ideally, surveillance should be a coordinated process in which the health department sets the agenda for surveillance, epidemiological, and statistical studies; contracts with a managed care plan to provide the information; uses the findings to assess health risks; and allocates resources to those events that pose the greatest risks.

Contracting with managed care organizations to identify clusters of diseases in the enrolled population is a desirable strategy. Not only does it identify health risks in the community, but it also provides the managed care plan with information that could serve as the basis for its own prevention strategies to avoid future treatment costs. In addition, managed care can assist in the early detection and control of emerging microbial threats through data collection and analysis. If managed care plans routinely reported the community's health status to offi

cials at public health departments, such disease clusters could be reported before a widespread epidemic occurred. Even with the onset of an epidemic, public health officials can take advantage of managed care's cost-effectiveness by contracting with a health plan for the clinical testing and treatment of large numbers of individuals at risk of particular infections.

There are no insurmountable legal obstacles to these activities. Delegation of public health activities raises a constitutional issue only when government power is exercised by a private entity that deprives a person of life, liberty, or power under the behest of the state. Data collection, analysis, reporting, and specimen testing are constitutionally permissible since no significant liberty or property rights are violated. In contrast, monitoring and prevention activities such as contact tracing, mandatory testing, and compulsory quarantine and isolation are constitutionally suspect when performed by the private sector, and therefore, it is important that public health departments retain these functions.

SUMMARY OF CHALLENGES AND OPPORTUNITIES

Jonathan R. Davis, Ph.D., *Editor*

Disease surveillance and monitoring activities are a cornerstone of public health practice. These activities provide information crucial not only for assessment of the status of public health, monitoring of health trends, and recommendation of priorities but also for evaluation of the effectiveness of public health programs. A partnership between public health surveillance activities and managed care systems has many potential benefits since a primary goal of both is the health of a population. However, as identified in the workshop discussions, several impediments must be overcome before surveillance through managed care can be conducted.

Understanding Professional Roles in Surveillance and Monitoring

Relatively few health care providers fully understand the importance of public health surveillance, the role of the provider as a source of data, and the role of public health departments in responding to infectious diseases. The lack of understanding of the health department's role in surveillance may have originated either from the absence of feedback from public health agencies indicating how data are used or from a lack of availability of the data to the public, providers, or potential users of those data. Workshop participants asserted that managed care systems must provide an opportunity for public health agencies not only to explain their roles in surveillance and response but also to establish partnerships as a way of ensuring bilateral communication on cases of infectious diseases and opportunities for preventing the spread of infectious diseases.

Health care providers need to understand their role as an important source of data in infectious disease control and the role of the health department in responding to an infectious disease. Managed care systems provide an opportunity for public health departments to explain their role in surveillance for infectious diseases and their responses to infectious diseases. Managed care organizations also have the opportunity to establish partnerships with public health agencies to prevent the spread of infectious diseases.

Ensuring Availability of Data

The possibility that fewer diagnostic tests will be performed in managed care systems as a result of cost-reduction requirements could lead to a decrease in the amount of information on emerging infectious diseases needed by public health officials. The trend in managed care toward chronic disease management rather than infectious disease control may hamper surveillance efforts as less value is placed on emerging infections. This concern deserves greater attention and more data are required to assess the impact of managed care on infectious disease control.

Pilot studies involving managed care organizations and the public health system could determine the quality, accuracy, and availability of data on infectious diseases. Partnerships between public health laboratories and managed care organizations could ensure that the necessary testing is completed and not neglected. Standards for a computer-based patient record will ensure the usefulness of patient records for population-based health.

Promoting Sharing of Data

Certain misperceptions and obstacles must be addressed if pilot studies are to go forward. Public health agencies are concerned that some managed care organizations treat patient data in a proprietary way and are thus unwilling to share those data, which may subsequently impede surveillance efforts. Fears about violation of confidentiality can prohibit sharing of electronic medical data, with the potential for hampering surveillance efforts. Data sharing between public health agencies and managed care systems should be encouraged but should also be attentive to protection of patient confidentiality. To accomplish this, managed care organizations need to be reassured that public health surveillance is not a regulatory function but rather a mechanism for monitoring the status of the public's health and identifying opportunities for improving community health status.

Even when sharing of data is accomplished, the incompatibility of computer networks among managed care organizations makes the sharing of information difficult, resulting in a lack of timely, accurate, and complete information on health care encounters. Compatible model systems should be developed so that

managed care systems' computers can effectively and quickly communicate locally as well as nationwide for assessment of disease threats. In addition, collaborative information systems such as population-based integrated programs could survey and monitor nosocomial infections. To avoid duplication of effort and maximize efficiency, a workshop speaker proposed that public health agencies need to work with managed care organizations to ensure that direct reporting is conducted from their laboratory data systems to public health agencies for surveillance purposes.

Tracking Nosocomial Infections

The increasing use of ambulatory-care settings for surgical operations and postoperative care may hinder the ability to adequately track and monitor nosocomial infections because of the decreased disease reporting capabilities of such settings. The lack of reporting ability may constrain the ability to swiftly disseminate information, which is critical, for example, to decrease the incidence of adverse events from antibiotics and, therefore, for surveillance and control efforts.

Collaborative information systems, such as those used by hospitals and HMOs, can provide a means of addressing the problems associated with surveillance and monitoring of nosocomial infections. Integrated population-based programs can address such infections in the context of changes in health care delivery. For example, although all hospitals and HMOs now have information systems that provide better data more efficiently than was previously possible, hospital integrated delivery systems and HMOs have data on the type of care delivered and outcomes at the various locations within their systems, thereby allowing analyses of care across the continuum. A collaborative effort between hospitals and HMOs can therefore help identify and address nosocomial infections. To maximize surveillance and monitoring efforts, however, public health agencies and other health care professionals involved in the care of individuals need to undertake similar collaborative efforts.

In addition to concerns regarding decreased reporting of nosocomial infections because of substantial resource constraints and because ambulatory-care settings are increasingly being used for surgery and care, workshop participants expressed apprehension regarding the timeliness of reporting of such infections as well as antibiotic resistance. Workshop participants indicated that the ability to disseminate information swiftly is critical to surveillance and control efforts. For instance, not only are postoperative surgical wound infections very costly, but they are also the most frequent type of hospital-acquired infections. Besides decreasing the incidence of such infections, a real-time surveillance mechanism may also serve as a means for decreasing the incidence of adverse drug events from the use of antibiotics.

Real-time surveillance capabilities could monitor adverse drug events and nosocomial infections, which would lead to immediate applications and interventions based on clinical practice guidelines. Artificial intelligence techniques can

also be used to detect markers that could then help identify specialist groups that are needed for patient consultations and help prevent hospital-acquired infections.

Already, bedside computers are providing monographs for formulary antibiotics in 1- and 5-year antibiograms that determine the susceptibility patterns of isolates that cause hospital-acquired infections. Computerization of patients' medication histories can provide physicians with the means to check for previous allergies. In addition, the data available online would remain accessible and would prevent pharmacists from accidentally dispensing medications that could result in allergic reactions. Surveillance efforts could be further enhanced by such methods by identifying patients who are infected or colonized with multi-drug-resistant organisms or patients whose antibiotic prescriptions do not coincide with prescriptions that would otherwise be recommended. An approach that emphasizes patient-specific information can stabilize antibiotic resistance patterns and can lead to a more sophisticated type of informed decision making that would be amenable not only to reducing costs but also to preventing the further emergence of antimicrobial resistance.

Accurate Reporting of Encounter-Level Data

Effective surveillance for emerging infections and varying infection trends requires reporting of an accurate diagnosis in a standardized manner and requires that the trends be monitored on a continuous basis. Although fairly common infections require only that a small but consistent portion of cases be recognized and reported for effective surveillance, conditions that occur infrequently require highly efficient capture of a diagnosis so that changes in their patterns can be recognized. Workshop participants expressed concern that sources of information for encounter-level data are typically incomplete or inaccurate. Hospitals as well as ambulatory-care settings have not traditionally focused on the identification of gaps in diagnostic information. Because administrative data have primarily been used to reimburse clinicians and hospitals, there has been no incentive to report observations unrelated to reimbursement; rather, the focus has been on the detection of excessive or fraudulent billings and not on assessment of the accuracy or completeness of data.

Effective surveillance will require more than just the implementation of good regulations for the reporting of recognized infections and the use of standards for the diagnosis of those infections and reporting on those infections. It will also require good encounter-level data for those reports. Although better information systems are important, substantial changes in provider incentives are needed to encourage clinicians to diagnose diseases and actually report those diagnoses. Those incentives are set up to generate the capture and transmission of fewer data. The system needs to be revamped so that new incentives are implemented to reward better diagnoses and reporting. Additionally, efforts need to be initiated to teach individuals how to perform coding correctly so that accurate diagnoses can be reported. By improving the quality of the diagnoses on which

surveillance is based, better diagnostic information should also reduce the use of expensive treatments as well as allow the use of more focused and less expensive therapy. Such care management can maximize the efforts to provide the right treatment to the right people at the right time and lead the way for an effective disease management program.

Overcoming Structural Barriers

Workshop participants expressed concern that there is a fundamental structural barrier between surveillance and practice in managed care. They felt that managed care has negatively affected public health laboratories and the microbiology laboratory infrastructure for a number of reasons, some of which are listed here. First, because managed care focuses on efficiency, there is generally a disincentive for disease reporting and for submission of isolates recovered from patients with emerging diseases. Second, many managed care systems typically have comprehensive contracts with large national laboratories; for instance, three laboratories (Laboratory Corporation of America, Quest Diagnostics, and SmithKline Beecham Clinical Laboratories) control 43 percent of the clinical testing in the United States today. Because of the interstate nature of this type of business, laboratory personnel may not always be aware of the state and local reporting requirements, which may exacerbate the problems of identification and monitoring of diseases. Third, there is a tendency for managed care organizations to provide empirical treatment, which results in reporting problems. Fourth, public-sector laboratory information systems have lagged behind private-sector systems in leveraging potential advantages for managed care. Finally, as people are placed into Medicaid managed care environments, discussions and contract terms generally do not contain provider expectations about surveillance monitoring and their effects on emerging infections.

Workshop participants identified a number of initiatives that addressed the barriers between surveillance and managed care practices. These opportunities are identified below, but they are by no means all inclusive. With integrated patient databases, there is a potential for seamless communication between laboratories, managed care organizations, and public health officials. Such communication could help dissolve the structural barriers between surveillance and practice in managed care organizations and subsequently facilitate the exchange of information.

Additionally, the large national laboratories that are used extensively by managed care systems need to implement better internal guidance policies to help identify which states require the reporting of which infectious diseases. Workshop discussions suggested the need to establish incentives for disease reporting and for isolate submission within managed care organization's policies and regulations; the lack of such incentives jeopardizes surveillance and monitoring efforts. Treatment based on scientific observations rather than on empirical knowledge must also be emphasized as a rule of thumb, especially in ambu

latory-care settings. Furthermore, because public health laboratories have not leveraged the potential advantages of working with managed care organizations, states need to increase the available resources in their respective public health laboratories to maximize the potential advantages for managed care systems. Finally, when states seek to contract out services for their Medicaid populations, such contracts must incorporate terminology that will take into account the need for surveillance and monitoring as well as emerging infection issues.

Summary

There is concern that managed care may have a negative effect on infectious disease surveillance and monitoring. For example, a feature of managed care is to shift patient care from inpatient to outpatient settings, where there are reduced diagnostic and patient management capabilities. Another concern is that managed care relies heavily on empirical diagnoses rather than laboratory data, which may further reduce disease reporting as well as the forwarding of pathogens for detailed analysis and epidemiological investigation. Consequently, public health laboratory practices may have to adjust their role in the overall health care system because fewer tests are available to identify new pathogens and their susceptibilities to therapeutic agents. This is coupled with fact that testing is being conducted primarily by three large commercial laboratories that frequently are not in the same state as the contracting HMO. Thus, it seems unlikely that the next outbreak will be detected through a single HMO, making the outbreak more difficult to track.

Given that the current system of managed care is evolving rapidly and that the level of heterogeneity is increasing among HMOs, there is concern that the extensive patient databases maintained by HMOs may remain uncoordinated and poorly networked. Such an outlook may complicate the present tasks of infectious disease surveillance and monitoring and may make it difficult to plan for future surveillance systems. Models of sophisticated, integrated data systems at the local level and of coordinated action to standardize databases and reporting at the regional level may be extended to other levels and specific diseases. Action at the state level may also be needed to improve the ability of the public health system to handle the information and samples provided by HMOs. There appears to be no legal impediment to privatizing or contracting out at least some of the functions of this public health surveillance system. These issues could be examined in a future workshop to examine the capacities of public health systems to respond to emerging infections.

5

Education and Outreach

Educational and outreach activities are important components for strengthening infectious disease surveillance, research, and prevention. Establishment of principles and guidelines for educational and outreach efforts in the health care industry has become more difficult in the changing health care environment. Health care trade associations can provide a mechanism for the coordination of such activities. The managed care industry must contend with conflicting policies arising from its economic imperatives. Inconsistent and sometimes conflicting communication of educational versus economic benefits can place undue burdens on physicians who are trying to achieve balance between good practices and economic pressures. Infectious disease management under such conditions can be a difficult and challenging task. However, efforts to revamp the system to encourage educational outreach programs not only for health care professionals but also for the general public are under way.

The following presentations discuss the effects of managed care on educational and outreach efforts in addressing emerging and reemerging infectious diseases.

COORDINATING HEALTH PLAN RESEARCH AND EDUCATIONAL EFFORTS

Presented by Richard Platt, M.D.
Director of Research, Harvard Pilgrim Health Care

The American Association of Health Plans (AAHP), a trade association for managed care organizations, is active in developing principles for participating members that conduct research and demonstration projects. AAHP fosters col

laborations between managed care organizations and traditional sponsors of research, such as the National Institutes of Health (NIH), the Agency for Health Care Policy and Research, and the Centers for Disease Control and Prevention (CDC), and facilitates the development of joint research agendas. Because of its large and diverse membership, AAHP can assist in assessing many aspects of the delivery of health care. Additionally, AAHP is responsible for testing the measures developed in the public health sector, such as CDC's immunization record system, and for developing demonstration programs in managed care organizations, such as the Tuberculosis Surveillance Program.

Given its position, AAHP can also pursue other educational and outreach opportunities through the managed care industry. Not only can AAHP encourage the dissemination of methods on behalf of the managed care industry, for example, by facilitating the creation of managed care guidelines, but it can also use data for the purpose of monitoring health care. For instance, AAHP could play an important facilitating role in the development and implementation of standards for dispensing data on antibiotic use. This would be an important development, since information about antibiotic use could be available (in theory) for a large and growing fraction of the U.S. population. In addition, data from managed care organizations could serve as a surveillance tool to monitor and address potential emerging infections.

IMPACTS OF MANAGED CARE SYSTEM'S EDUCATIONAL EFFORTS ON CONTROL OF ANTIBIOTIC USE

Presented by Benjamin Schwartz, M.D.

Deputy Director of the Epidemiology and Surveillance Division, National Immunization Program, Centers for Disease Control and Prevention

The CDC and its National Center for Infectious Diseases recognize that managed care organizations are well positioned to provide infectious disease-related health care education to providers and patients. This is facilitated by the availability of defined panels of providers with whom there is ongoing communication and a defined population of subscribers with whom communication may contribute to satisfaction and retention. Managed care organizations may also reap short-and long-term benefits from the provision of infectious disease-related health care education to providers and patients, including improved quality of care, significant cost savings, improved health care practices, and better member satisfaction. Despite these incentives, however, barriers must be overcome before a managed care organization can effectively implement infectious disease-related health care education activities. First, managed care organizations must judge the significance of a problem and determine the relative costs and benefits of intervention. Often, data that would allow organizations to choose where best to focus their efforts are lacking. Second, managed care or

ganizations may be unable or may be perceived to be unable to provide appropriate educational messages. Providers and patients may feel—in some cases correctly—that interventions are more focused on cost savings than on quality of care. Perhaps most importantly, organizations may retain policies that perpetuate the very behavior that educational initiatives are trying to change. For example, imperatives for clinicians to see more patients per day may conflict with providers' ability and availability to explain the rationale for treatment decisions.

Efforts to decrease the spread of antibiotic resistance through improved antibiotic use practices illustrate the importance of managed care systems in the education of patients. The development and spread of antibiotic resistance were not considered major problems by managed care organizations. Now, however, many such organizations recognize the threat of hospital-acquired resistant pathogens and also realize that this threat is a growing problem among patients with community-acquired infections. Rising concern has resulted from increased rates of resistance and treatment failures, and the medical and public health communities have placed a greater focus on these problems. For example, pneumococci, which are the leading cause of community-acquired meningitis, the second leading cause of bloodstream infections, and the leading cause of pneumonia and otitis media, are increasingly resistant to antibiotics. Currently, in some areas of the United States, more than a third of invasive pneumococcal isolates are resistant to one or more antibiotics. In other instances, some strains are not susceptible to any oral antibiotic, raising the specter that common infections, like ear infections or sinusitis, will require parenteral therapy.

Clinicians who work in managed care settings recognize that a major factor contributing to the spread of antibiotic resistance is the widespread and frequently unnecessary use of antimicrobial agents. Nevertheless, they continue to prescribe them for viral infections, which do not respond to antibiotics. Each year, up to 50 million courses of antibiotics may be prescribed unnecessarily for the treatment of the common cold, acute bronchitis, sore throat not caused by streptococcus, fluid in the middle ear that does not represent infection, and purulent runny nose that has been misdiagnosed as sinusitis. These antibiotic courses contribute nothing to patient care but do select for resistant pneumococci and other pathogens that can then spread or that can later cause more severe or difficult-to-treat infections.

Overall, physicians who work in managed care organizations are aware that they are overprescribing antibiotics. In focus group discussions with these physicians (conducted by CDC without physician knowledge of the sponsoring organization), participants reported that they could decrease antibiotic use in their own practices by 10 to 50 percent without having a negative impact on patient care (Barden et al., 1998). A number of reasons for the overuse of antimicrobial agents have been proposed. Studies indicate that economic factors influence the prescription practices of physicians who work in managed care organizations. For example, some studies suggest that physicians in managed care prescribed more antibiotics and performed fewer laboratory tests for patients with respiratory infections than their fee-for-service colleagues. This may have resulted in

response to pressures to decrease costs (thus, fewer tests) and to increase patient satisfaction (thus, responding to perceived demands for antibiotics) (Hueston et al., 1997). Additionally, physicians who work in managed care are encouraged to increase the number of patients whom they treat on any given day, resulting in decreased time with each patient and subsequently less time to discuss with patients situations in which antibiotics are not useful. Because physicians may receive a bonus for patient satisfaction, they may also prescribe antibiotics for patients who demand them, even when the physician knows that treatment will be ineffective but that patient satisfaction will likely result from the prescription of an antibiotic.

Controlling antibiotic use and resistance will entail effective communication to managed care organizations that judicious antibiotic use is beneficial to them. Physicians must understand that controlled use is feasible even in the context of a busy practice and is consistent with high levels of patient satisfaction. Patients must understand that controlled use will protect them from the harms associated with antibiotic resistance. Targets for educational interventions therefore include managed care administrators, health care providers, and patients. Reducing conflicting messages and providing incentives for good clinical practice will be important to achieving behavioral changes and reducing the rates of antibiotic resistance.

As an example, the principles of judicious antibiotic use for pediatric upper respiratory tract infections were published in the journal *Pediatrics* in January 1998 and provide a basis for educating physicians about optimal diagnostic and management practices. These principles, developed by CDC, the American Academy of Pediatrics (AAP), and the American Academy of Family Physicians, provide guidance to physicians on how to improve diagnostic and management skills to avoid the unnecessary dispensing of antibiotics. Development of these principles and other types of documents alone, however, cannot promote behavioral change. Although managed care organizations may be required to make financial investments, other, more proactive approaches are also necessary to promote changes in behavior. These may include provision of supporting materials, active promotion of desired behaviors through peer education, and provision of feedback to physicians on their own antibiotic use practices.

Besides educating the prescribing physician, CDC recognizes that it is important to educate the public. In an effort to communicate ways to combat antimicrobial resistance, CDC, in collaboration with AAP and the American Society for Microbiology, has produced a pamphlet entitled Your Child and Antibiotics. This pamphlet, published in both English and Spanish, relays two principal messages to parents: that antibiotics are not needed for all types of infections, and, when used unnecessarily, antibiotics can be harmful, More than a million copies of this pamphlet have been given to patients, and many copies have been distributed by managed care organizations.

In addition to providing educational materials and information to facilitate provider-patient communication, managed care organizations can take other actions to increase the impacts of judicious antibiotic use programs. For exam

ple, they have a responsibility to provide adequate time as well as incentives for physicians to participate in educational activities. Some managed care organizations have developed practice guidelines based on published principles. Other professional organizations are tracking the rates of antibiotic use among physicians and are directing their interventions toward those providers who prescribe the most antibiotics. For example, Kaiser Permanente provides economic incentives by reimbursing patients for medications judiciously prescribed in an effort to reduce the level of prescription medication use. In Michigan and Tennessee, the driving force for educational initiatives has primarily come from health plan purchasers. In Colorado, a statewide coalition that addresses antibiotic resistance was established after the state legislature considered a bill that would have punished physicians for antibiotic overuse. Various approaches to intervention can be effective in changing practices. Because managed care organizations have an incentive to reduce inappropriate antibiotic use, as well as halt the spread and mitigate the impact of antimicrobial resistance, they should be encouraged to address this problem in ways that fit their capabilities. Considering the range of policies that affect antibiotic use practices, changing those that act as disincentives to judicious antibiotic use may also be an important component of an intervention (IOM, 1998).

EDUCATION AND OUTREACH PERSPECTIVES OF THE NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Presented by Karl Western, M.D.

Assistant Director for International Research, National Institute of Allergy and Infectious Diseases, National Institutes of Health

Unlike health maintenance organizations and managed care organizations, the National Institute of Allergy and Infectious Diseases (NIAID) has focused on promoting the basic scientific underpinnings of clinical research instead of direct educational and outreach activities to the medical community. In response to public concern, NIAID has encouraged the development of strengthened capabilities in research on emerging and reemerging infectious diseases. It has primarily exercised such efforts by providing targeted administrative supplements to extramural research awards and by encouraging investigators and centers to submit Emerging and Reemerging Infectious Diseases applications in response to program announcements or requests for applications. These efforts specifically call for networking of the scientific community and have resulted in three new Emerging Virus Centers and four Hepatitis C Research Centers, which will form a research network in those areas.

Additionally, emerging infections were a prominent feature in NIAID's International Collaboration in Infectious Disease Research. Through these and other initiatives, NIAID hopes to prepare NIH-supported groups to cooperate

with local physicians and public health agencies in dealing with new or unforeseen problems. It is also anticipated that future increases in NIH's budget will provide additional funding for research on emerging infections.

MANAGED CARE SYSTEMS AND EMERGING INFECTIONS: EDUCATION AND OUTREACH

Presented by William B. Baine, M.D.

Senior Medical Advisor, Center for Outcomes and Effectiveness Research, Agency for Health Care Policy and Research

Although in everyday parlance "costs" may be conceived of in terms of monetary payments, economic theory considers the costs of medical care to be the resources—physicians and nursing time, chemical and biological products, supplies and equipment, vehicles, and buildings—that are used for patient care instead of other purposes (Garber et al., 1996). Managed care has reduced the level of spending for medical care, but reduced spending is not synonymous with reductions in the underlying cost of that care (Chernew et al., 1997). It is left to the provider to cope with decreased payments for services (Kuttner, 1998). Essentially, providers achieve this by increasing efficiency (e.g., reducing costs themselves) or by reducing care per capita (e.g., abbreviated patient care encounters and the use of fewer diagnostic tests and referrals). In addition, providers attempt to minimize uncompensated care and forego the treatment of patients who have no coverage (insurance) for medical care. They also try to reassign the professional roles of physicians, nurses, and medical technicians, resulting in a broadening of responsibilities, cross-coverage, and decreased specialization. Medical practices and hospitals may also gravitate toward consolidation or even merge to achieve greater economies of scale and to enhance their advantage in contracting with managed care organizations.

These activities pose educational barriers to physicians and other clinical staff, which in turn could hinder the ability to respond to issues dealing with emerging infections. The clinician may have less exposure to patients with infectious diseases, which are more prevalent in uncovered (uninsured) populations; less interaction with subspecialists; less continuity of care and fewer follow-up visits; and less autonomy because of managed care protocols. In addition, interactions between the primary care physician and consultants, as well as continuing education, may be reduced because of the pressures of increased patient volumes. Managed care systems may also foster an atmosphere in which physicians have less time to educate trainees or patients as emphasis is placed on reducing the number of patient encounters and increasing the amount of time spent on documentation. Essentially, the outcome may result in increased dependence on protocols and transforming the functional role of the physician in terms of how much autonomy and judgment are practiced in patient care.

Economic challenges in managed care settings are also prevalent in educational outreach efforts. There is a potential risk of biased enrollment, with capitated plans preferentially seeking low-risk clients who require less care. There is also the risk of disincentives in which capitated plans may limit costly services, for example, to patients with human immunodeficiency virus infection.

These scenarios could present dire problems in managed care. Certain drawbacks, however, might mitigate the restrictions imposed by managed care organizations. These include expansion of insurance coverage as well as provision of educational subsidies to physicians who take the time to educate their patients. These methods, however, cost money and may therefore not be attractive alternatives to some. Another concept is risk adjustment, in which reimbursement is tailored to the degree of difficulty involved in patient care. Current models, however, are still in rudimentary stages. In addition, these risk adjustment models also tend to resemble fee-for-service techniques, which managed care systems are attempting to avoid because of the economic implications resuiting from this reimbursement method. Other possibilities include self-referral to a subspecialist, application of outcomes research to guidelines themselves in an effort to ensure that compliance with guidelines does not displace attention to other clinical problems, and lastly, the controversial approach of forming provider-based managed care organizations.

SUMMARY OF CHALLENGES AND OPPORTUNITIES

Jonathan R. Davis, Ph.D., *Editor*

Managed care systems are in a stage of a rapid transition. Assistance with the delivery of health care and building strength in support of educational efforts is necessary to effectively deal with the myriad issues associated with the coordination of health plan research and educational and outreach efforts.

Widespread, unnecessary use of antibiotic agents is a major contributing factor in the spread of antibiotic resistance. Economic factors largely influence the prescription practices of managed care physicians, and patients do not fully understand when it is appropriate to take antibiotics. Emphasis on controlling costs in managed care can lead to incorrect diagnoses, underreporting of some infectious disease conditions, and inadequate follow-up care. The essential role that physicians can play in accurately reporting diseases is generally not adequately communicated. Managed care organizations are increasingly able to be accountable for the appropriateness and quality of clinical care. Not only do they have the infrastructure to improve infectious disease surveillance through the systematic collection of encounter-level data and the standardization of computerized systems for the monitoring of data on health care, but they are also equipped to educate providers on the importance of their role in accurate disease reporting. Not only does this accuracy improve the quality of clinical care, but it also helps control the spread of diseases by providing the best available treatment.

Promote Professional Education Efforts

Professional education efforts are needed to control this trend of rising rates of antibiotic resistance among microorganisms. Working with the managed care industry, organizations and associations such as AAHP can foster collaborations between managed care organizations and sponsors of research (e.g., CDC and NIH) to formulate priorities, encourage multipurpose dissemination of methods for the support of educational efforts, and better use data for the monitoring of health care. For instance, by playing a facilitating role in the development and implementation of standards for the dissemination of antibiotic use data, professional organizations could serve an instrumental role in ensuring that information about antibiotic use is readily available, In turn, this could be instrumental in serving as a surveillance tool to monitor and address potential emerging infectious diseases.

Encourage Judicious Antibiotic Use

More judicious antibiotic use behavior should be encouraged, and patients need to be better informed about appropriate antibiotic use. To facilitate this, managed care organizations must resolve the conflicting messages and the sometimes competing incentives of good clinical practice and cost control. Targets for educational interventions include managed care administrators, providers, and patients. Although the Forum cannot make recommendations, Forum members acknowledged that the following suggestions identified during the workshop discussion are key factors in controlling the indiscriminant use of antibiotics:

- Communicate to managed care organizations that judicious antibiotic use is beneficial to managed care industries.
- Encourage managed care organizations to provide adequate time and incentives for physicians to participate in educational activities.
- Convey to managed care physicians that judicious antibiotic use is feasible in the context of a busy practice and is consistent with a high degree of patient satisfaction when patients are adequately advised on proper antibiotic use.
- Provide guidance to physicians on ways to improve their diagnostic and management skills to avoid unnecessary dispensation of antibiotics. These principles have already been developed and are readily available to educate physicians about such practices.
- Use professional organizations to identify physicians who are prescribing the most antibiotics, and then focus interventions on those providers.
- Educate patients that antibiotics are not needed for all types of infections, and that when they are used unnecessarily in some circumstances, antibiotics may even do more harm than good to the individual patient. Managed care organizations could distribute such educational materials to all of their patients, or

such material could be provided at physicians' offices, which would also help facilitate provider-patient communication.

Invest in Educational Programs

Although the strengths of the educational programs of certain managed care organizations have been significantly enhanced, most such organizations have limited or suboptimum educational and outreach efforts in terms of emerging infections. Managed care organizations have the responsibility to educate providers regarding their critical role in accurate infectious disease reporting. Managed care organizations should invest in educational efforts on emerging infections and initiate partnerships with buyers to identify key educational program opportunities and increase the level of awareness of emerging infections beyond antimicrobial resistance.

Summary

The workshop participants recognized that managed care organizations could have positive impacts on education efforts. The guidelines developed by AAHP for the participation of member plans in research and demonstration projects is one example of the way in which coordinated efforts to develop and implement guidelines have been successful. In addition, several plans have collaborated in their efforts to identify problems and change physician behavior, for example, in the prescribing of antibiotics. The access to large numbers of physicians, patients, and families through managed care could be useful in other education and outreach efforts. However, not all managed care organizations have the same capability to participate in educational and outreach programs. Continued action and investment by NIH and CDC will be important to broadening the base of cooperation.

In contrast, several characteristics of managed care could have a negative effect on education and outreach efforts. Primarily, infectious diseases are often a health concern among the populations that are not covered by managed care organizations. Biased enrollment into managed care organizations often results in managed care physicians having less exposure to emerging infections, and the nature of their practice gives them fewer opportunities for consultation with specialists and reduced incentives for continuing education in the current diagnosis and therapy of infections diseases.

Panelists at the workshop felt that there was a need for increased investment in education and outreach for all health professionals in the area of emerging infections and the closely related area of antimicrobial resistance. NIH, CDC, and the pharmaceutical industry are pursuing multidisciplinary approaches to educating medical and public health professionals, but more programs are needed. Major purchasers of managed care also have an important role to play in

promoting the values of education and outreach, including free (protected) time or subsidies for continuing education and bonuses for judicious antibiotic prescription behavior. Other potential tools recognized include differential copaymerits, expanded self-referral, and assessments of collateral effects.

6

Drug Formularies

The efficacy of drug formularies in health care systems is in question. Formularies were present in hospitals before managed care became prevalent, and were intended to help reduce prescription drug costs and promote proper prescribing. In practice, however, costs have not been reduced and antibiotic resistance has risen. The following presentation summaries examine how managed care systems govern formulary management decisions, how pharmaceutical companies interact with the managed care system, and how formulary decisions could effectively address, in part, the problem of antibiotic resistance in emerging infections with respect to discovery and development of new agents.

REGULATORY ISSUES

Presented by Laurie Burke, R.Ph., M.P.H.

Chief of Managed Care Outcome and Labeling, Drug Marketing, Advertising, and Communication Division, Center for Drug Evaluation and Research, U.S. Food and Drug Administration

An important component of managed care systems in combating infectious diseases is the implementation of good regulatory policies, which is the responsibility of the U.S. Food and Drug Administration (FDA). Among FDA concerns is the proper dissemination of drug product information to health care practitioners and individuals responsible for making health care decisions. Another of its primary missions is to ensure that safe and effective drugs are available to the public as soon as possible. Because of its regulatory responsibility, FDA is concerned about how the changing health care environment will affect

society's health care needs. This is a major concern for FDA given that many changes are taking place in health care, such as a move toward managed care systems, a shift to more restrictive drug formularies, a move to outcomes-based research, increased availability of information, a restructuring of the pharmaceutical industry, and the rise of drug-resistant pathogens.

In an effort to address the challenges posed by the changing health care environment, FDA has implemented several initiatives. For instance, FDA is exploring how it can provide information and expertise useful for the evaluation of drug formularies and drug benefits programs. It is collaborating with other agencies, such as the Health Care Financing Administration (HCFA) and the Agency for Health Care Policy and Research, to sponsor a workshop intended to assist managed care organizations and HCFA with evaluating drug benefit designs. It is also implementing sections of the FDA Modernization Act of 1997 that deal both with the efficient and swift dissemination of information on new uses (offlabel information) of drugs and devices (Section 401) and with the dissemination of economic information in drug promotion (Section 114).

In addition, FDA recently published draft guidance on medical product promotion in the managed care environment. The agency acted because of evidence that suggested that medical product manufacturers could avoid regulatory oversight of promotional activities by allowing pharmacy benefit management companies and other health care organizations to disseminate volatile information on their behalf. Although not a legally binding document, the guidance represents FDA's expectations with respect to existing laws. Another draft guidance recently published by FDA has focused on policies related to advertising directly to consumers, which has resulted in a sharp increase in advertising on television. It is hoped that continued revision of draft guidance and policies will continue to have positive effects on the changing health care environment.

RELATIONSHIP BETWEEN MANAGED CARE FORMULARIES AND TREATMENT OUTCOMES

Presented by Susan Horn, Ph.D.

Senior Scientist, Institute for Clinical Outcomes Research, Vice President of Research for International Severity Information Systems, and Professor of Medical Informatics, University of Utah School of Medicine

Although formulary management is an important component in health care practice, its role in cost control and its effect on quality of care have not been well understood. In an effort to analyze the relationship between managed care formularies and treatment outcomes, the Institute for Clinical Outcomes Research (ICOR) conducted a 12-month study that analyzed the consequences of the cost-containment practices of health maintenance organizations (HMOs) and resulting outcomes. Six HMOs participated in a program that studied almost

13,000 patients with five different diseases: arthritis, asthma, ulcers, hypertension, and otitis media. The findings, published in the *American Journal of Managed Care* in March 1996, revealed that during a 12-month period, patients with these conditions had more than 99,000 office visits, incurred almost 500 emergency department visits and more than 1,000 hospitalizations, and used more than 240,000 different prescriptions (Horn et al., 1996). The 12-month study also examined practical cost-containment practices believed to have no negative repercussions on the quality of health care. These included greater control of second-opinion requirements, increased rigidity of gatekeepers and case managers, implementation of drug and physician office visit copayment levels, greater use of generic drugs, and greater limitation on formularies (defined as the percentage of FDA-approved drugs for a specific condition included in a provider's formulary and not requiring physician approval before generic prescription drugs are dispensed).

The ICOR study also controlled for patient variables to determine rates of health care utilization and treatment outcomes. The study confirmed that severely and acutely ill patients tend to consume more medical services. Findings also showed that visits to many different health care providers over the course of a year are associated with increased rates of utilization of health care services, along with increased rates of drug use, hospitalizations, and emergency hospital visits. After controlling for severity of illness and other confounding variables, the study found that for every condition (except otitis media), increased formulary restrictions were associated with increased numbers of physician office visits, emergency department visits, hospitalizations, and prescriptions and an increased cost of prescriptions over a 12-month period.

The methods used in the ICOR study to measure severity of illness include patient factors and their conditions, as well as the patient's physiologic symptoms and psychosocial characteristics. By controlling for differences in severity of illness among patients, data can be analyzed to determine which management strategies, interventions, and medications are most appropriate to provide better treatment outcomes. These methods are being implemented in many places—managed care settings, hospitals, long-term-care facilities, and ambulatory-care settings—in an effort to determine how to improve outcomes on the basis of patients' needs. This methodology also encourages health care systems to practice beyond their standard operating procedures and allows patient conditions to be identified more readily. The traditional method of using diagnostic codes, on the other hand, provides only a vague description of symptoms. If managed care systems use a more accurate picture of a patient's condition, physicians in these settings can become more knowledgeable about a patient's ailment and, therefore, can be better prepared to treat the disease.

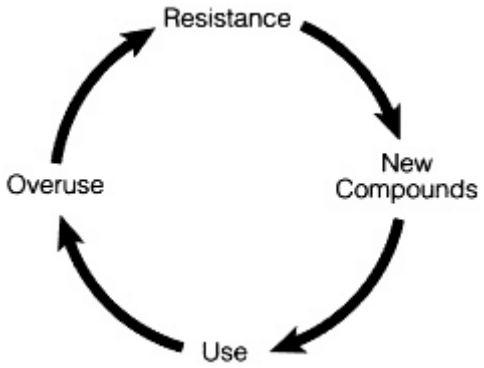

Figure 6-1 Drawbacks of the antibiotic era: the accelerating cycle of antibiotic resistance. Source: Modified from the work produced by John McGowan, Professor, Rollins School of Public Health, Emory University, Atlanta, Georgia.

BACTERIAL RESISTANCE, THE ANTIBIOTIC FORMULARY, AND OTHER MANAGEMENT STRATEGIES

Presented by Jerome J. Schentag, Pharm. D.

Professor of Pharmacy, State University of New York at Buffalo and Director, Clinical Pharmacokinetics Laboratory, Millard Fillmore Health System

It has become difficult to target the causes of antibiotic resistance in the current health care environment. There is reason for concern because the cycle of antibiotic resistance is not only complex but it also seems to be intensifying (Figure 6-1).

Several principal causes of endemic antimicrobial resistance have been proposed. Resistance patterns are believed to be the consequence of the many bacterial genetic pressures and antibiotics that humans have introduced into the environment. Subsequently, the importance of antibiotic selective pressure is increasingly a concern. The organisms that infect patients may develop resistance on the basis of the dose of the prescribed drug relative to the organism's susceptibility, a problem generally overlooked and understudied. In one study, researchers analyzing the relationship between dose and resistance for methicillin-resistant *Staphylococcus aureus* (MRSA), penicillin-resistant *Streptococcus pneumoniae*, and vancomycin-resistant *Enterococcus faecium* (VREF) in a large population of the Millard Fillmore Health System in Buffalo, New York, found that the manifestations of these infections resulted in an increasing incidence of serious infections. The use of suboptimal doses produced resistance in organisms from 93 percent of patients, whereas the use of optimal doses produced resistance in organisms from only 8 percent of patients.

Through extensive epidemiological and time course studies, researchers determined the endemic microbial resistance pattern in the Millard Fillmore Health System study. The linkage between these resistance patterns was exposure to an antibiotic at a dosage that was insufficient to exceed the minimum inhibitory concentration (MIC; or the lowest concentration of antibiotic to which an organism is susceptible) for the target organism for at least 80 percent of the dosing interval. For *S. pneumoniae*, antibiotic selective pressure was linked to the community use of oral cephalosporins, such as cefaclor. Findings also indicated that MRSA was linked to the use of cefazolin, whereas VREF was linked to the use of cephalosporins followed by the use of oral vancomycin. Researchers determined that this resistance pattern began in the early stages of hospitalization when at-risk patients received multiple doses of cephalosporins and other antibiotics. In addition, it was determined that the majority of these organisms originated within the infected patients and were not a result of cross transmission (Schentag et al., 1998).

In another study, patients with serious infections like nosocomial pneumonia required antibiotic therapy. Research demonstrated that the minimum effective antimicrobial dose consisted of an area under the inhibitory concentration titer (AUIC; an average level in serum over 24 hours in relation to the MIC) of 125. However, there was considerable variability in the actual AUICs for patients when antibiotics were given at the recommended dosages. When more than one antibiotic was used to treat a condition, higher doses of one drug were shown to reduce susceptibility to the other drug being used, as was the case with piperacillin and ceftazidime (Figure 6-2).

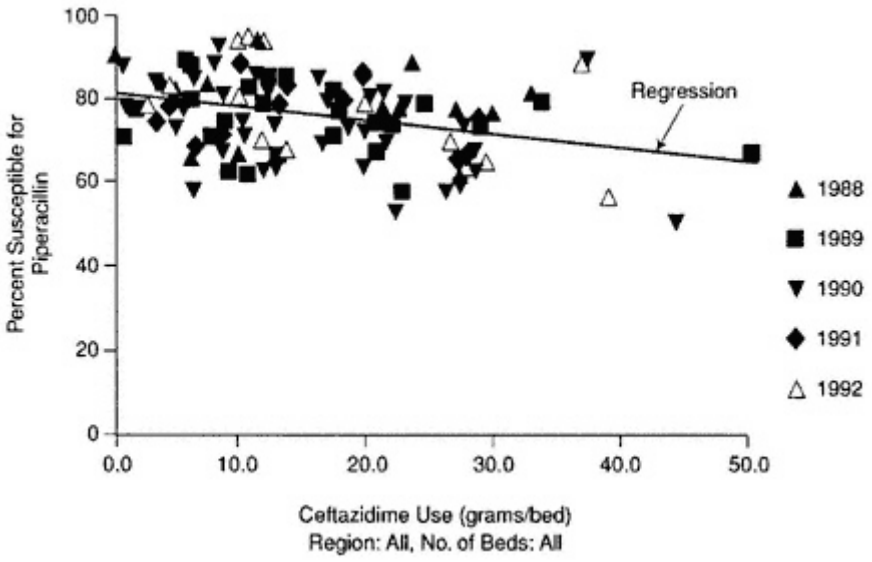

Figure 6-2
Percentage of Enterobacter cloacae isolates susceptible by antibiotic co-use.
Source: Resistance Web, available at http://resistanceweb.mfhs.edu.

Microbial resistance has also been exacerbated by the use of broadspectrum antibiotic therapy. When hospitals adopted formularies in the mid-1980s to control costs, antibiotic resistance among isolates from patients surged dramatically (Rifenburg et al., 1996). The resulting monopolistic use of antibiotics has favored situations in which the extensive use of certain antibiotics for the treatment of a broad array of conditions has created a situation favorable to the emergence of resistant bacterial strains (Schentag et al., 1998). The current epidemic of resistant gram-positive strains, for example, can be traced back to the initiation of the formulary system in hospitals. Because infection control measures are not designed to address either the endogenous production of a pool of resistant organisms or the increase in the inoculum arising from the use of broad-spectrum suppressive antibiotic therapy, it is critical that antibiotic selective pressure be managed if there is to be any hope of successfully suppressing the endemic resistance patterns.

Several management strategies have already been implemented to Counter some of the less desirable effects of formularies as well as microbial resistance patterns. Emphasis on dosing so that concentrations in serum exceed the MIC, for instance, is an important component of the antibiotic use management strategy. This technique proposes that the concentration in serum determined from the AUIC be greater than 125, or that the concentration in serum be greater than the MIC for 80 percent of isolates tested. When the dose does not exceed this level, the probability of resistance has been shown to increase dramatically. Additional antiresistance strategies have included cycling of both the prophylactic antibiotics and the antibiotics used for treatment. Switching of medications during the course of therapy, such as a change from intravenous cephalosporin combination regimens to oral ciprofloxacin after the third day of treatment, has shown promising results as an antiresistance strategy. By exposing the patient to a variety of drugs, it becomes more difficult for bacteria to develop resistance. In addition, this practice has also been shown to be cost-effective (Paladino et al., 1991).

As stated earlier, cost reductions have been a major focus in the health care industry. Hospitals have implemented several administrative changes to realize greater cost savings. These have included shifting to managed care options, capitation, and HMOs and terminating private practice and fee-for-service systems. During the mid-1990s, benchmarking techniques were used by hospitals to locate institutions that successfully controlled their expenditures on antibiotics. Between 1993 and 1996, a benchmarking survey of more than 140 institutions nationwide and in Canada revealed that hospitals with average numbers of beds (between 200 and 400 beds) witnessed an increase in total antibiotic expenditure of over $300 (current dollars) per occupied bed (OB). This represents a 4 to 5 percent annual increase in antibiotic expenditures per OB. Only 9 percent of all the institutions surveyed experienced significant decreases (more than $500 per OB) in total antibiotic expenditures, although changes in the antibiotics included in the formulary had been made in all of these institutions to try to decrease antibiotic costs (Rifenburg et al., 1996).

Although adoption of formularies has influenced the increase in the rates of antibiotic resistance in hospitals, there is no evidence that embracing this practice has produced significant cost savings, a primary objective of formulary implementation. In fact, total antibiotic expenditures have experienced little fluctuation, despite replacement of the drugs included in the formulary, because alterations in the drugs in a formulary have resulted in cost shifting between categories rather than an overall decrease in costs. An attempt to restrict the use of one particular type of antibiotic generally increases the rate of use of other, more expensive antibiotics or less expensive antibiotics used in multiple combinations. The resulting net effect of these changes has led to an increase in total antibiotic expenditures. The antibiotic formulary system appears to be floundering; it is controlling neither costs nor resistance. On the contrary, this system seems to be making both situations worse (Rifenburg et al., 1996).

In addition to tracking costs, benchmarking studies can be used to analyze the susceptibility patterns of indicator organisms and the antibiotic regimens prescribed to combat these pathogens. One particular study conducted by the State University of New York (SUNY) at Buffalo specifically looked for the resistance and antibiotic expenditure patterns that developed as a result of antibiotic use. The targeted combination of antibiotics and indicator organisms included the percentages of ceftazidime-resistant *Enterobacter cloacae*, piperacillin-and penicillin-(all penicillins) resistant *Escherichia coli*, fluoroquinoloneresistant *Pseudomonas aeruginosa*, vancomycin (intravenous and oral)-resistant *Enterococcus faecium*, and methicillin-and cephalosporin-resistant *Staphylococcus aureus* (Ballow and Schentag, 1992).

Rapid communication of medical information is a critical component in the management of antimicrobial resistance. The SUNY study compiled antibiotic resistance profiles for a large selection of indicator organisms. By making these data available on the Internet (http://resistanceweb.mfhs.edu), other institutions were able to quickly access information that could assist them with the development of management strategies that combat antibiotic resistance. Sharing of other types of information is also critical to becoming better prepared to address antimicrobial resistance. Again, the Internet has become an excellent tool to relay this information. Through this mechanism, hospitals can report critical health care information, such as antimicrobial management practices, antibiotic expenditures, antibiograms and other resistance trends, as well as overall expenditures. In addition, because the Internet is interactive, hospitals and pharmacies can enter their own data and track antibiotic use versus resistance in their own institutions.

Besides using the Internet, medical researchers have developed a computer software to help track resistance to antimicrobial agents. This software produces an integrated medical record obtained from patient pharmacy orders and admission history, laboratory results, and financial information. The system, manipulated in a prospective manner for the adoption of patient management strategies, can be useful in identifying when an intervention is necessary (Figure 6-3). Specifically, this can be accomplished by using the indices to identify

patients who are at high risk of therapeutic failure or who are infected with isolates that will acquire resistance in the early stages of therapy before remedial treatment fails.

For example, some studies demonstrated that calculations of the AUIC could be used to target prospective regimens by improving the chances of curing nosocomial pneumonia and other serious infections. An effective method has consisted of organizing a clinical intervention team in which antimicrobial regimens are optimized during the early stages of therapy to lower the chances of costly events, such as acquired bacterial resistance. Besides identifying when an intervention is needed, preliminary data indicate that (3-day) interventions have helped control antibiotic costs (Table 6-1). In essence, this iterative computerized system may become an attractive solution for implementation by managed care organizations; the antibiotic cost savings realized from interventions may cover most expenses associated with the adoption of new strategies.

Antibiotic resistance, especially endemic resistance, is firmly established in today's society. Current practices of antibiotic use have greatly contributed to this problem. Dispensation of new antibiotics alone will not counter antimicrobial resistance; thus, pharmaceutical companies cannot solely be responsible for effectively resolving this problem. A crucial step will involve changing the ways in which hospitals conduct business, such as by using the combined strategies of infection control and antibiotic management. Both of these measures will be critical if societies want to avoid a return to the conditions present in the pre-antibiotic era. [Editor's Note: For additional information on antimicrobial resistance, see the previous workshop report by the Institute of Medicihe's Forum on Emerging Infections: *Antimicrobial Resistance: Issues and Options*. (IOM, 1998).]

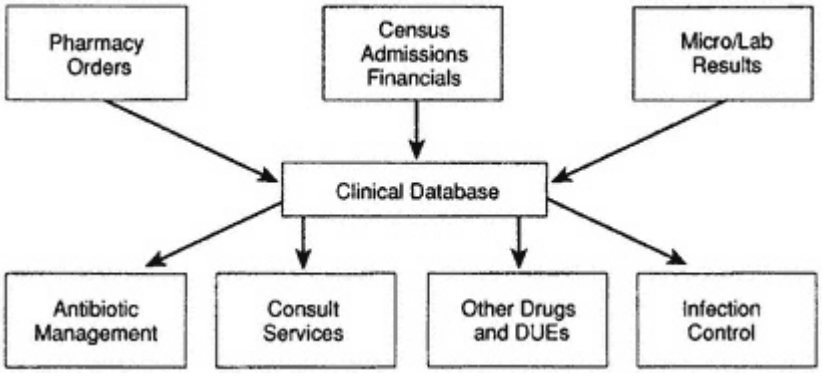

Figure 6-3 Computer-assisted outcomes management. Note: DUEs = drug usage evaluations. Source: Schentag et al., 1996.

TABLE 6-1 Summary of Cost Analysis for Two Treatment Groups, Including Drug and Ancillary Expenses

	Average Cost in Dollars (range)	
Intervention	Intravenous Treatment Group	Ciprofloxacin Group
Days 1–3 (per day)	61 (10–138)	62 (7–165)
Day 4+ (per day)	46* (6–170)	8 (6–40)
Total per patient	646	353
Savings per patient		293

* Does not include the costs of treatment continuation with oral antibiotics (e.g., dicloxacillin, cephalexin, co-trimoxazole). Inclusion of these costs increases the total cost but reduces the average cost per day to $36.
SOURCE: Paladino et al., 1991.

ECONOMICS OF RESTRICTIONS ON PHARMACEUTICALS

Presented by Douglas L. Cocks, Ph.D.

Senior Research Scientist for Health Economics, Health Services and Policy Research, Eli Lilly and Company

Historically, most formularies were established as a mechanism for reducing costs by limiting access to certain pharmaceuticals. Results from 30 studies that analyzed the effects of formulary restrictions indicated otherwise, especially when overall costs were considered (Figure 6-4).

It is important to acknowledge, however, that this investigation was not a true meta-analysis. These 30 studies not only varied considerably in quality but also involved many different health care settings and a wide range of providers and payers, including hospitals, managed care organizations, Medicaid, and nursing homes.* Although the findings suggest that formularies can control drug costs in some cases, these results further indicated that use of formularies was associated with increases in the costs of other health care services as well as overall costs. Nevertheless, all of these studies were deficient in one major area: none analyzed the effects of formulary restrictions on the health outcomes of patients. Research needs to concentrate on this area.

* From an economic perspective, Medicaid is a provider because it pays for the health care of beneficiaries. Also, as a combined federal and state program, Medicaid also determines the components of care that will be provided on a state-by-state basis. While the federal government mandates certain basic requirements, the states can expand these as they deem necessary for their constituents.

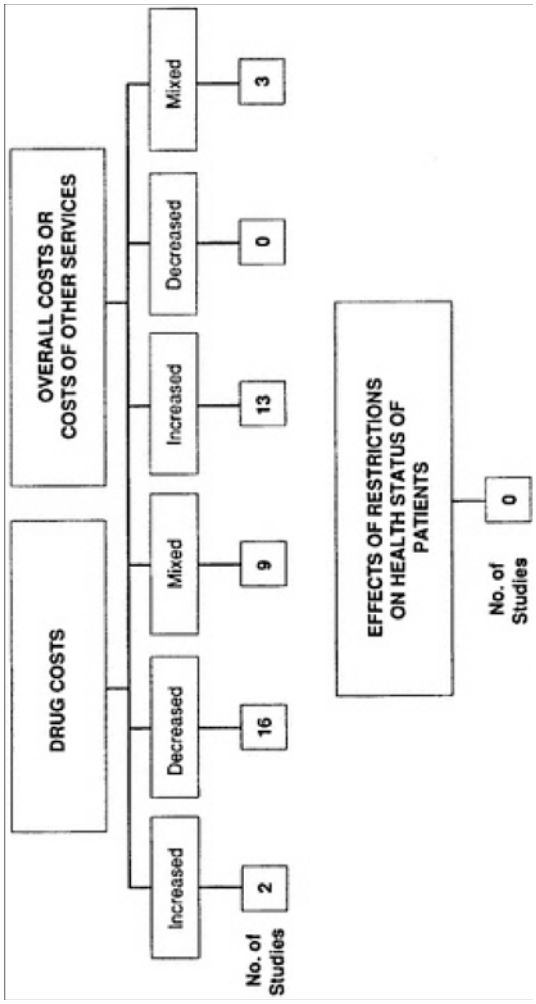

Figure 6-4 Pharmaceutical access restrictions and costs results from 30 studies. Source: Levy and Cocks. 1996.

SUMMARY OF CHALLENGES AND OPPORTUNITIES

Jonathan R. Davis, Ph.D., *Editor*

The changing health care environment has produced more restrictive drug formularies, a development originally intended to help reduce prescription drug costs while still maintaining quality health care. Some data suggest that these goals have not materialized and that formulary policies concerning antibiotics may be contributing to the rise in the rates of antibiotic resistance. The original goals of formularies need to be reevaluated. Although further studies are needed to address the increasing costs associated with formularies, some cost-containment practices may be possible without imposing negative repercussions on the quality of health care. These include greater control of second-opinion requirements, increased rigidity of gatekeepers and case managers, implementation of drug and physician office visit copayment levels, greater use of generic drugs, and greater limitations on formularies.

Ensuring Availability of Current Information on New Drugs

The Forum members wanted to highlight several initiatives that were discussed at the workshop and that could be implemented to adequately address the changing health care environment. As the regulatory agency of the government, FDA ensures that proper drug development information is disseminated to health care practitioners and individuals responsible for health care decision making and that safe and effective drugs are available to the public in the least amount of time. FDA can thus continue to administer several initiatives to try to make sure that there is a positive transition to a new health care environment. Not only can it provide information and expertise useful for the evaluation of drug formularies and drugs benefits programs, but it can also collaborate with other agencies in sponsoring workshops specifically intended to assist managed care organizations and other health care organizations with evaluating the designs of drug benefits programs. In addition, FDA is uniquely positioned to implement health care policies in an effort to efficiently and swiftly disseminate information on new uses of drugs and medical devices, as well as provide guidance on medical product promotion in the managed care environment and guidance on broadcast advertising policies. A continued revision of guidance and policy is likely to sustain the positive effect that FDA has on health care activities in the changing health care environment.

Managing Antibiotic Selective Pressure

Microbial resistance is exacerbated by the use of broad-spectrum antibiotic therapy, a practice often encouraged by drug formularies. The extensive use of

certain antibiotics for the treatment of a broad spectrum of medical conditions has created a situation favorable to a surge in the number of resistant strains. Furthermore, restricting the use of a particular antibiotic generally results in two outcomes: (1) increased use of other, more expensive antibiotics or (2) increased use of less expensive antibiotics in combinations. The net effect is an increase in total expenditures for antibiotics.

Because it is unlikely that pharmaceutical companies will discover and develop very narrow spectrum agents in the foreseeable future (since this activity is not economically feasible for them), it will become critically important to develop and implement strategies so that antibiotic selective pressure is effectively managed to suppress the endemic resistance patterns.

Management strategies can be implemented or continued to be enforced to counter some of the less desirable effects of formularies as well as microbial resistance patterns. Important antiresistance strategies include an emphasis on dosing on the basis of the concentrations achievable in the serum to decrease the probability of resistance and cycling of both prophylactic antibiotics and those being used in the treatment of a patient's condition. In addition, studies presented at the workshop suggested that switching of medications during the course of therapy, besides being cost-effective, has been shown to be a promising strategy for fighting infections. By using this technique, by which patients are exposed to a variety of drugs, it becomes more difficult for bacteria to develop resistance. Although workshop participants outlined several strategies, they suggested that additional research be conducted to avoid public health risks from managed care formulary decisions.

Need for New Management Strategies for Cost Reduction

Databases are needed to help determine which management strategies, interventions, and medications are most appropriate for providing better treatment outcomes on the basis of the patient's needs. Such databases could be used to identify the effects of drug formulary restrictions on the health outcomes of patients.

Other management strategies that would not compromise the quality of care need to be considered. Workshop participants clearly made the point that antibiotic formularies in managed care organizations are expected to continue to be decided mostly on the basis of procurement costs until data are validated. Because it is becoming increasingly difficult to target antibiotic resistance in the current health care environment, cutting corners in this area will likely exacerbate the problem. Instead, sensible management tactics in managed care could concentrate on the standardization of treatment for costly medical conditions as a way of reducing costs in health care practice. These could include treatments for such conditions as complete hip replacements, heart failure treatments, diabetes, and asthma. However, workshop discussions highlighted the need for more studies to address the effects of formulary restrictions on the health outcomes of patients. This is a major gap on which research efforts need to concentrate.

Achieving Quality Care and Cost Containment

In some cases, the level of use of antibiotics for patients who need them is being reduced as a result of increased pressures to reduce costs. Not only does this breed patient dissatisfaction, but also, most importantly, this activity may compromise the quality of health care and thereby increase incidences of infection. New strategies are required to realize cost savings from lower levels of antibiotic use as a result of formulary management decisions, such as conducting benchmarking studies and developing an iterative computerized system to help track antimicrobial resistance.

Health care policies that provide efficient and swift dissemination of information on new uses of drugs, and that provide guidance on the promotion of medical products in the managed care environment should be implemented. Additionally, workshop participants proposed that, after controlling for severity of illness, minimization of costs and services can be attained while simultaneously controlling costs. This line of argument leads to discussions about the use of databases as a tool for achieving such results by taking into account several patient factors. Databases can help determine which management strategies, interventions, and medications are most appropriate for the provision of better treatment outcomes on the basis of the patient's needs. Although the traditional method of using diagnostic codes provides only a vague description of symptoms, the database methodology encourages health care systems (including managed care settings, hospitals, long-term care facilities, and ambulatory-care settings) to provide services outside their traditional roles and allow patients' conditions to be identified more readily. By obtaining a more accurate picture of a patient's condition, physicians can better ascertain the patient's ailment and thus be in a better position to treat the symptoms. In turn, this may translate into cost savings, in addition to an increased quality of care and faster care.

Summary

Discussions of the preliminary data on drug formularies suggested that formulary restrictions fail to control the overall costs of health care or to improve the quality of care. The drugs available in formularies vary widely among providers. With respect to infectious diseases, however, it appears that formulary restrictions—particularly the monopolistic use of a few broad-spectrum drugs—may actually contribute to the emergence of antibiotic resistance. Better data are still needed on these issues, for in the absence of these data, providers may likely continue to base formulary decisions primarily on cost instead of on the desire to improve the quality of care and to limit the spread of antibiotic resistance.

The panelists thought that it would be desirable to allow physicians to prescribe a greater variety of antibiotics, especially narrow-spectrum drugs, and when trying to treat infections caused by specific microorganisms to adjust the dosage and duration of therapy to match the needs of particular patients. Several

examples of evidence-based, computer-aided systems are available to assist with this kind of therapeutic decision making. In the longer term, it would be desirable to develop technology that bridges the gap between diagnosis and treatment by rapidly identifying the infectious agent but also pointing the way to a highly targeted therapeutic agent. However, few orphan drugs that have been developed to treat rare emerging infectious diseases were identified, and the realities of the pharmaceutical industry (and of clinical trials with small populations of patients) militate against the development of narrow-spectrum, low-volume drugs, particularly when the restrictions created by the use of drug formularies are considered. FDA is developing guidelines for off-label use, product marketing information, direct advertising to the consumer, and on the role of pharmaceutical benefits management companies; the effects of these regulations on drug development and drug formularies remain to be determined.

7

Concluding Remarks

Joshua Lederberg, Ph.D.

A common theme that ran throughout the workshop was the heterogeneity and continuing rapid evolution of the managed care industry. Although a few large health maintenance organizations (HMOs) were highlighted as effective research and demonstration partners, it was recognized that others have very different capabilities and corporate cultures, leading to the repeated observation that HMOs, as well as public health agencies and microbiology laboratories, are extremely heterogeneous. As the dramatic restructuring of the nation's health care system evolves, forging better partnerships with managed care systems will likely have a strong positive effect not only on health care delivery but on many aspects of the public health enterprise as well.

Nonetheless, the incentive structure for managed care organizations provides few inducements for such organizations to take the broader and longer term public health-oriented view. Some of the incentives, even those concerning quality assurance for individual patients and for formulary restrictions, may be considered ambiguous and seem to intensify the problems facing public health. Beyond that, however, the evidence regarding managed care's actual performance and impact on emerging infections is at times confusing or missing. Because managed care is not monolithic, some plans have integrated services and sophisticated research capabilities, whereas others provide little more than cost reimbursement for conventional health care services.

Subsequently, it would be unrealistic to expect the managed care industry by itself to develop and implement solutions for the problems identified during the workshop. Yet, it is clear that the managed care industry could become a productive partner in this undertaking, particularly if it obtains financial support to cover the marginal costs of research and demonstration activities. Specific examples include the gathering of drug-dispensing data and crude surveillance of multi-drug-resistance among the organisms that cause tuberculosis and sexu

ally transmitted diseases. It is possible that some HMOs will garner a competitive advantage in being viewed as progressive, research-oriented organizations. Major purchasers of managed care will also have an important role alongside the managed care industry in developing and implementing solutions to confront emerging infections. Likewise, there are ample opportunities for academic health centers and government agencies to play the role of catalyst, as well as partner in research, for greater participation by managed care in addressing the public health threat of emerging infections.

A related common theme was the need for better information to support the provision of quality health care. For example, preliminary studies indicate that formulary practices may have an adverse impact on antibiotic resistance, prompting the need for additional comprehensive data on formulary practices and the impacts that drug formularies may have on infection control. The use of outcomes information was identified as one way of developing and implementing new clinical practice guidelines. One of the most promising fruits from the workshop discussion was the identification of the potential for integrated, computer-assisted medical information systems to assist physicians in diagnosing and treating infectious diseases; to assist managed care organizations in tracking antibiotic use, costs, and outcomes; and to assist public health agencies in monitoring and even preventing emerging infections and antibiotic resistance.

Many of the issues raised during the workshop, including both the use of drug formularies and surveillance, have international as well as domestic implications. In particular, it was explained that there are three health systems in Latin America—private, public, and employee systems—but that many of the providers in the region work with all three systems. As governments face increasing pressure to downsize, the impacts of that change on the vital public health functions of surveillance, control, and prevention of infectious diseases are a shared concern among all systems. In the United States, it is important to involve the National Institutes of Health, the Centers for Disease Control and Prevention, and private groups that are working on these issues in international deliberations. Unfortunately, it was noted that the subject of managed care was not part of the current White House foreign policy initiative in the area of infectious diseases. Nevertheless, the present discussion pointed to the need to bring the private sector into those deliberations in the future.

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Appendix A

Veterans Health Administration and Infectious Disease

The Veterans Health Administration (VHA) has four congressionally mandated missions (Kizer, 1999):

- Provide health care services to the nation's veterans.
- Conduct educational programs that enhance the quality of care provided.
- Conduct research programs that enhance the quality of care provided.
- Serve as a backup to the U.S. Department of Defense medical system and assist in the provision of health care during times of emergencies and natural disasters.

One of the largest health care systems in the nation, VHA is the largest component of the U.S. Department of Veterans Affairs (DVA), accounting for half of its budget, approximately $18 billion, and 80 percent of its staff. In addition, certain infectious diseases (Levine, 1998), such as AIDS and tuberculosis, occur at higher rates among the population that it serves, and therefore, VHA can provide unique insights into researching, monitoring, and teaching others about infectious disease.

The VHA is organized into 22 Veterans Integrated Service Networks (VISNs). VISNs are centered around the concept that health care should be based on the population that it serves and not on the facilities in which it is delivered. As a result, each VISN is composed of 7 to 10 hospitals, 25 to 30 ambulatory-care facilities, and is designed to align resources around patients, forcing the VISN to pool and coordinate its resources and services (Kizer, 1997).

VHA's systemwide move to greater efficiency has also included major innovations in the information technology department. Software, such as the Clinical Information Resources Network, allows VHA physicians to view the primary care data for a patient anywhere within their own VISNs and to share

those data with other VISNs. In addition, programs such as the unique Emerging Pathogens Initiative allow VHA to conduct surveillance and monitor emerging pathogens anywhere in the VHA hospital system.

This appendix is intended to acquaint the reader with selected programs and aspects of the VHA which are unique, rather than provide a comprehensive review of all VHA programs that address infectious diseases. The following discussions address the five thematic areas discussed in the workshop summary (i.e., research, clinical practice, surveillance and monitoring, education, and drug formularies) and highlight some of the opportunities presented by the VHA system.

CLINICAL RESEARCH

In fiscal year 1997, the VHA research budget totaled more than $900 million. This funding included funds from a congressional appropriation, extramural grants awarded to individual researchers, and indirect support from the medical care budget. The Office of Research and Development (ORD) is the organizational structure responsible for allocating research dollars among the DVA facilities across the nation currently participating in research and development activities. Although the ORD consists of four research branches, the two most relevant to infectious disease are the Cooperative Studies Program (CSP) and the Medical Research Service (MRS).

CSP began in 1946 with landmark research in the treatment of tuberculosis (DVA, Office of Research and Development, 1997). CSP plays the important role of reviewing and providing administrative coordination to researchers nationwide who wish to conduct large, multisite clinical research studies. Indeed, more than 100 DVA hospitals are involved in cooperative studies. CSP provides an opportunity for researchers in infectious disease to coordinate and share resources and patient populations in the course of their investigations.

MRS is the main research branch responsible for biomedical research that enhances the quality of care received by veterans. One of the core research centers is the Center for AIDS and HIV Infection, with locations in Georgia, New York, California, and North Carolina.

Antimicrobial resistance is another research focus in VHA. Current projects include mechanisms of resistance in *Mycobacterium tuberculosis* , an investigation of the signal pathways in antibiotic resistance, and structure-function relationships of relevant enzymes such as the SHV-1 b-lactamase and amine oxidase.

VHA's Emerging Pathogens Initiative (EPI) has been in operation since 1998, serving as the data source for many research projects. One recent EPI finding showed a concordance between addiction disorders and hepatitis C virus infection, information that is important in designing intervention strategies and therapeutic trials. A second study with EPI data found that group A streptococcus afflicted a younger, disproportionately female population, thereby delineat

ing a women's health issue that would not otherwise have been recognized. (Refer to Chapter 4 for a more thorough discussion of EPI.)

CLINICAL PRACTICE

Information Technology

VHA operates 172 hospitals, 132 nursing homes, 73 home health care programs, and more than 650 outpatient clinics. In 1998, these facilities, along with other contractual programs, served 3.4 million of 9.4 million individuals who qualified for care (Kizer, 1999). However, DVA has experienced dramatic changes in the past few years, eliminating more than half of its acute-care beds and, from 1994 to 1998, increasing by 43 percent the number of ambulatory-care visits per year (Kizer, 1999). Most importantly, the creation of VISNs resulted in a need to integrate clinical data on a VISN-wide basis.

The Computerized Patient Record System (CPRS) allows all individuals on the health care team to view demographic data, future appointments, advanced directives, medications, orders, and progress notes. The Clinical Information Resources Network (CIRN) serves as the means for transmitting those data across the VHA network. CIRN ensures that a patient's primary care provider can receive all data on that patient's care, no matter where it was originally delivered. CIRN presents an opportunity to monitor health care delivery patterns and to allow VHA to modify clinical guidelines on the basis of current physician practices (DVA, Veterans Health Administration, 1998).

Homelessness

VHA is the nation's largest direct provider of services to homeless people, providing health care to more than 80,000 homeless people each year (Robert Rosenheck, Director, Veterans Administration Northeast Program Evaluation Center, personal communication, August 1999). In fact, on any given day in 1996, homeless people accounted for 13.5 percent of all hospital admissions (Wilson and Kizer, 1997).

Homelessness presents a unique set of circumstances for the treatment of infectious diseases. Physician monitoring is limited to the patient's motivation to seek care, and living conditions are often sub-standard. Since these conditions often involve sharing congregate spaces with large numbers of individuals, the transmission of communicable diseases cannot easily be prevented.

However, care of homeless veterans could be improved by use of EPI to identify the most prevalent infections and comorbidities and devise effective prevention strategies. For example, EPI data showed that for fiscal year 1998, 8.1 percent of all patients with hepatitis virus infection were homeless (Kralovic et al., 1999). Since EPI can identify the emerging pathogens that affect homeless

populations the most and VHA treats more homeless individuals than any other healthcare system in the nation, the EPI can also serve as an invaluable public health investigative tool. This information could be very useful to the VHA's Homeless Veterans Treatment and Assistance Program, which seeks to identify and ameliorate the causes and effects of homelessness among veterans.

SURVEILLANCE AND MONITORING

Emerging Pathogens Initiative

EPI has been online since 1998 and is operated by the Program Office for Infectious Diseases. EPI allows VHA to track emerging pathogens on a national level, with no additional labor required at the local level. This automated computer program is an innovative and unique effort capable of searching all VHA inpatient records and retrieving patient-specific information (e.g., age, sex, comorbidities, zip code, and ethnicity) when it identifies a positive laboratory test for a specific pathogen. Identifiable pathogens include hepatitis C virus, *M. tuberculosis*, penicillin-resistant pneumonococci, vancomycin-resistant enterococci, leishmania, *Escherichia coli* O157, the virus that causes dengue, *Cryptosporidium*, CJD, group A streptococcus, *Candida* in the bloodstream, *Clostridium difficile*, legionella, and plasmodium, which causes malaria (Roselle et al., 1999).

EPI data are collected once a month and are forwarded to a central processing computer in Austin, Texas. The data are analyzed after a 2-week period, during which hospitals may identify software problems that have resulted in obvious errors. This is intended to serve as a human check on an otherwise automated system. The combination of identifying emerging pathogens and obtaining patient-specific information allows epidemiological analyses, future projections, and outcome assessment.

Annual Infectious Diseases and Infection Control Report

Since 1991, all DVA medical facilities have provided data concerning pathogens and control measures via an electronic survey. These data, including the number of infection control practitioners, physicians, and clerical staff at each facility, as well as information regarding relevant organisms and pathogens, are then analyzed by the Infectious Disease Program Office. For instance, when VHA wanted to determine whether their efforts to reduce *M. tuberculosis* infection rates via a central planning effort were effective, they analyzed the *M. tuberculosis* infection rates by use of the data received in the annual survey. Data that were collected between 1992 and 1997 showed that the number of cases of tuberculosis had dropped 44 percent. VHA received confirmation of its effectiveness of their efforts since this decrease was greater than that seen in the U.S. population.

EDUCATION

VHA's educational mission is to ensure an adequate supply of clinical care and allied health providers for veterans and the nation. VHA facilities train more than 100,000 individuals from more than 40 health professions every year. VHA directly funds approximately 9,000 physician residency positions and 10 percent of the nation's graduate medical trainees. It is also affiliated with 105 of the nation's 126 medical schools, training 22,000 medical students for at least part of their clinical rotations every year (Kizer, 1997). In addition, the number of ambulatory-care VHA training sites is increasing, providing opportunities not often found at academic health centers.

The sheer number of trainees allows VHA to have a tremendous impact on future medical practice, an impact that is unparalleled by that of any other health care organization in the nation. In addition, the resources at VHA can produce reference manuals and guidebooks that smaller organizations cannot easily provide. One example relevant to infectious disease is the *Emerging Pathogens Guidebook*. This volume, which serves both as a reference for current practitioners and as a textbook for a workshop in the year 2000, is intended to assist in the prevention of the spread of infectious diseases. In addition, the guidebook serves to provide information and guidance to DVA health care teams. The teams can then modify their health care workplaces to improve infection control practices and minimize the occurrence of nosocomial infections.

DRUG FORMULARY

The DVA National Formulary, adopted on June 1, 1997, is meant to provide better patient care at a lower cost. Before that date, each VISN was responsible for maintaining its own formulary and making all formulary decisions. The change to the national formulary instituted a tiered system, splitting the decision making process between VHA's Pharmacy Benefits Management Strategic Healthcare Group, each individual VISN, and each facility within a VISN. Each VISN maintains a formulary that provides at least all the drugs on the national level, and facilities maintain formularies that provide at least all the drugs on the VISN and national levels. The tiered system works in conjunction with an "open" and "closed" drug classification system.

When VHA has secured a national contract with a drug manufacturer to provide particular pharmaceuticals, the drugs are considered to be in "closed" drug classes. In this case, individual VISNs or facilities cannot add additional pharmaceuticals to the formulary. Non-formulary drugs can be prescribed through a procedure used to identify unique clinical circumstances that warrant the use of nonformulary prescriptions, such as the therapeutic failure of all existing formulary pharmaceuticals. The four classes of drugs characterized as "closed" are proton pump inhibitors, alpha-blockers, HMG coeneyme A reductase inhibitors, and angiotensin-converting enzyme inhibitors.

All other drugs listed in the formulary are considered "open" and must be provided by DVA facilities. However, in contrast to the "closed" classes of drugs, local areas may use additional therapeutic agents in an effort to best serve their patient populations. Antibiotics are treated in this manner and are not restricted by the national formulary.

The flexibility offered by a tiered system has allowed certain VHA facilities to design their own procedures for using antibiotics. For instance, the Portland VHA facility uses the services of an infectious diseases team to make an annual review of antimicrobial agents as they pertain to their local patient population. The infectious diseases team consists of clinical microbiologists, physicians, and pharmacists. For any particular drug, the team may allow physicians complete freedom in ordering prescriptions or may require physicians to obtain approval from the team before ordering their use (Larry Strausbaugh, hospital epidemiologist and staff physician, Veterans Administration Hospital Center, personal communication, August 1999).

As indicated in the workshop summary, controversy surrounds the use of formularies and the DVA National Formulary has not been spared. Questions have been raised by both the veterans served by VHA and members of the U.S. Congress who appropriate funds to the VHA. As a result, the Institute of Medicine is currently engaged in a study, mandated by the U.S. Congress, to analyze the DVA National Formulary. Its primary objectives include answering the following the questions:

1. Is the DVA National Formulary overly restrictive and does it prevent physicians from meeting the unique health care needs of veterans?
2. What are the potential costs to DVA health care associated with the DVA National Formulary?
3. What are the effects of the DVA National Formulary and related policies on quality of care?
4. How does the DVA National Formulary compare with private insurance formularies for drugs and devices and with other government formularies (e.g., that of Medicaid)?

As was the case with VHA's association with educational institutions, the uniqueness of the DVA National Formulary lies in its sheer strength and size. Currently, DVA spends approximately $1 billion on pharmaceuticals annually (Kunzi, 1999), including about $170 million on antimicrobial agents. This provides VHA with a large amount of leverage when contracting for new pharmaceuticals. In addition, the Veterans Health Care Act of 1992 requires pharmaceutical companies to offer selected products to VHA at the Federal Ceiling Price, which is approximately equal to the average nonfederal manufacturer's price plus a 24 percent discount (Kunzi, 1999).

Appendix B

Glossary and Acronyms

Acronyms

AAFP	**American Academy of Family Physicians** (www.aafp.org)
AAHP	**American Association of Health Plans** (www.aahp.org)
AAMC	**Association of American Medical Colleges** (www.aamc.org)
AAP	**American Academy of Pediatrics** (www.aap.org)
ACOG	**American College of Obstetricians and Gynecologists** (www.acog.com).
AHCPR	**Agency for Health Care Policy and Research** (www.ahcpr.gov)
ASM	**American Society for Microbiology** (www.asmusa.org)
CALINX	**California Information Exchange** (www.calinx.org).
CDC	**Centers for Disease Control and Prevention** (www.cdc.gov).
DHHS	**U.S. Department of Health and Human Services** (www.os.dhhs.gov).
FDA	**U.S. Food and Drug Administration** (www.fda.gov).
HCFA	**Health Care Financing Administration** (www.hcfa.gov).
NCI	**National Cancer Institute, National Institutes of Health** (www.nci.nih.gov).
NCID	**National Center for Infectious Diseases, Centers for Disease Control and Prevention** (www.cdc.gov/ncidod/ncid.htm).
NIAID	**National Institute of Allergy and Infectious Diseases, National Institutes of Health** (www.niaid.nih.gov).

NIH **National Institutes of Health** (www.nih.gov).

PBGH **Pacific Business Group on Health** (www.pbgh.org).

Glossary

This glossary is intended to define terms commonly encountered throughout this workshop summary as well as some terms that are commonly used in the managed care industry. This glossary is not all-inclusive. New terms and new usages of existing terms will emerge with time and advances in technology. Definitions for the terms presented here were compiled from a multitude of sources, which are listed at the end of the glossary.

Academic Health Centers (AHCs): Academic health centers, or AHCs, consist of health care institutions that are owned by or closely affiliated with a university or medical school. AHCs also have at least one additional health professional program, and are engaged in undergraduate and graduate medical education, biomedical research, and delivery of patient care.

Antibiotic: Class of substances or chemicals that can kill or inhibit the growth of bacteria. Originally antibiotics were derived from natural sources (e.g., penicillin from molds), but many currently used antibiotics are semisynthetic and are modified by the addition of artificial chemical components.

Antibiotic resistance: Property of bacteria that confers the capacity to inactirate or exclude antibiotics or a mechanism that blocks the inhibitory or killing effects of antibiotics.

Antimicrobial agents: Class of substances that can destroy or inhibit the growth of pathogenic groups of microorganisms, including bacteria, viruses, parasites, and fungi.

Bacteria: Microscopic, single-celled organisms that have some biochemical and structural features different from those of animal and plant cells.

Basic research: Fundamental, theoretical, or experimental investigation to advance scientific knowledge, with immediate practical application not being a direct objective.

Benchmark: For a particular indicator or performance goal, the industry measure of best performance. The benchmarking process identifies the best performance in the industry (health care or non-health care) for a particular process or outcome, determines how that performance is achieved, and applies the lessons learned to improve performance.

Broad-spectrum antibiotic: An antibiotic effective against a large number of bacterial species. It generally describes antibiotics effective against both gram-positive and gram-negative classes of bacteria.

CAMAS (Completeness and Accuracy of Managed-Care Administrative Data Sets): A single study involving the accuracy and completeness of administrative data sets, funded by a grant from the California HealthCare Foundation to CALINX (California Information Exchange).

Capitation: A per member, per month payment to a health care provider or health plan for each member enrolled, regardless of the amount of care that a member requires.

CHAMPUS (Civilian Health and Medical Program of the Uniformed Services): A cost-sharing program that helps eligible military families and retirees and retiree families pay for civilian care when military care is not available. CHAMPUS is now called TRICARE Standard in most of the country.

Clinical practice guidelines: Systematically developed statements that assist practitioners and patients with decision making about appropriate health care for specific clinical circumstances.

Clinical research: Investigations aimed at translating basic, fundamental science into medical practice.

Clinical trials: As used in this workshop summary, research with human volunteers to establish the safety and efficacy of a drug, such as an antibiotic or a vaccine.

Clinicians: One qualified or engaged in the clinical practice of medicine, psychiatry, or psychology, as distinguished from one specializing in laboratory or research techniques in the same fields.

Disease: The condition in which the functioning of the body or a part of the body is interfered with or damaged. In a person with an infectious disease, the infectious agent that has entered the body causes it to function abnormally in some way or ways. The type of abnormal functioning that occurs is the disease. Usually the body will show some signs and symptoms of the problems that it is having with functioning. Disease should not be confused with infection.

Efficacy: As used in this workshop summary, the probability of benefit to individuals in a defined population from a medical technology applied for a given medical problem under defined conditions of use.

Emerging infections: Any infectious disease that has come to medical attention within the last two decades or threatens to increase in the near future (IOM, 1992). Many times, such diseases exist in nature as zoonoses and emerge as human pathogens only when humans come in contact with a formerly isolated animal population, such as monkeys in a rain forest that are no longer isolated because of deforestation. Drug-resistant organisms could also be included as emerging infections since they exist because of human influence. Some recent examples of agents responsible for emerging

	infections include human immunodeficiency virus, Ebola virus, and multi-drugresistant *Mycobacterium tuberculosis*.
Endemic:	Disease that is present in a community or common among a group of people; said of a disease continually prevailing in a region.
Etiology:	Science and study of the causes of diseases and their mode of operation.
FDA Modernization Act of 1997:	An act to amend the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act to improve the regulation of food, drugs, medical devices, and biological products.
Federal Food, Drug, and Cosmetic Acts of 1938 and 1962:	Laws that require a manufacturer to prove the safety and effectiveness of a drug before it can be marketed.
Fee-for-service system:	The traditional health care payment system under which physicians and other providers receive a payment for each unit of service that they provide.
Formulary:	List of drugs approved for the treatment of various medical indications. It was originally created as a cost-control measure, but it has been used more recently to guide the use of antibiotics on the basis of information about resistance patterns.
Group model HMO (health maintenance organization):	A type of HMO whereby an organized group of practitioners contracts with an HMO to provide services, often on a mutually exclusive basis. The provider organization receives a negotiated, per capita payment which may be distributed to individual clinicians by salary, capitation payments, fee-for-service reimbursements, or incentive payments.
HEDIS (Health Plan Employer Data and Information Set):	A set of standardized performance measures for health plans related to member satisfaction, quality and access, physician network, utilization, membership, and finance.
HIPAA (Health Insurance Portability and Accountability Act of 1996):	An act designed to protect health insurance coverage for workers and their families when workers change or lose their jobs.
HMO (health maintenance organization):	An organized system of health care that arranges a comprehensive range of health care services to a voluntarily enrolled population in a geographic area on a primarily prepaid and fixed periodic basis. This health care service plan requires its subscriber members, except in a medical emergency, to use the services of designated physicians, hospitals, or other providers of medical care. HMOs typically use a capitation payment system that rewards providers for cost-effective management of patients.
Immunogenicity:	The property that endows a substance with the capacity to provoke an immune response or the degree to which a substance possesses this property.

Incidence: The frequency of new occurrences of disease within a defined time interval. Incidence rate is the number of new cases of a specified disease divided by the number of people in a population over a specified period of time, usually 1 year.

Individual Practice Association (IPA) model: A model in which an HMO contracts with Independent Practice Associations (IPAs) to provide care. The IPAs are generally directed and often owned by member providers who retain their independent practices but use the IPAs to obtain managed care contracts and, on occasion, to administer care-related services.

Infection: The entry and development of an infectious agent in the body of a person or animal. In an apparent, "manifest" infection, the infected person outwardly appears to be sick. In an unapparent infection, there is no outward sign that an infectious agent has entered that person at all. Infection should not be confused with disease.

Invasive isolates: A pure culture of a microorganism that is capable of (1) penetrating the host's defenses, (2) entering host cells, or (3) passing through mucosal surfaces and spreading in the body.

MCO (managed care organization): An organization that arranges for health care delivery and financing and that is designed to provide appropriate, effective, and efficient health care through organized relationships with providers. Includes formal programs for ongoing quality assurance and utilization review, financial incentives for covered members to use the plan's providers, and financial incentives for providers to contain costs. Managed care plans vary greatly in the degree to which benefit coverage is offered, monitored, and conditioned upon certain criteria being met by the subscriber member and the member's primary care physician.

Medicaid: A federal government program that helps pay for health care for indigent and disabled persons. The federal government reimburses a percentage of each state's expenditures; the states determine eligibility.

Medicare: A federal government health care insurance program for people age 65 and over and for disabled people. Medicare helps pay for hospitalization charges, stays in skilled nursing facilities, physician charges, and some associated health care costs.

Methicillin-resistant *Staphylococcus aureus* (MRSA): Strictly speaking, a *Staphylococcus aureus* strain resistant to the antibiotic methicillin. In practice, MRSA strains are generally resistant to many antibiotics and some are resistant to all antibiotics except vancomycin, such that the acronym is now generally used to mean "multi-drug-resistant *S. aureus*."

MIC (minimum inhibitory concentration): The lowest antibiotic concentration that prevents bacterial growth.

Mixed model HMO (health maintenance organization):	A combination of two or more types of managed care organizations.
MSO (management services organization):	An organization that provides management, administration, and support services to individual physicians or group practices.
Neonate:	A newborn infant.
Network model HMO (health maintenance organization):	A type of HMO which contracts with individual clinicians, groups or IPAs, and hospitals to provide care. The contracts are usually not exclusive, and providers may be paid by capitation, fee-for-service, or other mechanisms. Clinicians may contract with the HMO directly or through an intermediary organization such as a medical group or IPA.
Nosocomial infection:	An infection that is acquired during hospitalization but that was neither present nor incubating at the time of hospital admission, unless it is related to a prior hospitalization, and that may become clinically manifest after discharge from the hospital.
Outpatient services:	Medical and other health care services not requiring hospitalization. These services may be provided by a hospital or other qualified facility or supplier, such as mental health clinics, rural health clinics, mobile X-ray units, or freestanding dialysis units. Such services include outpatient physical therapy services, diagnostic X-ray and laboratory tests, and radiation therapy.
PHO (physician hospital organization):	A legal entity formed or owned by hospitals and physicians to obtain payer contracts. Physicians may retain ownership of their practices but agree to accept managed care patients under terms negotiated by the PHO.
POS (point-of-service) plan:	An organized system of health care that is provided by a health maintenance organization and that provides the option of delivering services outside of the network for a higher copayment or deductible.
PPO (preferred provider organization):	A network, discount, fee-for-service provider arrangement with incentives to stay inside the network. This arrangement allows services outside of the PPO network but with an increased copayment or deductible, or both. A PPO has some structured quality and utilization management.
Prenatal:	Existing or occurring before birth.
Primary care:	Basic or general health care, traditionally provided by family practice, pediatric, and internal medicine physicians.
Primary care physician:	A general practitioner, board-certified or boardeligible family practitioner, internist, obstetrician/gynecologist, or pediatrician who has contracted with a managed care organization (MCO) to provide primary care to subscriber members and who refers, authorizes, supervises, and coordinates the provision of all health care of subscriber members in accordance with the MCO contract.

Program Announcement (PA):	A public announcement describing the goals and scope of a proposed scientific project awaiting approval from a specific scientific organization.
Prophylactic antibiotics:	Antibiotics that are administered before evidence of infection with the intention of warding off disease.
Public Health Service Act of 1944:	An act to consolidate and revise the laws relating to the U.S. Public Health Service.
Requests for Applications (RFA):	A public announcement from a scientific organization requesting applications from qualified people to perform a specific research assignment.
Sepsis:	The presence of pathogenic microorganisms or their toxins in blood or other tissues.
Staff model HMO (health maintenance organization):	An HMO in which practitioners are salaried employees of the HMO. The practitioners may also receive a bonus or other incentive income based on the performance of the HMO.
Surveillance systems:	Used in this workshop summary to refer to data collection and record-keeping to track the emergence and spread of disease-causing organisms such as antibiotic-resistant bacteria.
Tertiary care:	The aspect of inpatient care dealing with illnesses or conditions requiring specialized techniques, such as coronary artery bypass surgery, renal hemodialysis, and treatment of severe burns.
Vaccine:	A preparation of living, attenuated, or killed bacteria or viruses, fractions thereof, or synthesized or recombinant antigens identical or similar to those found in the disease-causing organisms that is administered to raise immunity to a particular microorganism.
Zoonotic disease or infection:	An infection or infectious disease that may be transmitted from vertebrate animals (such as rodents) to humans.

Definitions for this glossary were compiled from the following sources:

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Appendix C

Workshop Agenda

INSTITUTE OF MEDICINE
NATIONAL ACADEMY OF SCIENCES
FORUM ON EMERGING INFECTIONS
Managed Care Systems and Emerging Infections: Opportunities for Strengthening Surveillance, Research, and Prevention
March 23–24, 1998

MONDAY, MARCH 23, 1998

8:00 a.m.	Continental Breakfast
8:30	**Welcome and Opening Remarks** Joshua Lederberg, Ph.D. Chair, Forum on Emerging Infections
8:45	**Keynote Address** Margaret Hamburg, M.D. Assistant Secretary for Planning and Evaluation U.S. Department of Health and Human Services
9:00–11:00	**PANEL I: BASIC AND CLINICAL RESEARCH** **Moderator**: Frederick Sparling, M.D., Forum Member
9:00	**AAMC Perspective on Basic and Clinical Research** David Korn, M.D. Senior Vice President for Biomedical and Health Science Research Association of American Medical Colleges

Opportunities for Population-Based Clinical Research Using Data from Managed Care Organizations
Frank DeStefano, M.D., M.P.H.
Medical Epidemiologist, Vaccine Safety and Development Activity
National Immunization Program, Centers for Disease Control and Prevention

Conducting Clinical Research Within Managed Care Organizations
Walter Stamm, M.D.
Professor of Medicine and Head, Division of Allergy and Infectious Diseases
University of Washington School of Medicine

Clinical Research: The Challenge or Promise of Managed Care
Lana Skirboll, Ph.D.
Associate Director, Office of Science Policy
National Institutes of Health

9:45 **Discussion**

10:50 **Break**

11:00 a.m.–1:00 p.m. **PANEL II: CLINICAL PRACTICE GUIDELINES**
Moderator: Vincent Ahonkhai, M.D., Forum Member

11:00 **Making Guidelines Instrumental: Theory versus Practice**
Richard E. Dixon, M.D.
Medical Director, National Independent Practice Association Coalition

Realities of Implementing Guidelines
Nora Morris, M.A.
Assistant Director/Senior Analyst, Healthcare Education and Research Foundation, Inc.

Clinical Practice Guidelines for Emerging Infections and Managed Care
Anne Schuchat, M.D.
Chief, Childhood and Respiratory Diseases Branch
Bacterial and Mycotic Disease Division, National Center for Infectious Diseases
Centers for Disease Control and Prevention

11:30 **Discussion and Working Lunch**

1:00–3:00 p.m. **PANEL III: SURVEILLANCE AND MONITORING**
Moderator: Carlos Lopez, Ph.D., Forum Member

1:00 **Collaborative Surveillance Efforts and Monitoring of Data**
Richard Platt, M.D.
Director of Research, Harvard Pilgrim Health Care of New England

LDS Hospital's System
John Burke, M.D.
Department of Clinical Epidemiology, LDS Hospital

An Employer's Perspective
Thomas Davies, M.P.A., J.D.
Manager of Managed Care, GTE Corporation

Laboratory-Based Reporting and Managing Encounter-Level Data
Richard E. Dixon, M.D.
Medical Director, National Independent Practice Association

Laboratory-Based Reporting Issues
Robert Rubin, M.D.
President and Chief Operating Officer
The Lewin Group

Surveillance and Monitoring: Issues at the Legal Interface
René Bowser, J.D.
Georgetown University Law Center

Managed Care and Infectious Disease Surveillance: Opportunities for Collaboration
Denise Koo, Ph.D.
Director, Division of Public Health Surveillance and Informatics
Epidemiology Program Office, Centers for Disease Control and Prevention

1:40 **Discussion**

2:50 **Break**

3:00–4:30 p.m. **PANEL IV: EDUCATION AND OUTREACH**
Moderator: Renu Gupta, M.D., Forum Member

3:00 **Coordinating Health Plan Research and Educational Efforts**
Richard Platt, M.D.
Director of Research, Harvard Pilgrim Health Care of New England

Perspective on Managed Care Systems' Impact on Education and Outreach from the National Center for Infectious Diseases
Ben Schwartz, M.D.
Deputy Director, Epidemiology and Surveillance Division
National Center for Infectious Diseases, Centers for Disease Control and Prevention

Education and Outreach Perspectives by the National Institute of Allergy and Infectious Diseases
Karl Western
Assistant Director for International Research
National Institute of Allergy and Infectious Diseases
National Institutes of Health

Managed Care Systems and Emerging Infections: Education and Outreach
William Baine, M.D.
Center for Cost and Financing Studies
Center for Outcomes and Effectiveness Research
Agency for Health Care Policy and Research

3:30 **Discussion**

4:30 **Adjournment**

TUESDAY, MARCH 24, 1998

8:00 a.m. Continental Breakfast

8:30–10:00 a.m. **PANEL V: DRUG FORMULARIES**
Moderator: David Shlaes, M.D., Ph.D., Forum Member

8:30 **Regulatory Issues**
Laurie Burke, R.Ph., M.P.H.
Chief of Managed Care Outcome and Labeling, Drug Marketing, Advertising, and Communication Division
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

Relationship Between Managed Care Formularies and Treatment Outcomes
Susan Horn, Ph.D.
Senior Scientist, Institute for Clinical Outcomes Research
Vice President of Research for International Severity Information Systems
Professor of Medical Informatics, University of Utah School of Medicine

Bacterial Resistance, the Antibiotic Formulary, and Other Management Strategies
Jerome Schentag, Pharm. D.
Director, Clinical Pharmacokinetics Laboratory
Millard Fillmore Health System
Professor of Pharmaceutics and Pharmacy
State University of New York at Buffalo

The Economics of Restrictions on Pharmaceuticals
Douglas L. Cocks, Ph.D.
Senior Research Scientist for Health Economics
Eli Lilly & Company

9:00 **Discussion**

9:50 **Break**

10:00 a.m.–12:00 noon **GENERAL DISCUSSION**

General Discussion
Moderator: Joshua Lederberg, Ph.D., Forum Chair

10:00 **Summary of Sessions by Panel Moderators**
Panel I: Basic and Clinical Research Frederick Sparling, M.D.
Panel II: Clinical Practice Guidelines Vincent Ahonkhai, M.D.
Panel III: Surveillance and Monitoring Carlos Lopez, Ph.D.
Panel IV: Education and Outreach Renu Gupta, M.D.
Panel V: Drug Formularies David Shlaes, M.D., Ph.D.

11:00 a.m.	**Discussion**
12:00 noon	**Closing Remarks** Joshua Lederberg, Ph.D. Chair, Forum on Emerging Infections
12:15 p.m.	**Adjournment**

Appendix D

Forum Member and Staff Biographies

FORUM MEMBERS

JOSHUA LEDERBERG, Ph.D., is University Professor of Molecular Genetics and Informatics at The Rockefeller University, New York, N.Y. His lifelong research, for which he received the Nobel Prize in 1958, has been in genetic structure and function in microorganisms. He has a keen interest in international health and was cochair of a previous Institute of Medicine Committee on Emerging Microbial Threats to Health (1990–1992). He has been a member of the National Academy of Sciences since 1957 and is a charter member of the Institute of Medicine. Dr. Lederberg is the chair of the Forum on Emerging Infections.

VINCENT AHONKHAI, M.D., is Vice President and Director at SmithKline Beecham Pharmaceuticals and is responsible for Clinical R&D and Medical Affairs in Anti-Infectives and Biologicals, North America. He has held this position since 1995 overseeing a product portfolio that includes antibiotics, antivirals, and vaccines. After completing medical school and internships in Nigeria, Dr. Ahonkhai obtained additional training in pediatric residency, followed by a fellowship in infectious diseases in adults and pediatrics at the State University of New York-Downstate Medical Center, Brooklyn, N.Y., from 1975 to 1980. He then joined the faculty as Assistant Professor, Department of Pediatrics. In 1982, Dr. Ahonkhai started his pharmaceutical industry career as Associate Director, Infectious Diseases, at Merck, where he rose to director level. Subsequently, he moved to the Robert Wood Johnson Pharmaceutical Research Institute, where he served first as Head of Infectious Diseases and later as Executive Director, Dermatology and Wound Healing. Dr. Ahonkhai is board-certified in pediatrics and is a long-standing member and fellow of several professional organizations including the American Medical Association, National Medical Association, American Society for Microbiology, Infectious Diseases Society of

America (fellow), Pediatric Infectious Diseases Society, and American Academy of Pharmaceutical Physicians (Vice President, Membership Development Committee, and board member).

STEVEN J. BRICKNER, Ph.D., is Manager of Medicinal Chemistry at Pfizer Central Research, where he leads a team of medicinal chemists that is focused on the discovery and development of new antibacterial agents designed to meet the growing problems with resistance. He has more than 15 years of pharmaceutical industrial research experience, all directed at the discovery of novel antibiotics. Before joining Pfizer, he led a team that discovered and developed linezolid, the first oxazolidinone to undergo phase III clinical evaluation. Dr. Brickner is recognized as a world expert on this new class of antibacterial agents.

NANCY CARTER-FOSTER, M.S.T.M., is Director of the U.S. Department of State's Emerging Infectious Diseases Program and is responsible for heading the department's policy coordination on infectious diseases and human immunodeficiency virus-AIDS issues and integrating international health issues with economic and national security implications into U.S. foreign policy. She coordinates with the State Department's 250 embassies, missions, and agencies to address global infectious disease priorities and to effect a unified United States' government response. Ms. Carter-Foster has been a foreign affairs advisor to the then Majority Whip of the U.S. House of Representatives, Congressman William H. Gray, and was the U.S. chief negotiator on international population issues, and the roles and status of women and international health issues which lead to the United Nation's (UN) World Conference on Population and Development, the UN Conference on Environment and Development (UNCED), and a myriad of other bilateral and multilateral fora. She also has a background in environmental systems management, ocean affairs, law of the sea, and coastal zone development.

GAIL H. CASSELL, Ph.D., is Vice President, Infectious Diseases, Drug Discovery Research, and Clinical Investigation at Eli Lilly & Company. Previously, she was the Charles H. McCauley Professor and (since 1987) Chair, Department of Microbiology, University of Alabama Schools of Medicine and Dentistry at Birmingham, a department which ranked first in research funding from the National Institutes of Health since 1989 under her leadership. She is a member of the Director's Advisory Committee of the National Centers for Disease Control and Prevention, Dr, Cassell is past president of the American Society for Microbiology, a former member of the National Institutes of Health Director's Advisory Committee, and a former member of the Advisory Council of the National Institute of Allergy and Infectious Diseases. She also has served as an adviser on infectious diseases and indirect costs of research to the White House Office on Science and Technology and was previously chair of the Board of Scientific Councilors of the Center for Infectious Diseases Centers for the National Centers for Disease Control and Prevention. Dr. Cassell served 8 years on the Bacte

riology-Mycology 2 Study Section and served as its chair for 3 years. She serves on the editorial boards of several prestigious scientific journals and has authored over 250 articles and book chapters. She has been intimately involved in the establishment of science policy and legislation related to biomedical research and public health. Dr. Cassell has received several national and international awards and an honorary degree for her research on infectious diseases.

GORDON DeFRIESE, Ph.D., is Professor of Social Medicine, Epidemiology, and Health Policy and Administration and Director of the Cecil G. Sheps Center for Health Services Research at the University of North Carolina at Chapel Hill. He received his Ph.D. from the University of Kentucky College of Medicine. Some of his research interests are in the areas of health promotion and disease prevention, medical sociology, primary health care, rural health care, cost-benefit analysis, and cost-effectiveness. He is a member of the Global Advisory Group on Health Systems Research of the World Health Organization in Geneva, past president of the Association for Health Services Research and the Foundation for Health Services Research, and a fellow of the New York Academy of Medicine. He is founder of the Partnership for Prevention, a coalition of private-sector business and industry organizations, voluntary health organizations, and state and federal public health agencies based in Washington, D.C., that have joined together to work toward the elevation of disease prevention among the nation's health policy priorities.

RENU GUPTA, M.D., is Vice President, Medical Safety and Therapeutics of Corarice. As an infectious disease specialist, Dr. Gupta is active in a number of professional societies, including the Infectious Diseases Society of America and the American Society for Microbiology, where she is a member of the committee on education. She is a frequent presenter at the Interscience Conference on Antimicrobial Agents and Chemotherapy and other major infectious disease congresses and has been published in leading infectious disease periodicals such as *Journal of Virology*, the *Journal of Infectious Diseases*, and *Antimicrobial Agents and Chemotherapy*. Dr. Gupta received her M.B. and Ch.B. from the University of Zambia. Subsequently, she served as Chief Resident in Pediatrics at the Albert Einstein Medical Center and as a Fellow in Infectious Diseases at the Children's Hospital of Philadelphia. She was also Postdoctoral Fellow in Microbiology at the University of Pennsylvania and the Wistar Institute of Anatomy and Biology, where she conducted research on the pathogenesis of infectious diseases. From 1989 to mid-1998, Dr. Gupta was with Bristol-Myers Squibb Company, where she directed clinical research as well as strategic planning for the Infectious Diseases and Immunology Division. For the past several years, her work has focused on a better understanding of the problem of emerging infections. Dr. Gupta currently chairs the steering committee for the SENTRY Antimicrobial Surveillance Program.

MARGARET A. HAMBURG, M.D., is the Assistant Secretary for Planning and Evaluation at the U.S. Department of Health and Human Services. Previously, she was the Health Commissioner for the City of New York. She holds appointments as Adjunct Assistant Professor of Medicine at the Cornell University Medical Center and Assistant Professor of Public Health at the Columbia University School of Public Health. In her previous position as special assistant to National Institute of Allergy and Infectious Diseases Director Anthony Fauci, M.D., she played a major role in research administration and policy development in the area of infectious diseases. She serves on the Board of Scientific Counselors of the Center for Infectious Diseases at the Centers for Disease Control and Prevention. She received her M.D. from Harvard Medical School and completed her internship and residency in internal medicine at New York Hospital/Cornell Medical Center and is board-certified in internal medicine. Dr. Hamburg is the author of many scientific articles and the recipient of numerous awards for distinguished public service.

DIETER HINZEN, biographical information is not available.

JAMES M. HUGHES, M.D., is Assistant Surgeon General and Director of the National Center for Infectious Diseases (NCID) at the Centers for Disease Control and Prevention (CDC). He was named Deputy Director of NCID in 1988 and became Director of the Center in 1992. He joined CDC as an Epidemic Intelligence Service Officer in 1973, during which time he focused on the epidemiology of foodborne, waterborne, and other diarrheal diseases. Dr. Hughes received his M.D. in 1971 from Stanford University. He is board-certified in internal medicine, infectious diseases, and preventive medicine. He is a Fellow of the American College of Physicians and the Infectious Diseases Society of America.

J. STANLEY HULL is Vice President of Marketing for Gastrointestinal and Anti-Infectives Research at Glaxo Wellcome. He is responsible for developing revenue forecasts and expense budgets and for reviewing marketing plans for these therapeutic areas. More of his attention is given to pipeline products to ensure that these products are developed to meet customer needs. Before taking his current position, he served as Vice President of Marketing for Glaxo Pharmaceuticals, where he was involved in the commercial development of products in the gastrointestinal, antibacterial, anesthesia, and antiviral therapeutic areas. He has served in various sales and marketing positions in the pharmaceutical industry since he began his career in 1978. He holds a B.S. degree in business administration and economics from the University of North Carolina at Greensboro.

SAMUEL L. KATZ, M.D., is Chairman of the Board of the Burroughs Wellcome Fund and Wilburt C. Davison Professor and chairman emeritus of pediatrics at Duke University Medical Center. He has concentrated his research on infectious diseases, focusing primarily on vaccine research and development,

having developed the attenuated measles virus vaccine with Nobel Laureate John F. Enders which is now used throughout the world. He is a past-chair and member of the Public Policy Council of the infectious Diseases Society of America. Dr. Katz has served on a number of scientific advisory committees and is the recipient of many prestigious awards and honorary fellowships in international organizations. Dr. Katz received his M.D. from Harvard Medical School. After his medical internship at Beth israel Hospital, he completed his pediatrics residency training at the Massachusetts General Hospital and the Boston Children's Hospital. Then he became a staff member at Children's Hospital, working with Nobel Laureate John F. Enders. He has chaired the Committee on Infectious Diseases of the American Academy of Pediatrics (the Redbook Committee), the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention, the Vaccine Priorities Study of the Institute of Medicine (IOM), and several World Health Organization (WHO) and Children's Vaccine Initiative panels on vaccines and human immunodeficiency virus infections. He is a member of many scientific advisory committees and boards including those of the National Institutes of Health, IOM, and WHO. Dr. Katz's published studies include more than 100 original scientific articles, 60 chapters in textbooks, and many abstracts, editorials, and reviews. He is the co-editor of a textbook on pediatric infectious diseases and has given more than 70 named lectures in the United States and abroad.

KENNETH W. KIZER, M.D., M.P.H., is President and Chief Executive Officer of the National Quality Forum. Formerly, he served as the Under Secretary for Health at the U.S. Department of Veterans Affairs, Veterans Health Administration. As the Under Secretary for Health, he was the highest ranking physician in the federal government and the chief executive officer of the health care system in the U.S. His professional experience before joining the U.S. Department of Veterans Affairs includes serving on the boards of Health Systems International, Inc., and the California Wellness Foundation. He is board-certified in five medical specialties and has authored over 300 chapters, book chapters, and other reports in the medical literature. Dr. Kizer has held senior academic positions at the University of California, Davis, and continues as an Adjunct Professor of Public Policy at the University of Southern California. He is a fellow of the American College of Emergency Physicians, the American College of Occupational and Environmental Medicine, the Royal Society of Health, and the Royal Society of Medicine. Dr. Kizer is an honors graduate of Stanford University and the University of California, Los Angeles.

WILLIAM KOHLBRENNER, Ph.D., is Director of Antiviral Research in the Pharmaceutical Products Division at Abbott Laboratories in North Chicago, Ill. He received his Ph.D. from the State University of New York and completed postdoctoral training at the Molecular Biology Institute at the University of California, Los Angeles. Dr. Kohlbrenner has contributed to a number of industrial research programs focused on the discovery of novel antibacterial and antiviral

agents. He has coauthored many articles on the fundamental aspects of various microbial therapeutic targets and the molecular basis of drug action. He has a strong interest in the development of resistance to antimicrobial agents and in devising appropriate therapeutic strategies for effectively dealing with drug resistance problems.

JOHN R. LaMONTAGNE, Ph.D., is Deputy Director of the National Institute of Allergy and Infectious Diseases (NIAID) at the National Institutes of Health. Previously, Dr. LaMontagne was Director of the Division of Microbiology and Infectious Diseases at NIAID. Within NIA1D, he has also served as Director of the AIDS Program and Influenza Program Officer. Dr. LaMontagne received his Ph.D. in microbiology from Tulane University and did a postdoctoral fellowship in the laboratory of Julius Youngner at the University of Pittsburgh. There he devoted his efforts to the characterization of vital products produced by cells persistently infected with Newcastle disease virus. His interests are in vaccine research and development.

CARLOS LOPEZ, Ph.D., is Research Fellow, Research Acquisitions, Eli Lilly Research Laboratories. He received his Ph.D. from the University of Minnesota in 1970. Dr. Lopez was awarded the NTRDA postdoctoral fellowship. After his fellowship he was appointed Assistant Professor of Pathology at the University of Minnesota, where he did his research on cytomegalovirus infections in renal transplant recipients and the consequences of those infections. He was also appointed assistant member and head of the Laboratory of Herpesvirus Infections at the Sloan Kettering Institute for Cancer Research, where his research focused on herpes virus infections and the mechanisms involved. Dr. Lopez's laboratory contributed to the immunological analysis of the earliest AIDS patients at the beginning of the AIDS epidemic in New York. He is coauthor of one of the seminal publications on this disease, as well as many scientific papers and is co-editor of six books. Dr. Lopez has held consultantships with numerous organizations including the National Institutes of Health, the U.S. Department of Veterans Affairs, and the American Cancer Society.

STEPHEN S. MORSE, Ph.D., is a Program Manager in the Defense Sciences Office at the Defense Advanced Research Projects Agency (DARPA). Dr. Morse is also Assistant Professor of Virology at The Rockefeller University, where he has been since 1985. In July 1996, he joined the faculty of Columbia University School of Public Health, Division of Epidemiology. Dr. Morse is a virologist and immunologist with research interests in viral effects on Tlymphocyte development and function, viral zoonoses, and methods for studying viral evolution. He was principal organizer and Chair of the 1989 Conference on Emerging Viruses at the National Institutes of Health, and is a member of the Institute of Medicine Committee on Emerging Infections (1990–1992), a current member of the Institute of Medicine Committee on Xenograft Transplantation, and Chair of the Microbiology Section of the New York Academy of Sciences.

He is Chair of ProMed (Program for Monitoring Emerging Infections), formed in January 1993, to encourage development of initiatives for anticipating and responding to worldwide emerging infections.

SOLOMON MOWSHOWITZ, Ph.D., is President of Diligen, a New York City biotechnology consultancy. Diligen performs due diligence in biotechnology, as well as technical consulting, grant writing, technology transfer, and opportunity assessment. Dr. Mowshowitz received his Ph.D. in biochemistry from the Albert Einstein College of Medicine in 1970, and is licensed to practice before the United States Patent and Trademark Office. He taught microbiology and infectious diseases at the Mount Sinai School of Medicine in New York from 1970 to 1984. Beginning in 1985, he held senior positions at a series of commercial biotechnology firms, most recently having served as Vice President, Research and Development at AMBI, Inc. until 1998. Dr. Mowshowitz's primary expertise is in the areas of infectious diseases, cancer therapeutics, DNAbased diagnostics (including forensics), and patent law.

STUART L. NIGHTINGALE, M.D., is Associate Commissioner for Health Affairs, U.S. Food and Drug Administration, U.S. Department of Health and Human Services. Dr. Nightingale earned his M.D. from New York University School of Medicine and then served as intern (mixed medicine) at Montefiore Hospital and Medical Center in New York, as a resident in internal medicine (including 1 year as a fellow in adolescent medicine) at Montefiore Hospital and Medical Center, and as a resident in anatomical pathology at New York University School of Medicine. He is board-certified in internal medicine, a fellow of the American College of Physicians, and a member of the American Medical Association and the American Public Health Association. Dr. Nightingale heads the Office of Health Affairs of the U.S. Food and Drug Administration (FDA), after prior appointments at several universities, the National Institute of Drug Abuse, and the Executive Office of the President of the United States. Dr. Nightingale has published numerous articles on the impact of federal and state legislation and regulations on medical practice, health fraud, protection of human subjects of research, policy formulation and drug regulation, safety and efficacy determinations and the health effects of FDA-regulated products, and drug abuse prevention, He has received the Award for Distinguished Service, Special Action Office for Drug Abuse Prevention, Executive Office of the President, the Public Health Service Superior Service Award, and FDA's Award of Merit on three occasions. He received the Achievement Award from the American Association of Physicians for Human Rights and received the Presidential Meritorious Executive Rank Award.

MICHAEL T. OSTERHOLM, Ph.D., M.P.H., is the Chairman and Chief Executive Officer of the Infection Control Advisory Network. Previously, Dr. Osterholm was the State Epidemiologist and Chief of the Acute Disease Epidemiology Section for the Minnesota Department of Health. He is also an Adjunct Professor of the Division of Epidemiology, School of Public Health, at the Uni

versity of Minnesota. He has received numerous research awards from the National Institute of Allergy and Infectious Diseases and the Centers for Disease Control and Prevention (CDC). He serves as Principal Investigator for the CDC sponsored Emerging Infections Program in Minnesota. He has published more than 140 articles on various emerging infectious disease problems. He is past President of the Council of State and Territorial Epidemiologists and chairs its Committee on Public Health, and is a member of the Board of Scientific Counselors, National Centers for Infectious Diseases, CDC, and a member of the National Advisory Committee on Microbial Criteria for Foods, U.S. Department of Agriculture. He recently served as a member of the Committee on the Department of Defense Persian Gulf War Syndrome Comprehensive Clinical Evaluation Program of the Institute of Medicine.

DAVID M. SHLAES, M.D., Ph.D., is Vice President for Infectious Diseases Research at Wyeth-Ayerst Research. Before joining Wyeth-Ayerst, Dr. Shlaes was Professor of Medicine at the Case Western Reserve University School of Medicine and Chief of the Infectious Diseases Section and the Clinical Microbiology Unit at the Veterans Affairs Medical Center in Cleveland, Ohio. He has served as a grant reviewer for the U.S. Department of Veterans Affairs Infectious Diseases Merit Review Board and the National Institutes of Health Special Study Section on Biology of Mycobacteria. He has published widely in peerreviewed journals, and his interest is in antimicrobial agents and chemotherapy and antibiotic resistance.

JOHN D. SIEGFRIED, M.D., is Associate Vice President for Medical, Regulatory and Scientific Affairs at the Pharmaceutical Research and Manufacturers of America. Dr. Siegfried is a pediatrician with 25 years in clinical practice and for the past decade has been involved with pharmaceutical research and development in the medical and regulatory affairs section of the R.W. Johnson Pharmaceutical Research Institute. He began his career with the U.S. Public Health Service as Medical Officer on the Rosebud and the Redlake lndian Reservations and completed his active pediatric practice as Chief of Pediatrics and Chief of the Medical Staff at the Al Hada Hospital and Rehabilitation Center in Taif, Saudi Arabia. As a volunteer physician, Dr. Siegfried regularly staffs the Whitman Walker AIDS Clinic in the District of Columbia as well as its clinic for sexually transmitted diseases.

P. FREDERICK SPARLING, M.D., is a J. Herbert Bate Professor of Medicine, Microbiology and Immunology at the University of North Carolina (UNC) at Chapel Hill and is Director of the North Carolina Sexually Transmitted Infections Research Center. Previously, he served as Chair of the Department of Medicine and Chair of the Department of Microbiology and Immunology at UNC. He was president of the Infectious Disease Society of American in 1996–1997. He was also a member of the Institute of Medicine's Committee on Microbial Threats to Health (1991–1992). Dr. Sparling's laboratory research is in

the molecular biology of bacterial outer membrane proteins involved in pathogenesis, with a major emphasis on gonococci and meningococci. His current studies focus on the biochemistry and genetics of iron-scavenging mechanisms used by gonococci and meningococci and the structure and function of the gonococcal prion proteins. He is pursuing the goal of a vaccine for gonorrhea.

STUDY STAFF

JONATHAN R. DAVIS, Ph.D., is currently a Senior Program Officer at the Institute of Medicine (IOM). His primary charge is as Study Director of IOM's Forum on Emerging Infections and the Roundtable on Research and Development of Drugs, Biologics, and Medical Devices. Dr. Davis was formerly the Science Officer for the Emerging Infectious Diseases and HIV/AIDS Program in the U.S. Department of State's Bureau of Oceans and International Environmental and Scientific Affairs. Prior to his work at the State Department, Dr. Davis was an Assistant Professor of Medicine and Head of the Malaria Laboratory at the University of Maryland School of Medicine where he was the principal and co-principal investigator on grants investigating the fundamental biology of malaria transmission, and on the development and testing of candidate malaria vaccines in human volunteers. Dr. Davis has a M.S. in Medical Entomology and Parasitology from Clemson University, and a Ph.D. in Immunology and Infectious Diseases from The Johns Hopkins University School of Hygiene and Public Health. Dr. Davis is an *ad hoc* reviewer for several professional scientific journals, and currently holds adjunct faculty appointments at The Johns Hopkins University School of Hygiene and Public Health, the University of Maryland School of Medicine, and the Uniformed Services University School of the Health Sciences.

POLLY F. HARRISON, Ph.D., is the founder and head of the Alliance for Microbicide Development, an investigator-led consortium of small biopharmaceutical companies, scientists, and advocates whose objectives are to advocate for microbicide development and educate the public and policy communities about its importance; track and communicate product progress through the research and development pipeline; foster building of a funding base to support combination and comparative studies; improve the efficiency of preclinical development processes; and explore, research, and inform interested parties about critical topics. Before she founded the Alliance, Dr. Harrison worked for two decades in the developing world as a medical anthropologist and policy analyst in a range of activities related to women's health. She then went on to serve as Senior Program Officer at the Institute of Medicine (IOM) and as Director of its Division of International Health. In the former position, she established and directed the IOM's Forum on Emerging Infections. Her undergraduate and graduate degrees are from Mount Holyoke College and the Catholic University of America, respectively. She is a governing counselor of the American Public Health Association

and a fellow of the American Anthropological Association and serves as an adjunct professor at The Johns Hopkins University School for Advanced International Studies. Her personal research interests continue to center on ways to motivate the participation of the biopharmaceutical industry in developing products that have low perceived profitability but high value for worldwide public health.

VIVIAN P. NOLAN, M.A., is the Research Associate for the Forum on Emerging Infections and for the Roundtable on Research and Development of Drugs, Biologics, and Medical Devices. Before joining the Institute of Medicine (IOM), Ms. Nolan was a Science Assistant in the Division of Environmental Biology at the National Science Foundation (NSF) where she worked on grants administration, research projects, and policy analyses on environmental and conservation biology issues. Ms. Nolan is a recipient of a NSF Directors Award for the policy-oriented, interdisciplinary Water and Watersheds collaborative NSF-U.S. Environmental Protection Agency grants program. Ms. Nolan is pursuing her doctorate in environmental science and public policy from George Mason University. Her graduate work has included research and policy analysis on issues ranging from environmental, biodiversity conservation, sustainable development, human health, and emerging and reemerging infectious diseases. In August 1998, she participated in an educational program in Kenya that studied the relationship between ecological degradation and emerging infectious diseases. Ms. Nolan was awarded an M.A. in science, technology and public policy in 1994 from the George Washington University, and in 1987 she simultaneously earned two bachelor's degrees in international studies and Latin American studies.

NICOLE AMADO, was the Project Assistant for the Institute of Medicine's (IOM) Forum on Emerging Infections and for the IOM Roundtable on Research and Development of Drugs, Biologics, and Medical Devices. Ms. Amado was formerly a Project Coordinator for the Cystic Fibrosis Foundation. Prior to her work at the Cystic Fibrosis Foundation, she was a Panel Assistant with the Chemical Manufacturers Association. Ms. Amado has considerable experience in project organization, research and analysis, and administrative problem solving. Ms. Amado earned a bachelor's degree in biology from the University of Louisville in 1994.

CHRISTINA THACKER joined the Institute of Medicine's (IOM) Health Sciences Policy Division in January 1997. She worked as the Research Assistant on the IOM's Forum on Emerging Infections and the Roundtable on Research and Development of Drugs, Biologics, and Medical Devices. Before joining the IOM, Ms. Thacker worked on policy issues pertaining to legal immigration and advocated on behalf of immigrants and refugees in the United States. She received a bachelor's degree in history and German from Wake Forest University. Ms. Thacker is currently pursuing a law degree from the University of Michigan at Ann Arbor.

GRETCHEN KIDDER, is a Research Associate for the Alliance for Microbicide Development in Silver Spring, MD. She graduated from the University of Vermont with a B.S. in biology in 1991. Upon graduation, Ms. Kidder moved to Seattle, Washington, to begin graduate studies in epidemiology and work and research in the chlamydia laboratory at the University of Washington. She went on to research a primate model being developed to test microbicidal products. Ms. Kidder worked as a Research Assistant for the IOM's Forum on Emerging Infectious Diseases and the Roundtable on the Development of Drugs, Medical Devices, and Biologics at the Institute of Medicine until 1998.