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AHCPR
Agency for Health Care Policy and Research

2101 East Jefferson Street, Rockville, MD 20852
Public Affairs Branch 301/594-1364

FOR IMMEDIATE RELEASE
Wednesday, June 8, 1994

Contact: Public Health Service
(301) 594-1364
Bob Isquith ext. 173
Bob Griffin ext. 169
Paula Zeller ext. 148

AHCPR EXPANDS OUTCOMES RESEARCH

The U.S. Public Health Service's Agency for Health Care Policy and Research today announced the award of six grants, totaling approximately $33 million, to support a second generation of special clinical studies. The studies, known as Patient Outcomes Research Teams (PORT-II), are designed to determine "what works best" in clinical treatment for common diseases and conditions.

The grants were announced by Linda K. Demlo, Ph.D., AHCPR's acting administrator. "These new studies will further advance our understanding of what constitutes effective and cost effective health care," said Dr. Demlo. "Health care consumers, providers, and third party payers all will benefit from this research."

(more)

Richard Greene, M.D., Ph.D., director of AHCPR's Center for Medical Effectiveness Research, said that work is still underway on 14 first-generation PORTs, funded by the agency between 1989 and 1992. Those projects have succeeded in documenting the evidence, or lack thereof, in support of many current clinical practices, including radical surgery for localized prostate cancer, spinal fusion for low back pain, and gallbladder surgery in asymptomatic patients with gallstones. PORTs also have illuminated the importance of understanding patient preferences and other nonclinical variables that affect clinical decisions, and in developing new measures and methods for patient outcomes research.

The PORT-IIs, or second generation of PORTs, are designed to retain and build upon the basic goals of the original research program. They expand the original approach by permitting researchers to employ experimental, quasi-experimental or observational studies, as well as any appropriate clinical, epidemiological or social science methods and data that are available.

The six PORT-II grants announced today were awarded to:

o Georgetown University, Washington, D.C. ($6.8 million) Principal Investigator: Jack Hadley, Ph.D. (202) 342-0107 - A five-year project to determine the outcomes and cost-effectiveness of three common treatments for local breast

cancer in the elderly, including modified radical mastectomy, breast conserving surgery with radiotherapy and breast-conserving surgery without radiotherapy. Choice of treatment as well as short- and intermediate-term outcomes will be analyzed based on prospective data from a cohort of approximately 800 newly-diagnosed breast cancer patients, aged 65 or older. A retrospective analysis also will be conducted, based on random samples of breast cancer surgeons and their Medicare patients who were treated in 1992. This analysis is designed to validate and extend the treatment choice model to a national sample, and to measure 5-year outcomes.

- Stanford University School of Medicine, Stanford, CA. ($4.9 million) Principal Investigator: Mark A. Hlatky, M.D. (415) 723-6426 - A five-year study to develop a model to help physicians decide how best to screen and treat patients at risk for sudden cardiac death. Heart disease is the leading cause of death in the United States, and half of those deaths are sudden and unexpected, occurring within an hour of symptom onset. Cardiac arrhythmias, or irregular heartbeat, have been identified as strong risk factors for sudden cardiac death. Researchers will document in a prospective patient cohort the effectiveness of different management strategies, including use of implantible cardiac defibrillators, on patients' functional status, quality of life, health care cost, and mortality.

- The Johns Hopkins School of Medicine, Baltimore, MD. ($7.6 million) Principal Investigator: Oliver Schein, M.D., M.P.H (410) 955-8179 - A four-year study to determine the value of medical testing prior to cataract surgery. Laboratory tests, including blood count, electrolytes, chest X-ray and electrocardiogram, are routinely ordered for patients who undergo cataract surgery, at an annual cost of approximately $150 million, although the importance of these tests has not been shown. Twenty thousand patients aged 50 or older who are scheduled for cataract surgery will be randomized to receive, or not receive, the preoperative tests. Based on assessment of medical outcomes during cataract surgery, and up to one week post-operatively, researchers will develop recommendations on the appropriate use of preoperative medical tests.

- Massachusetts General Hospital, Boston, MA. ($6.0 million) Principal Investigator: Michael J. Barry, M.D. (617) 726-4106 - A five-year project to define current patterns of diagnosis and treatment of prostate disease, including benign prostatic hyperplasia (BPH) and localized prostate

cancer. This study will determine the optimal pattern of screening for prostate cancer with the tumor marker prostate specific antigen (PSA), better define the effectiveness of aggressive treatment of localized prostate cancer with radical prostatectomy or radiation therapy, and evaluate alternative treatments for BPH.

- Trustees of Health and Hospitals of the City of Boston, Inc., Boston, MA. ($500,000) Principal Investigator: Alan Meyers, M.D., M.P.H. (617) 534-4233 - A three-year project to evaluate the safety and effectiveness of homemade cereal-based oral rehydration solutions (ORS) for treating potentially fatal diarrheal dehydration among children aged 2-24 months of age. Diarrhea with dehydration is a common illness among young children, accounting for 10 percent of hospitalizations and 500 deaths per year among children under age five. Although commercial products are widely available, their cost may serve as an economic barrier to use by poor families, whose children are most likely to suffer diarrheal dehydration. Researchers will compare outcomes for patients treated with a commercial product with those who receive a homemade cereal-based preparation.

- The Johns Hopkins University School of Medicine, Baltimore, MD. ($7.5 million) Principal Investigator: Neil Powe, M.D., M.P.H., M.B.A. (410) 955-4128 - A five-year project to study factors that influence decisions about mode of dialysis for patients with end-stage renal disease (ESRD). Approximately 200,000 patients currently undergo chronic dialysis at a cost of $30,000 per year per patient; Medicare expenditures for dialysis now exceed $6 billion annually. Researchers will assess patient outcomes and costs of alternative dialysis prescriptions, and formulate optimal dialysis strategies that take into account the perspectives of patients, providers and payers.

AHCPR expects to award additional PORT-II grants during Fiscal Years 1995 and 1996. In addition to the 20 PORTS now underway, AHCPR is supporting approximately 85 other medical effectiveness research projects.

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Where We Are

Findings from MEDTEP studies are mounting, and several distinct kinds of products and benefits are starting to emerge. In the remaining time, I hope to peak your interest in some of the specific accomplishments and expected future findings of our outcomes research studies by focusing on examples of these.

- The PORT on **Low Back Pain** has conducted meta-analyses to ascertain the effectiveness of several widely used diagnostic tests (including myelography, magnetic resonance imaging, computed tomography, and thermography). The important, general finding has been the surprisingly poor quality of the medical literature on which current practice rests. The PORT has published articles identifying serious flaws in the design of research studies previously cited in support of the use of these tests, and suggesting that these tests are often used unnecessarily, or that one is used when another may be more specific and sensitive, or less invasive. Ongoing analyses by the PORT will help to define appropriate indications for each of these tests. Similar deficiencies in the quantity and quality of clinical evidence in support of one or another treatment have been reported by other PORTs based on critical and systematic evaluation of the available literature.

- Most PORTs have developed measures of functional status specific to the condition under study. For example, the Cataract PORT has developed a 14-question measure of visual function for assessing the extent to which cataracts affect a person's ability to perform usual activities, such as reading, driving, and other valued activities. This measure based on patient-reports has been widely endorsed as a valuable test of whether or when to remove the cataract -- a much better test than mere presence of cataract or traditional measures of visual acuity, glare, etc. The same measure can be used to assess the outcome of cataract surgery. The AHCPR panel which developed clinical practice guidelines for cataract emphasized the need for a measure of this type. Over 1,350,000 cataract procedures are performed annually.

- The PORT on community-acquired **Pneumonia** has focused on variations in the most expensive component of pneumonia care, i.e., hospitalization. Their work is leading to development of a measure for identifying patients who are at low risk of death or serious complications. They estimate that about 60% of pneumonia patients can be safely managed in ambulatory settings or with shorter hospital stays.

- The PORT on Prostate Disease has uncovered a virtual epidemic of surgery for localized prostate cancer, that flies in the face of the extraordinarily weak evidence that elderly men benefit, and evidence based on patient

surveys by the PORT that the risk of serious complications following surgery had been greatly understated. So compelling are these findings that the PORT has gained the confidence and support of the urological community, the Veterans Administration, and NCI which will collaborate in funding a controlled clinical trial for radical surgery vs. radiation vs. watchful waiting.

- A study in our pharmaceutical outcomes program has published an article in NEJM revealing troubling racial disparities in receipt of medication to prevent PCP among patients with HIV disease. 82% of whites but only 58% of African Americans whose CD4 cell counts (below 500) made them eligible were receiving PCP prophylaxis as recommended by NIH guidelines. The disparity was even greater for people with the lowest CD4 cell counts (below 200), all of whom should receive preventive therapy.

- Another study in our pharmaceutical outcomes program calls to question the value of early therapy with zidovudine. This study compared quality of life for patients with asymptomatic HIV infection receiving different doses of AZT and placebo. Differences in average time with neither a progression of disease nor an adverse event were significant, but small, ranging from 15.7 to 14.8 months. For patients receiving AZT in accordance with current recommednations, the increase in quality of life associated with delay in the progression to HIV disease is approximately the same as the decrease in quality of life due to severe side effects of therapy. Earlier studies, on which the treatment recommendations are based, **did not assess Q of L or cost.**

AHCPR

fact sheet

Agency for Health Care Policy and Research

June 1994

2101 East Jefferson Street, Rockville, MD 20852

Medical Treatment Effectiveness Program

Patient Outcomes Research Teams — PORTs and PORT-IIs

Establishment of the Agency for Health Care Policy and Research (AHCPR) and its Medical Treatment Effectiveness Program (MEDTEP) in 1989 brought major investment in a set of special studies known as Patient Outcomes Research Teams (PORTs). For clinical problems as diverse as cataract, childbirth, and schizophrenia, each of the 14 PORTs employs a similar, multimethod strategy to identify and address major questions of treatment effectiveness. These projects are succeeding in documenting the state of the evidence in support of many common clinical practices, identifying promising areas for research, and demonstrating the relative effectiveness and cost effectiveness of different interventions. They are also contributing to the development of clinical practice guidelines, illuminating the importance of understanding patient preferences and other nonclinical variables that affect clinical decisions, and developing new analytic methods and measures of outcomes. The original PORTs, all of which are 5-year projects, will conclude between mid-1994 and late 1997.

In July 1993, AHCPR initiated the second generation of PORT research, "PORT-II," with publication of a one-time Request for Applications. Ongoing interest in PORT-II studies is described in a May 1994 Program Announcement and the corresponding June 1994 Grant Announcement. PORT-IIs build on and retain the basic goals of the original PORTs. PORT-IIs continue the PORT tradition of developing important new evidence for clinical practice and breaking new methodological ground. They address outstanding issues of effectiveness and cost effectiveness in terms of the outcomes that matter to patients and the realities of clinical practice, from a multidisciplinary perspective and with multiple research methods. A common feature of PORT-II projects is their potential for developing convincing scientific evidence about the effectiveness, or ineffectiveness, of particular health care services and procedures for the prevention, diagnosis, treatment, or management of clinical conditions. Like all MEDTEP research, PORT-IIs address important questions regarding clinical conditions that are: (1) common, (2) associated with high cost, and (3) surrounded by open and documented controversies over which clinical strategies are best. Also, like all MEDTEP projects, the new PORTs address the dimension of "effectiveness," i.e., does the intervention work in the typical clinical setting, for the typical patient? Wide generalizability of research findings, to the entire population or to major subgroups, is a hallmark of MEDTEP research.

PORT-IIs do not use the standardized approach of the original PORT model; instead, they employ whatever individual methods and combinations of methods can most efficiently answer the questions at hand. PORT-IIs may use experimental, quasi-experimental, or observational study designs; any appropriate clinical, epidemiologic, or social science method(s); and any appropriate data.

In assessing effectiveness, PORT-IIs measure a broad set of patient outcomes that emphasize the patient's perspective. This includes survival, symptom relief, quality of life, functional status and costs, both short- and long-term. PORT-IIs also consider how patient preferences influence evaluations of effectiveness and cost effectiveness. Different patients with similar conditions weigh differently the costs, risks, and benefits of the same treatment options; there may be no single "optimal" treatment — or outcome — for all patients.

The first six PORT-IIs, representing a first-year investment of $7 million, were awarded in mid-1994. They expand AHCPR's "portfolio" beyond the mainly hospital-based conditions emphasized in the original PORTs and add attention to women's health issues and clinical problems in ambulatory care settings. These projects are listed on the back page.

U.S. Department of Health and Human Services
Public Health Service

FY 1994 PORT-II Awards

Project Title
Principal Investigator, Institution
Project Period

PORT-II for Prostatic Diseases
Michael Barry, M.D., Massachusetts General Hospital
September 1, 1994 to August 31, 1999

Care, Costs, and Outcomes of Local Breast Cancer
Jack Hadley, Ph.D., Georgetown University
September 30, 1994 to September 29, 1999

Cardiac Arrhythmia PORT
Mark Hlatky, M.D., Stanford University
August 1, 1994 to July 30, 1999

Homemade Cereal-Based Oral Rehydration Therapy
Alan Meyers, M.D., Health and Hospitals of the City of Boston
July 1, 1994 to June 30, 1997

Dialysis Care: Choices, Outcomes, Costs and Tradeoffs
Neil Powe, M.D., Johns Hopkins University
July 1, 1994 to June 30, 1999

Value of Medical Testing Prior to Cataract Surgery
Oliver Schein, M.D., Johns Hopkins University
September 1, 1994 to August 31, 1998

AHCPR anticipates award of additional PORT-IIs during fiscal years 1995 and 1996. Interested investigators should obtain a copy of the June 1994 PORT-II Grant Announcement, AHCPR Publication No. 94-0077. Copies of this Grant Announcement, as well as complete application kits, may be obtained by contacting Global Exchange Inc., 7910 Woodmont Avenue, Suite 400, Bethesda, MD 20814-3015; telephone: (301) 656-3100, Fax: (301) 652-5264. Investigators are also encouraged to contact the Center for Medical Effectiveness Research (CMER) to discuss research interests. CMER's telephone number is: (301) 594-1485. PORT-II applications use the R01 grant mechanism, and applications (on form PHS No. 398) may be submitted for any of the recurring receipt dates of October 1, February 1, and June 1.

U.S. Department of Health and Human Services

Public Health Service
Agency for Health Care Policy and Research
Executive Office Center, Suite 501
2101 East Jefferson Street
Rockville, MD 20852

Official Business
Penalty for Private Use $300

AHCPR

AHCPR Pub. No. 94-0083
June 1994

DEPARTMENT OF HEALTH AND HUMAN SERVICES
U.S. PUBLIC HEALTH SERVICE

Agency for Health Care Policy and Research
Office of Program Development
Program Planning, Research Development, and Evaluation Branch

Executive Office Center
2101 East Jefferson Street, Suite 603
Rockville, Maryland 20852
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TO:	FAX number:	202 456-7431
	Name:	Karen Guss
	Organization:	Old Exec. Ofc. Bldg.
	Telephone:	202 456-5603

FROM:	Name:	Irma E. Arispe, Ph.D. Evaluation Officer
	FAX Number:	(301) 594-2157

Number of pages including this page:

MESSAGE: March 28, 1995

Medical Effectiveness Research

Question:

How does medical effectiveness research improve quality of care? Can you give examples?

Answer:

Outcomes and effectiveness research improves quality in two ways.

First, outcomes and effectiveness research answers the question, "What treatment works and what does not?" for typical patients seen by typical practitioners in many different community settings. This is different from research at NIH where clinical trials are done in very controlled situations with highly selected patient. It also means that outcomes research looks at practices that are already in use today, rather than just focusing on new treatments. In this way, the findings help doctors and patients to choose treatments that are truly effective.

For example, the PORT on back pain showed that there was no evidence that a particular type of back surgery was effective in the treatment of certain back problems.

Second, outcomes and effectiveness research evaluates any treatment or intervention against a broad range of outcomes, not just whether the disease was cured. In other words, outcomes research allows one to broaden the concept of "quality" to encompass patient preferences and satisfaction. Particular outcomes or complications of treatment have different values or importance to different individuals.

Need for Federal Role in Health Services Research

Question:

Why should the Federal government be involved in health services research? Shouldn't this be left to the private sector?

Answer:

Private sector organizations often focus on particular markets or areas for expansion based on portability. The Federal government is in the position of looking at markets from a different perspective and addresses issues such as underserved ares or oversaturated areas where costs are rising despite cost containment measures.

The Federal government can examine issues such as quality of care and access to care on a national scale, unlike private sector organizations that are inclined to focus on narrow issues in particular geographical areas or markets.

As the largest payor of health care services in the country the Federal government also has an obligation to the taxpayers and beneficiaries of its programs to assure the most effective and efficient means of delivering and financing such services.

Resources for research and development in the private sector are limited and there is a shortage of persons available with the expertise needed to conduct health services research, a Federal agency can make the most efficient use of limited skills and personnel by bringing together scientists, clinicians, and others to conduct research in a central location.

- Federally-supported health services research represents the best chance for policy makers to have ready access to unbiased, accurate information.

Clinical Practice Guidelines

Question:

Why should the Federal government be involved in the development of clinical practice guidelines, especially when specialty societies and professional medical associations are developing their own? Why can't this activity be privatized?

Answer:

There are multiple reasons for a continued Federal role in the development of practice guidelines.

1) The guidelines supported by AHCPR are a public good that can be shared with all interested parties. The guidelines can be used by health care providers in all types of delivery settings--managed care plans, fee-for-service practice, or in HMOs.

2) The Federal government is the largest payer of health care services in this country. Through the Medicare, Medicaid, FEHB, CHAMPUS, VA and DoD health programs, the Federal government finances (directly and indirectly) nearly 40% of all health care delivered in this country. The costs of this care are growing rapidly. Thus, merely from a budgetary perspective, the Federal government has a substantial interest in the development and use of practice guidelines that can reduce costs, while increasing the quality, effectiveness and efficiency of health services.

3) AHCPR is viewed as an impartial agency. It has neither operational responsibilities for any Federal health program, nor is it linked to any particular research agenda. Thus, it serves as a moderator among parties with conflicting interests. They are not influenced by competing economic motives of providers or purchasers which could bias their recommendations.

Coordination Between Agencies to Develop and Implement Quality Measures

Q: What efforts are being made to coordinate government activities to develop and implement quality indicators?

A: A number of efforts across agencies in the Department of Health and Human Services ensure coordination in the development, testing and implementation of quality indicators. Each agency contributes its own expertise while building on the experience and skills of other Agencies.

For example, within the Public Health Service, HRSA, SAMSHA, and CDC are working together to develop a consolidated set of performance indicators to assess the quality of health care in the programs funded under block grants. The Health Resources and Services Administration (HRSA), which is concerned with access to and quality of care provided in maternal child health programs; rural and migrant health care programs; and care provided to persons with AIDS, focuses on the implementation of quality measures in state and local health care settings which deliver these services. The CDC's programs are more closely concerned with population based assessment of health status, and measures related to preventive services. The Substance Abuse and Mental Health Services Administration (SAMHSA) is concerned specifically with issues related to the prevention and treatment of addictive and mental disorders. Finally, AHCPR, through its focus and experience in medical effectiveness and health services research, contributes the science based quality measurement tools which permit the assessment of clinical quality of care. PHS workgroups ensure ongoing communication among all the agencies.

AHCPR focuses on the development of quality indicators for use across all age groups and medical conditions. Many of the indicators useful for assessing quality provided to beneficiaries in the Medicare program, are used by the Health Care Financing Administration as well as by other organizations for quality oversight and quality improvement efforts. AHCPR is also compiling a centralized information source on clinical performance measures, including measures used in DHHS agencies and in other public as well as private sector health care organizations.

CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

NIOSH

National Institute for Occupational Safety and Health
Office of the Director
200 Independence Avenue, SW
Room 317B, HHH Bg.
Washington, D.C. 20201
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Fax: 202/260-4464

FACSIMILE TRANSMISSION

DATE: 3/24/95 PAGES: 17 (including cover)

TO: Karen Guss

PHONE: 456-5603 FAX: 456-7431

FROM: **Sharon Morris, Special Assistant to the Director**

NOTE: These are some briefing materials on TB respirators and the NIOSH respirator regulations. I will be gone from March 27-April 7. If you have questions call

Bryan Hardin for technical questions - 205-8556
Kathy Sykes for policy questions - [redacted] 401-3740

NIOSH RESPIRATOR REGULATION
42 CFR Part 84

BACKGROUND

Beginning with the Federal Coal Mine Health and Safety Act of 1969, respirators have been certified by HHS and DOL under an antiquated dual-department regulatory program contained in 30 CFR Part 11, as originally promulgated in 1972. Since that time NIOSH has had principal responsibility for respirator testing and certification.

NIOSH has been frustrated in attempts that began in the late 1970s to revise these regulations. Obstacles to change have been:

Technical complexity and the broad scope of change involved in a single, comprehensive revision of 30 CFR 11, and

The complication of coordinating revisions between two separate agencies--the Mine Safety and Health Administration (MSHA) within DOL and NIOSH within HHS.

In 1985 MSHA and OMB agreed that NIOSH should have the lead responsibility in revising these old rules.

In 1987 NIOSH published an NPRM that would have recodified 30 CFR 11 as HHS regulations at 42 CFR Part 84 while at the same time comprehensively revising them. MSHA concurrently published a proposal to eliminate the old 30 CFR 11 once the new 42 CFR 84 was finalized. This attempted regulatory reform failed due to the complexity of the comprehensive revision and resistance by respirator manufacturers. Reforms that were generally recognized as needed and beneficial could not be achieved because of resistance to a limited number of issues.

To minimize these problems, NIOSH has now adopted a modular approach to this rulemaking. A series of modules will address various aspects of the 1987 NPRM and additional issues subsequently identified. They will be proposed in sequence with a separate notice and comment period for each module.

This is the first of these modules. Addressing the greatest public health priority first, it will:

Recodify 30 CFR 11 in its entirety to 42 CFR 84,

Limit the joint role for MSHA to respirators used for mine emergencies and mine rescue,

Introduce new filter efficiency tests to resolve recognized leakage problems with some current filters, and

Establish 'sunset' dates after which filters certified under 30 CFR 11 may no longer be manufactured, distributed, or sold.

PUBLIC HEALTH SIGNIFICANCE

FILTER LEAKAGE: Since 1987 four independent studies have shown that some certified dust/mist (DM) and dust/fume/mist (DFM) respirators allow unacceptable leakage through their filters of the small-size (<2 micron) particles that are most likely to reach the deep lung and cause respiratory problems. NIOSH issued a report on those data in 1992, and scientific and manufacturer reviewers agreed that the data showed significant filter leakage problems with many disposable respirators certified under 30 CFR 11. These studies raise serious public health concerns and underscore the urgent need to remove regulatory impediments to a new generation of respirators.

TUBERCULOSIS: CDC has published draft (1993) and final (1994) guidelines for preventing the transmission of tuberculosis in health-care facilities. Those CDC guidelines established minimum performance criteria that are met only by the most protective class of respirators (HEPA) certified under 30 CFR 11. These respirators are the most expensive type and also have high breathing resistance, which makes them uncomfortable for some individuals to use. The new generation of respirators is urgently desired by the health-care industry to ease problems in protecting workers against tuberculosis and to help hold down health care costs. All filters certified under 42 CFR 84 will exceed the CDC performance criteria.

ISSUES AND CONTROVERSIES

RESPIRATOR MANUFACTURERS: Some manufacturers are prepared now to submit filters for certification under the new protocols specified in 42 CFR 84. Others are not and they may raise objections because they may be at a competitive disadvantage if they cannot quickly produce the new generation of filters. The manufacturers' trade association and most companies, including the largest single manufacturer of respirators, have been supportive of the modular approach to reforming respirator regulations in general and of this module in particular.

HEALTH CARE: This industry is anxiously awaiting the new generation of filters. The use of respirators for protection against TB is new to this industry. They reluctantly used DM or DFM respirators prior to the 1993 draft CDC guidelines. Since that time they have been forced to use HEPA-filter respirators because that is the only currently available class that meets the CDC criteria. HEPA respirators are significantly more expensive than DM or DFM respirators. A single-use HEPA filter respirator generally costs $7 to $10, while single-use non-HEPA respirators cost $1 to $8 when purchased in bulk. The health care industry has claimed that use of HEPA filters adds enormously to the annual cost of health care nationwide. Some of the new generation of filters certified under 42 CFR 84 will be introduced at prices comparable to DFM respirators. Costs are expected to decline in time as competition among manufacturers increases. The health care industry is therefore extremely anxious for the new filter classes to be available.

PUBLIC COMMENT

NIOSH published a proposed rule (59 FR 26850) to establish a new 42 CFR part 84, on May 24, 1994. On May 26, 1994, NIOSH published a notice in the Federal Register (59 FR 27257) for an extension of the public comment period and a rescheduling of a public meeting. A public meeting was held to obtain comments on the proposal in Washington, D.C. on June 23-24, 1994.

A total of 303 comments on the proposal were received from safety professionals, respirator manufacturers, representatives of industrial and health-care facilities, and workers' associations. The distribution of these comments was 126 from health-care workers; 96 from health-care facilities; 15 from associations of health-care professionals; 17 from trade or manufacturers' associations, 8 private citizens; 6 regulatory agencies (federal, state, county); 5 respiratory protection experts; 3 workers' organizations; 2 instrument manufacturers; 1 representative of industrial hygiene professionals; and 1 Federal Advisory Committee.

MODULAR APPROACH

The modular approach will allow improvements to be implemented on a priority basis and facilitate adaptation to new requirements by the manufacturers and users of respirators. It will minimize the potential for disruption in the supply of certified respirators and facilitate public participation in rulemaking. Some anticipated future modules are:

Assigned Protection Factors

Fit Testing

Powered Air Purifying Respirators

Quality Assurance Requirements

Gas and Vapor Requirements

Positive Pressure SCBA Requirements

Simulated Workplace Protection Factor Test

Administrative Program (application submittal and processing, fee structure, etc.)

ICAAC - Talking Points

I. Introduction

A. National outbreak of TB has led to increasing occupational exposure to *M. tuberculosis.*

B. At risk for exposure: occupational groups at risk for silicosis, workers in institutional settings such as hospitals, residential care facilities, nursing homes, correctional facilities, homeless shelters, and autopsy rooms.

C. Occupationally acquired TB is avoidable and preventable.

II. Hierarchy of Controls

A. Early recognition and treatment are vital to overall reduction of TB.

B. Prevention also requires the use of industrial hygiene controls, including engineering controls, administrative controls, and personal protective equipment.

1. Engineering Controls (Slide 1 - Engineering Controls)

a. Function primarily by isolating the hazard from the worker

b. Negative pressure isolation rooms for any suspected or known TB patient will minimize the spread of droplet nuclei outside the patient room.

c. Local exhaust ventilation, general ventilation, and ultraviolet germicidal irradiation (UVGI) can also be employed inside of such isolation rooms to inactivate, remove and/or dilute TB droplet nuclei.

2. Administrative Controls (Slide 2 - Administrative Controls)

   a. Identification and isolation of patients

   b. All workers in health care facilities, not just those providing direct patient care, should have frequent purified-protein derivative (tuberculin) skin tests.

   c. All facilities should emphasize worker training and education.

3. Personal Protective Equipment (Slide 3 - Personal Protective Equipment)

   a. Since (pulmonary) TB is transmitted by inhalation of airborne droplet nuclei contaminated with *M. tuberculosis*, respiratory protective devices are also vital in protecting workers.

   b. Each of the recommendations CDC and OSHA have made concerning control measures to protect health care workers have included worker respiratory protective devices.

III. CDC/NIOSH/OSHA Respirators Recommendations (Slide 4 - Timeline of Recommendations)

A. 1990 CDC Tuberculosis Guidelines

1. Stated that "surgical masks may not be effective in preventing inhalation of droplet nuclei."

2. Recommended the use of disposable "particulate respirators," while acknowledging that "the efficacy of particulate respirators in protecting susceptible persons from inhalation of tuberculosis has not been demonstrated."

3. Particulate respirator was defined generally as a disposable respiratory protective device that is designed to filter out particles 1-5 microns in diameter, with no specific reference to the three classes of dust-mist, dust-fume-mist, or high-efficiency air (HEPA) filters as certified under Federal regulations (31 CFR Part 11) which were published in 1972.

4. Since the generic term particulate respirator was used, the implication was that any of these three filter types would meet the intent of the 1990 Guidelines.

B. NIOSH 1992 Guidelines (Slide 5 - 1992 NIOSH Recommended Guidelines)

1. In a 1992 draft report, NIOSH presented peer reviewed data showing that there was significant leakage of small size particles ($\leq$ 2 microns) through the filters of certain dust-mist and dust-fume-mist respirators.

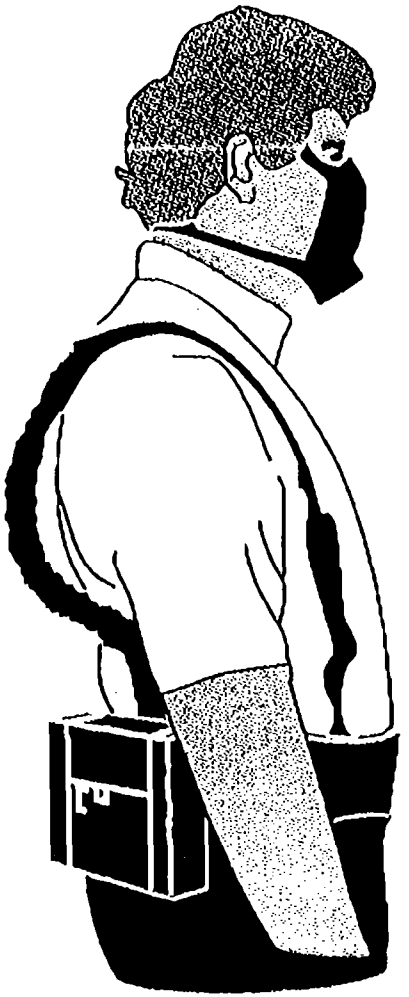
2. In August 1992, OSHA made a formal request to NIOSH to recommend which respirator should be required for health care workers to prevent occupational acquisition of TB.

3. NIOSH recommended:

   a. In areas where potential or confirmed TB patients were being cared for -- the use of NIOSH-certified, halfmask respirators equipped with high-efficiency particulate (HEPA) filters. (Slide 6 - PAPR picture)

   b. In the most hazardous locations/procedures (bronchoscopies etc.) -- air-line supplied, positive pressure, half-mask respirators. (Slide 7 - Air-line Supplied picture)

PAPR



Air-Line Supplied

C. 1993 CDC Draft Guidelines (Slide 8 - Timeline of Recommendations)

1. Issued in response to increasing reports of outbreaks of both drug-susceptible and multidrug-resistant TB, and growing concern about transmissions from patient-to-patient and patient-to-health care worker.

2. Emphasized hierarchy of controls.

3. Outlined respirator performance criteria.

4. Stated that only HEPAs were known to consistently meet or exceed performance criteria, although some dust-mist or dust-fume-mist respirators might.

5. Only HEPAs are certified by NIOSH, as required by OSHA.

D. 1993 OSHA Compliance Memo

1. Relies on the hierarchy of controls and requires respirators in those situations CDC has identified where engineering and other controls would not be effective in preventing worker exposure.

2. Requires that all respiratory protective devices be certified by NIOSH.

3. Working to develop standard for occupational exposure to TB.

E. 1994 NIOSH concurs with CDC

1. Reviewed interim status of research and events subsequent to the 1992 NIOSH respirator recommendations.

2. In the place of the Institute's 1992 recommendation (PAPRs), NIOSH now recommends that workers exposed to patients with infectious tuberculosis wear respirators that meet the CDC performance criteria.

F. CDC Final Guidelines

1. Modified after receiving extensive public comment

2. Respirator Criteria (Slide 9 - CDC Final Guidelines - October 1994)

   a. Filter efficiency of $\geq$ 95%, for 1 micron particles, at flow rates of up to 50 L per minute

   b. Fit tested to obtain a face-seal leakage of $\leq$ 10%

   c. Fit the different facial sizes and characteristics of HCWs, which can usually be met by making the respirators available in at least three sizes

   d. Ability to be checked for facepiece fit, at each use, in accordance with standards established by OSHA and good industrial hygiene practice

3. (Slide 10 - CDC Final Guidelines Quote) In selected settings, a level of respiratory protection exceeding the standard criteria and compatible with patient-care delivery (e.g. more protective negative-pressure respirators; powered air-purifying particulate respirators [PAPRs]; or positive-pressure air-line half-mask respirators) should be used.

G. NIOSH revision of respirator regulations

1. Respirators with high-efficiency particulate air (HEPA) filters are the only NIOSH-certified devices that meet or exceed the standard criteria in CDC's Final Guidelines and meet OSHA's respiratory protection standard.

2. While some believe that dust-mist and dust-fume-mist filters can be effective in preventing the transmission of TB, there is currently no certification procedure to evaluate their ability to meet the CDC criteria.

3. NIOSH has been working for some time to upgrade existing procedures for testing and certifying respirators. (Slide 11 - Respiratory Protection Against M. Tuberculosis)

4. NIOSH has adopted a modular approach to respirator certification revision.

   a. Seven modules have been proposed

   b. First module would revise respirator filter penetration tests and remove the regulations that currently impede marketing new generation respirators.

   c. The new certification process includes testing respirators with a particle size of approximately .3 microns and will certify respirators at three levels of filter efficiency (i.e., 99.97%, 99%, and 95%).

5. Improved testing requirements will enable manufacturers to produce more practical and economical respirators that will satisfy the criteria in the CDC Final Guidelines and the OSHA Compliance Memorandum.

6. These new regulations have been placed on an accelerated schedule and should result in a final rule sometime this year.

IV. NIOSH Efforts (Slide 12 - NIOSH Efforts)

A. Revising respirator regulations

B. Evaluating Engineering Controls

1. Evaluating efficacy of UVGI as a control method for TB -- in collaborative effort with CDC's National Center for Prevention Services and National Center for Infectious Diseases.

2. Evaluating four ventilation configurations in a study of local exhaust and general ventilation in health care facilities.

C. Developing sampling methods for *M.tuberculosis* for industrial hygienists to use in evaluating biological indoor air contaminants in settings where exposure to TB is likely.

D. At the request of workers and employers, NIOSH has also conducted various health hazard evaluations focusing on the transmission of TB (including multi-drug resistant strains) in health care and other workplace settings.

Tracie –

MEMORANDUM

TO: Nelson Reyneri
FROM: Karen Guss
DATE: March 24, 1995
RE: Carol Rasco's remarks

Carol Rasco will be addressing the Society for Healthcare Epidemiology of America's annual scientific and planning meeting. SHEA's "mission statement" follows this memo.

The bulk of Carol's speech will be about health care reform. However, she will also be addressing some of the specific concerns of SHEA's organization. One of these concerns is regulations that affect the health of hospital personnel. I'd like for Carol to be able to talk briefly about what is going on at OSHA with respect to such regulations. Carol will also be taking questions.

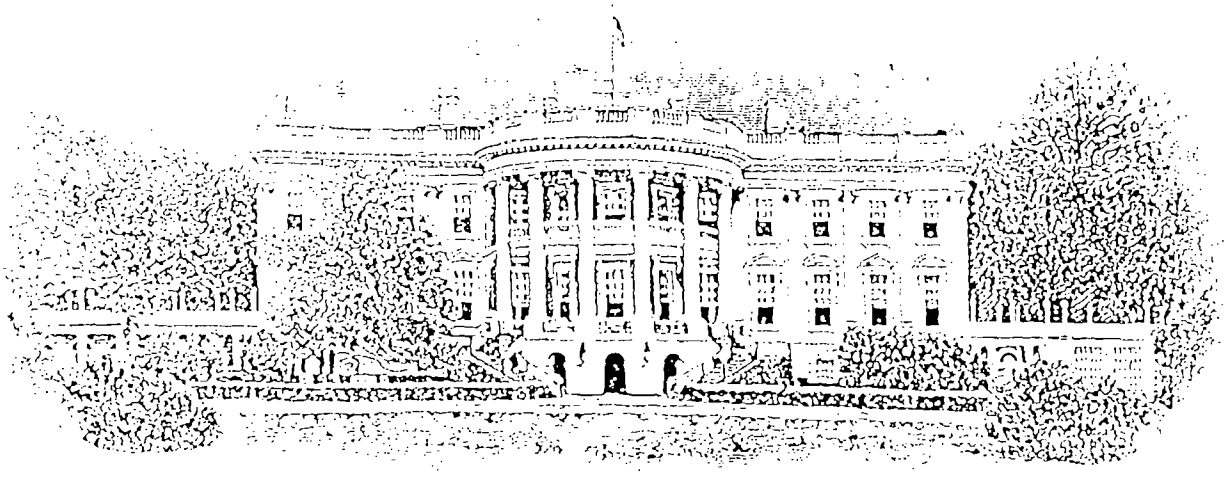
What would be most helpful to me would be:

- a couple of paragraphs about activity at OSHA that relates to SHEA's interest in health care employee health regulations
- Q & As that flag any hot and/or controversial issues that are likely to be asked about by this group

I hope to have this information by early Tuesday. Please let me know if this timeframe will not work for you. I can be reached at 456-5603 and my fax number is 456-7431.

Thank you in advance for your assistance.

The White House



DOMESTIC POLICY

FACSIMILE TRANSMISSION COVER SHEET

TO: Nelson Reyneri

FAX NUMBER: 219-6064

TELEPHONE NUMBER: 219 6092

FROM: Karen Guss

TELEPHONE NUMBER: 456 5603
FAX 456 7431

PAGES (INCLUDING COVER): 4

COMMENTS: Thanks! Please call me if you need more information.

Karen

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES • Public Health Service

CDC

CENTERS FOR DISEASE CONTROL AND PREVENTION

"The Nation's Prevention Agency"

CENTERS FOR DISEASE CONTROL
AND PREVENTION
Washington Office
202-690-8598
FAX: 202-690-7519

DATE 3/27/95 PAGES 7 + Cover

TO Karen Kuss
The White House

Phone: 456-5603

Fax: 456 7431

FROM Robert Irwin

Phone:

COMMENTS/NOTES

March 27, 1995

THE CHILDHOOD IMMUNIZATION INITIATIVE

The goals of the Childhood Immunization Initiative (CII) are to strengthen efforts to immunize children and to reduce or eliminate vaccine preventable diseases. Specifically, the CII seeks to increase vaccination levels for two-year-olds to at least 90 percent for the initial and most critical doses in the vaccine series by 1996.

The Centers for Disease Control and Prevention, along with its public and private sector partners, is making progress to meet these goals. Immunization coverage levels for 1993 (the most recent year for which complete data are available) were the highest ever reported, although almost two million 19-35 month old children were still not yet fully immunized.

The CII consists of the following five broad areas:

-- Improving the quality and quantity of vaccination delivery services.

--Reducing vaccine costs for parents through the Vaccines for Children Program (VFC).

--Increasing community participation, education, and partnerships.

--Improving disease surveillance and vaccination coverage.

--Improve Vaccines and vaccine use.

THE CHILDHOOD IMMUNIZATION INITIATIVE IMPLEMENTATION AND CURRENT ISSUES

The Childhood Immunization Initiative (CII) aims to strengthen efforts to immunize children and prevent disease. Specific goals of the program include eliminating or reducing vaccine preventable diseases, increasing vaccination levels for 2-year-old children to at least 90 percent for the initial and most critical doses in the vaccine series, and building a vaccine delivery system to maintain these achievements in the United States. The Centers for Disease Control and Prevention, along with its public and private sector partners, is making progress to meet these goals. Immunization coverage levels for 1993 were the highest ever reported, although almost 2 million 19-35 month old children were still not yet fully immunized. Based on 1994 reporting to date, national goals for the elimination of diphtheria, polio due to wild virus, tetanus in children less than 15 years of age, and congenital rubella syndrome are close to being met. The CII focuses on five broad areas of activity designed to attain the goals for 1996 and beyond. The following information covers progress and issues related to each area of the CII.

I. IMPROVING THE QUALITY AND QUANTITY OF VACCINATION DELIVERY SERVICES

- In September 1994, CDC awarded $33 million in incentive awards to States which fully vaccinated at least 50 percent of children by 2 years of age.
- An additional $38 million was awarded to States meeting immunization coverage objectives in their Immunization Action Plans (IAP).
- $86 million was awarded to States in January, 1995 to strengthen IAP activities.
- CDC has been examining strategies to increase immunization levels in addition to implementing the VFC program. Recent studies have identified several program areas with the potential to have a significant impact in achieving immunization goals -- linkages with WIC, clinic assessments, reminder/recall systems and eliminating missed opportunities. CDC is working with its partners to implement these activities.
- CDC supports efforts to develop immunization registry systems to monitor vaccination levels in States. In FY94, CDC awarded a total of $8.3 million to assist in the development of integrated registry systems in each State. An additional $8.3 million will be awarded in FY95 to supplement these efforts.

II. REDUCING VACCINE COSTS FOR PARENTS THROUGH THE VACCINES FOR CHILDREN PROGRAM (VFC)

Current survey results from the States indicate the VFC program is continuing to move ahead:

- 36 States have reported a centralized distribution system is in place to ship vaccines to both public and private providers. 13 States and the District of Columbia distribute vaccine to only a portion of enrolled providers (combination system). Of these, 6 States are proposing to wait for the establishment of an alternative vaccine distribution system by CDC to deliver to remaining providers. Alaska has elected not to participate in the VFC program.

- Over 20,000 private provider sites were enrolled in the VFC program as of mid-January, 1995.

- Almost 8,000 public provider sites are enrolled in VFC. Public clinics include Health Departments, Migrant and Community Health Centers, Rural Health Centers, Indian Health Centers, and clinics at public hospitals.

- 16 States reported they are universal and purchase vaccines for all children served by both public and private providers, up from 12 States prior to the initiation of VFC. Universal States make publicly purchased vaccine available to ALL providers to immunize ALL children in their practices.

- States are continuing to enroll public and private providers.

- The VFC ordering system is operating effectively. As of mid-January, over 1300 bulk VFC/317 orders have been processed, totaling over $127 million in vaccine purchases.

III. INCREASING COMMUNITY PARTICIPATION, EDUCATION, AND PARTNERSHIPS

- The outreach components of the CII are designed to increase awareness of child immunization, enhance community participation, and expand public-private partnerships. Outreach coordinators in the HHS regions facilitate coordination among the many public and private sector organizations working in the childhood immunization effort, and provide training and assistance in coalition building and communications strategies.

- Regional outreach meetings were convened this fall throughout the country and brought together thousands of individuals from all sectors of the community including those from health, business, government, religious, civic, and community organizations. The purpose of the meetings was to facilitate greater coordination among these organizations and to provide a forum for exchange of ideas about successful strategies at the state and community level. Keynote speakers included Secretary Shalala and Dr. Satcher.

- CDC is teaming up with the business and entertainment communities to promote

childhood immunization. Organizations such as McDonald's, Gerber and General Mills are including immunization messages in their marketing and promotional activities and singer Bonnie Raitt publicized local immunization efforts during her recent concert tour.

- CII outreach efforts are getting the immunization message out to the public through television, radio, outdoor and print public service announcements. As of September 1994, more than $1.5 million in free media has been generated and over 10,000 billboards installed. In addition, a national toll-free hotline was established to give all parents a place to get basic information about child immunization and to link parents with a local source of information.

- Education and training activities are an important component of CDC's program. In January 1995, CDC conducted, by satellite, the first live nationwide interactive course on the epidemiology and prevention of vaccine-preventable diseases. Over 17,000 individuals participated in this well-received seminar. The course is designed for physicians, nurses, volunteers, and others who manage and work in immunization, communicable disease, and/or infection control programs.

- CDC is building and strengthening partnerships with national organizations and other Federal agencies. CDC has joined forces with the AMA to develop new immunization curriculum materials for undergraduate, residency, and continuing medical education. In addition, the CII is fostering collaboration with HCFA, USDA, Head Start and the Corporation for National Service (Americorps).

IV. IMPROVE DISEASE SURVEILLANCE AND VACCINATION COVERAGE

- Vaccination coverage levels have improved between 1992 and 1993. National Health Interview Survey data report up-to-date coverage levels (4DTP/3OPV/1MMR) are 67 percent in 1993, up from 55 percent in 1992. (See Appendix I)

- CDC is making gains in disease prevention. Cases of rubella and *Haemophilus influenzae* type b (Hib) are at or near all time low levels, and CDC has received provisional reports of 895 cases of measles in 1994. While this is higher than last year, it is the second lowest number of measles cases ever reported, and activity during the last few months is at record or near record low levels. (See Appendix II)

V. IMPROVE VACCINES AND VACCINE USE

- A working group of the Advisory Committee on Immunization Practices, the American Academy of Pediatrics, and the American Academy of Family Physicians has completed work on developing a harmonized childhood immunization schedule. The new simplified schedule was introduced in January 1995.

- The Advisory Committee on Immunization Practices met on October 19-20 and voted unanimously to recommend that all children age 11-12 years should be given Hepatitis B vaccine if they have not previously received this vaccine as infants. This recommendation for universal Hepatitis B vaccination of adolescents will be incorporated into a revised Hepatitis B statement which will be presented to the Committee at the February meeting. Also during the February meeting, ACIP is

expected to vote on whether this recommendation should be included in VFC.

Immunization Levels of 19-35 Month Old Children United States 1992 and 1993, Goals for 1996 and 2000

Vaccine	1992	1993	Goals 1996	Goals 2000
DTP 3+	83%	88%	90%	90%
DTP 4	59%	72%	-	90%
OPV 3	72%	79%	90%	90%
Measles-containing	83%	84%	90%	90%
4DTP/3OPV/1MMR	55%	67%	-	90%
Hib 3+	28%	55%	90%	90%
Hep B3	-	-	70%	90%

Comparison of Cases of Vaccine Preventable Diseases 1988 - 1992 and 1993

	Median annual cases 1988 - 1992	1993
Diphtheria	4	0
Measles	9,643	312
Mumps	4,866	1,692
Pertussis	4,083	6,586
Polio (paralytic)	9	3
Rubella	396	192
CRS	11	5
Tetanus	53	48
Hep B	21,102	13,361
Haemophilus influenzae	2,764*	1,419

* Cases reported in 1991, not previously notifiable nationally

SHEA *The Society for Healthcare Epidemiology of America, Inc.*

TO:
Karen Guss
Fax: 202-456-7431

FROM: BPS
Bryan Simmons, M.D.
President, SHEA

SUBJECT:
Carol Rasco's speech

DATE:
March 23, 1995

There are no official SHEA legislative initiatives. However, I will give you my personal "wish list". I think many SHEA members will agree with this list.

First, there is a need for a uniform system of quality measures, sometimes called "indicators", that can be used to compare the quality of care provided by healthcare systems. This objective was mentioned in President Clinton's draft health reform bill. I have attached several pages of this draft. According to the plan a National Health Board would establish a national quality management system and manage a "performance-based system of quality management." The draft plan also states that "to measure quality, the Board develops and implements standards to establish a National Health Information System." This need still exists. The Joint Commission on Accreditation of Health Care Organizations (JCAHO) planned to establish a common set of quality indicators to be used by all hospitals. However, resistance to this plan has resulted in new JCAHO plans to allow a variety of non-comparable quality indicator systems. The government should facilitate the study of proposed national quality indicator systems in order to ensure valid and fair comparisons among healthcare institutions. SHEA is currently working with JCAHO on a plan to study indicators.

Second, the Centers for Disease Control (CDC) in Atlanta should expand its mission into healthcare quality management in partnership with JCAHO and key professional organizations. CDC is the world's leading authority on using epidemiology to improve public health. The study of quality indicators is basically an epidemiology study. In fact, most quality management in healthcare would

benefit greatly from the science of epidemiology. The study of the quality of healthcare is among the top priorities for our nation, partly because of the tremendous pressures to control healthcare costs. Yet, the world's premier epidemiology organization is not involved in one of our nations most important epidemiology projects. CDC should not remain on the sidelines.

Third, our members want the National Institute for Occupational Safety and Health (NIOSH) to recertify respirators for hospital use. I am attaching a draft letter about this topic.

I hope that my thoughts are useful. Thanks for asking.

/ps
Enclosures
/ps

SHEA

QUALITY MANAGEMENT AND IMPROVEMENT

Health reform transforms the current prescriptive quality assurance program into a quality-management system focused on performance measures and continuous improvement.

Quality assurance programs in the current system rely on external checks, forms and process manuals. Insurance carriers, peer review organizations, state and federal inspection agencies audit the work being done in hospitals, doctors' offices and laboratories, and penalize the providers if they fail to follow rules. Patients play a minor role, lacking reliable information upon which to compare the quality of health plans, providers or treatments.

Under the American Health Security Act, customer-focused continuous improvement assures quality improvement.

NATIONAL QUALITY MANAGEMENT PROGRAM

The National Quality Management Program develops the quality information and accountability program. An advisory council under the National Health Board, appointed by the President, oversees the program.

The council consists of 15 members representative of the population, including representatives of consumer groups, health plans, states, purchasers of care and experts in public health and quality of care and related fields of health service research.

The National Quality Management Program:

- Develops the core set of quality and performance measures and consumer survey questions and updates them over time to reflect changing goals for quality improvement in health care.

- Conducts consumer surveys that measure access to care, use of health services, outcomes and satisfaction.

  As part of that effort, the program develops sampling strategies to ensure that performance reports reflect populations difficult to reach with traditional consumer-sampling methods, including consumers who fail to enroll in a health plan or resign from plans.

- Sets national goals for performance on selected quality measures.

- Establishes minimal standards of access and quality for plans on selected measures.

- Supports research, technology assessment and development of reliable tools for measuring health outcomes.

- Evaluates the impact of health reform on the quality of care.

- Reports annually on performance of the health care system.

- Reviews and recommends changes to the quality measures annually and establishes a five-year priority list for measures to be included in the future.

- Uses the national network of regional centers to obtain quality management data. (See section on "Information Systems and Administrative Simplification")

PERFORMANCE REPORTS

The National Quality Management Program under the National Health Board develops a core set of measures of performance that apply to all health plans, institutions and practitioners. It publishes annual performance reports outlining the results of those measures for each health plan, creating a public system of accountability for quality and providing consumers with meaningful information.

It also provides annual reports to the states on the comparative performance of health plans and state quality programs. Quality reports include information on the performance of alliances and health plans on as many as 50 measures of access to care, appropriateness of care, health outcomes, health promotion, disease prevention and satisfaction with care.

It provides the results of a smaller number of quality measures for health care institutions, doctors and other practitioners if the available information is statistically meaningful. State performance reports include trends, performance on national quality measures and on goals for national performance on access, appropriateness and health outcomes.

The following criteria determine the selection of national measures of quality performance:

- The measures reflect important aspects of care in terms of prevalence of illness, morbidity, mortality or cost.
- The set is representative of the range of services provided to consumers by the entities in question.
- Measures are reliable and valid and data needed for calculation can be obtained without undue burden.
- Performance on measures included in the set vary widely among the entities on the performance report.
- When the measures are rates of process of care, these processes are linked by strong scientific evidence to health outcomes.
- When the measures are outcomes of care, performance lies within the control of providers and adequate risk adjustment can be accomplished.
- The measures incorporate minimal standard for meeting public health objectives.

I am writing to urge you to support the plan of the National Institute of Occupational Safety and Health (NIOSH) to revise respirator certification. As you know there has been a resurgence of tuberculosis (TB) in several cities in the United States. Some strains of TB are very resistant to therapy and almost untreatable. Patients infected with TB usually get admitted to hospitals, where hospital personnel are at risk for becoming infected. This problem has been addressed recently by the Centers for Disease Control, which issued "Guidelines for Preventing the Transmission of Mycobacterium tuberculosis in Health-Care Facilities, 1994" on October 28, 1994, in their publication Morbidity and Mortality Weekly Report (MMWR). These guidelines require use of a mask to protect hospital personnel when they are in close contact with a TB patient. These masks are called "respirators" and must be certified by NIOSH before they can be used in health care facilities. Unfortunately only one type of mask, a HEPA respirator, is currently certified. This respirator is cumbersome to use. NIOSH has proposed changing its respirator certification process to allow several other types of respirators to be used. These respirators are less expensive, seem to work as well as HEPA respirators, and are more acceptable to personnel. This recertification of respirators requires a change in regulations. However, this change in regulations is now being held up because of the overall anti-regulatory environment in Washington, DC. In fact,

this change in regulations can be called a "down regulation" because the rules of respirator use will actually be loosened by the new regulations. Further, this change is supported by all interested parties, including the national infection control societies (the Society for Healthcare Epidemiology of America--SHEA--and the Association of Professionals in Infection Control and Epidemiology--APIC), the American Hospital Association, major labor unions, and of course the CDC, NIOSH, and OSHA.

On behalf of SHEA I am trying to get the new regulations passed. Would you please use your contacts in Washington, DC, to see if we can get this process moving. I don't believe anyone opposes the change, which should create a "win-win" situation for all those involved.

INFECTIOUS DISEASE CONSULTANTS

MICHAEL S. GELFAND, M.D., F.A.C.P.
BRYAN P. SIMMONS, M.D., F.A.C.P.
KERRY O. CLEVELAND, M.D.

INFECTION IN DISEASE AND INTERNAL MEDICINE
901-726-8231

188 S. BELLEVUE
SUITE 419
MEMPHIS, TN 38104

FACSIMILE TRANSMISSION

TO: Karen Guss
NAME

NUMBER OF PAGES: 8
(including this page)

DATE: 3-23-95

COMPANY/ORGANIZATION

TIME: 3 1.05

ADDRESS

FAX NUMBER:
202 456 7431

CITY/STATE/ZIP

FROM: Dr Bryan Simmons

FAX NUMBER: (901) 726-8249

SUBJECT: _____

MESSAGE:

Terry Yamauchi 501 3201100?

INFECTIOUS DISEASE CONSULTANTS

MICHAEL S. GELFAND, M.D., F.A.C.P.
BRYAN P. SIMMONS, M.D., F.A.C.P.
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FACSIMILE TRANSMISSION

TO: JULIE DEMEO
NAME

COMPANY/ORGANIZATION

ADDRESS

CITY/STATE/ZIP

NUMBER OF PAGES: 5
(including this page)

DATE: 3/20/95

TIME: 3:45 PM EASTERN

FAX NUMBER: 202-456-2878

FROM: BRYAN SIMMONS, MD, PRESIDENT SHEA

FAX NUMBER: (901) 726-8249

SUBJECT: SHEA Annual Meeting
TALK BY CAROL RASCO

MESSAGE:

ATTACHED ARE SEVERAL ITEMS WHICH SHOULD PROVE USEFUL. FIRST IS A DESCRIPTION OF SHEA (THE AUDIENCE). SECOND IS A DESCRIPTION OF THE SYMPOSIUM (HEALTH CARE DELIVERY: WHAT DOES THE FUTURE HOLD?) THIRD IS SCHEDULE FOR THIS SYMPOSIUM. PLEASE CALL ME IF YOU NEED ANY MORE INFORMATION. DR TERRY YAMAUCHI, OF ARKANSAS CHILDREN'S HOSPITAL, WILL INTRODUCE MS RASCO AND CAN PROVIDE ADDITION INFORMATION. LAST IS INFORMATION ABOUT THE HOTEL.

APPENDIX I

What Is SHEA?

The Society for Healthcare Epidemiology of America (SHEA) was organized in 1980 to foster the development and application of the science of healthcare epidemiology. Healthcare epidemiology is broadly defined as any activity designed to study and/or improve patient care outcomes in any type of healthcare institution or setting. Activities may include epidemiologic and laboratory investigation, surveillance, prevention and control programs, policy development and implementation, education and information dissemination, and cost-benefit assessment of prevention and control programs. Historically, most SHEA activities have been related to nosocomial infections. However, in recent years, SHEA members have devoted increasing efforts to evaluating non-infectious outcomes of healthcare and bringing epidemiologic principles to bear on other quality-of-care issues. Individuals working or interested in healthcare epidemiology are welcome as SHEA members.

SHEA Mission

SHEA's mission is to promote the highest quality of patient care in all healthcare settings.

- As an organization, SHEA will provide leadership and advocacy to influence public policy in standard setting, prevention and control of infectious diseases and other threats to patient health and safety as the voice of healthcare epidemiology.

- In healthcare settings, SHEA members will manage programs for continuous quality improvement built upon uniform hospital data bases under the direction of highly qualified and appropriately compensated epidemiologists.

- To advance the scientific base of healthcare epidemiology, SHEA will actively support research in prevention, control and outcomes and will support the education of a cadre of highly-trained quality assurance professionals.

- To communicate the best scientific and quality assurance methods nationally and internationally, SHEA will promote communication among colleagues, support graduate education programs, and provide education and training to the field.

Major SHEA Activities

- Journal
- Annual Meeting
- Educational Courses
- Position Papers

SHEA

THE SOCIETY FOR HEALTHCARE EPIDEMIOLOGY OF AMERICA
FIFTH ANNUAL SCIENTIFIC MEETING
APRIL 2 - 4, 1995
SAN DIEGO, CALIFORNIA

Plenary 2 Health Care Delivery: What Does the Future Hold? (organized by Decker/Simmons)

Moderator: Bryan Simmons

* Special Update on Current Political Realities of Health Care
Carol H. Rasco
35 minutes

Role of the JCAHO in Improving Quality as the Health Care Delivery System Changes
Paul Schyve
35 minutes; development of functional, performance based standards; the IMS system, including infection control and the project to monitor indicators; evaluation of integrated health care networks

BREAK

Moderator: Michael Decker

Impact of Health Care Delivery Changes on Quality Improvement Activities
Stephen Schoenbaum
25 minutes; measurement of clinical care: report cards; implementation of clinical guidelines

Impact of Health Care Delivery Changes on the Hospital Epidemiologist
James Allen
25 minutes: Retrospective: The impact of previous changes in the health care delivery and financing systems on the practice of hospital epidemiology; Update: Current status of health system reform efforts and market forces; Projection: Potential impact of managed care systems on hospital epidemiology; Opportunity: Charting the course of hospital epidemiology in the future

January 19, 1995

By FAX to: Melissa Bishop, 609-853-0411
Bryan Simmons, 901-726-8249
David Bell, 404-639-6459

Dear Colleagues:

I was called a few days ago by Dr. James Allen at the AMA, who said he would have to cancel his talk at the SHEA Annual Meeting on Monday morning; his employers required that he be at Cold Spring Harbor, Long Island that same evening. After negotiation, Dr. Allen agreed to present his talk earlier in the schedule, so that he could catch a plane that would get him to New York by 10PM. Drs. Allen and Schyve have accepted the following changes; I have notified Dr. Schoenbaum and presume his acceptance, as the change is so minor for him (see attachments).

Note that these changes require that the Coffee Break be moved from 10AM to 9:50AM, in order to allow the speakers to speak for their previously allotted time. The revised schedule is:

MONDAY APRIL 3

8:30 Introduction, Simmons (no change)
8:40 Political Realities (no change)
9:15 Audience questions (no change)
9:20 *Impact of Health Care Delivery Changes on the Hospital Epidemiologist*
James R. Allen, MD, MPH, Vice-President, Group on Science, Technology, and Public Health, American Medical Association
9:45 Audience questions
9:50 Coffee Break
10:20 *Role of the JCAHO in Improving Health Care Quality in the Era of Health Care Reform*
Paul M. Schyve, MD, Joint Commission on Accreditation of Healthcare Organizations, Oakbrook Terrace, Illinois
10:55 Audience Questions
11:00 *Impact of Health Care Delivery Changes on Quality Improvement Activities*
Stephen Schoenbaum, MD, MPH, Harvard Community Health Plan of New England, Brookline, Massachusetts
11:25 Audience questions
11:30 Lunch

If you see any problem with this, please let me know.

Sincerely,

Michael D. Decker, MD, MPH

File
SHEA
1995 annual meeting

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Agency for Health Care Policy
and Research
2101 East Jefferson Street
Rockville MD 20852

March 23, 1995

NOTE TO: Karen Guss, Assistant to the First Lady

From: Claire Maklan, Deputy Director, Center for Medical Effectiveness Research

The following information is provided in response to your request regarding outcomes research, for a speech at the upcoming meeting of the Society for Health Care Epidemiology. If you would like additional information or need clarification, please call me (301/ 594-1485).

1. The enclosed paper entitled "Methodological Challenges and Innovations in Patient Outcomes Research" contains a brief, basic introduction to AHCPR's Medical Treatment Effectiveness Program (p. JS14). In the same paper (pp. JS15-16), you will find an explanation of what AHCPR means by "outcomes."

It is worth noting that "outcomes research" means different things to different people. In particular, some audiences equate it with outcomes *management*. Some identify it solely with analysis of large databases. In contrast:

-AHCPR's program of medical effectiveness research assesses effectiveness *in terms of* patient outcomes.

- AHCPR research stresses a broad range of outcomes, that includes traditional clinical endpoints (mortality, morbidity, complications), but also includes cost, and more subjective outcomes such as functional status, symptom relief, quality of life, and satisfaction with care.

- AHCPR research emphasizes generalizability of results (i.e., "effectiveness," as opposed to "efficacy").

- AHCPR research employs a full range of clinical, epidemiological, and social science methods. It represents a new way of defining research problems, not a single way to study them.

- AHCPR is the leader in outcomes/effectiveness research within the Federal government.

2. To date, AHCPR has awarded approximately 200 research projects (from very small to very large) under MEDTEP. (This does not include the agency's "general health services" research projects focused on issues of cost, quality, and access.) Those which

most directly address "outcomes" are focused on one or another clinical condition. The conditions (and, sometimes, procedures) addressed are common, and costly. Thus, ongoing research focuses on, among other things: low back pain, prostate disease, diabetes, depression, schizophrenia, HIV/AIDS, breast cancer, and hysterectomy.

The general parameters for the research portfolio are described in the enclosed Grant Announcement (pp. 2-3). That document also includes more discussion of the themes and objectives of MEDTEP research (p.2)

The enclosed document entitled "MEDTEP Research Projects, 1989 to Present" identifies all the projects funded as of May 1994. It illustrates the breadth of topics addressed and identifies the institutions to which the grant (or, occasionally, contract) is awarded.

The major effectiveness research projects awarded since May 1994 are the 7 "PORT-IIs." Six of these are described in the enclosed Fact Sheet, on "PORTs and PORT-IIs" and in the enclosed press release from June 8, 1994. Most recently, we funded a PORT-II on depression.

3. The final 2-page item, "Where We Are," highlights some of the important findings of outcomes/effectiveness research projects to date.

Enclosures

ABBREVIATED RESUME

TERRY YAMAUCHI, M.D.

EDUCATION:	Portland State University University of Oregon Medical School UCLA-Harbor General (internship, residency, and fellowship)
TRAINING:	Postdoctoral Fellowship in Infectious Diseases and Microbiology -UCLA, Los Angeles, CA
FACULTY:	UCLA - Los Angeles, CA University of Arkansas for Medical Sciences and Arkansas Children's Hospital, Little Rock, AR Centers for Disease Control, Atlanta, GA
SOCIETIES:	Dr. Yamauchi is a member of more than 30 scientific societies including Society of Pediatric Research, American Pediatric Society, Infectious Diseases Society of America, American Society of Microbiology, Pediatric Infectious Disease Society, and American Academy of Pediatrics
HOBBIES:	Hunting, fishing, softball and magic
PUBLICATIONS:	Dr. Yamauchi has published more than 190 articles and book chapters. Dr. Yamauchi is Senior editor of the bi-monthly newsletter "Nosocomial News" which has a national readership. He has served as a medical consultant for the "Today Show" and has made several instructional video tapes on Infectious Diseases.
CURRENT POSITION:	Professor and Acting-Chairman, Department of Pediatrics, Pediatric Infectious Diseases, University of Arkansas College of Medicine and Arkansas Children's Hospital, Little Rock, AR
PAST EXPERIENCE:	Former member of Governor Bill Clinton's state cabinet, Director of Department of Human Services; Associate Dean, University of Arkansas for Medical Sciences

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b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

[001]

TERRY YAMAUCHI, M.D.

PERSONAL HISTORY:

Address:

Home - P6/b(6)

office - Arkansas Children's Hospital
800 Marshall St.,
Little Rock, AR 72202

Date & Place of Birth: P6/b(6)

Marital Status: Married: Wife - Alison Marcia Walker Yamauchi

Children: Two: Jill Marie P6/b(6)
Geoffrey Paul P6/b(6)

EDUCATION AND DEGREES:

1955-57	Narimasu High School Tokyo, Japan
1957-59	David Douglas High School Portland, Oregon
1959-63	Portland State University Portland, Oregon, B.S.
1963-67	University of Oregon Medical School, M.D., Cum Laude, Portland, Oregon

PROFESSIONAL TRAINING:

1967-68	Rotating Intern, UCLA - Harbor General Hospital Torrance, California
1968-70	Resident-in-Pediatrics UCLA - Harbor General Hospital, Torrance, California

1969-70	Chief Resident-Pediatrics UCLA - Harbor General Hospital, Torrance, California
1970-72	Post-Doctoral Fellow, Infectious Diseases and Microbiology - UCLA, Los Angeles, California

MILITARY SERVICE: None

FACULTY AND STAFF APPOINTMENTS:

1994-present	Acting-Chairman, Department of Pediatrics, University of Arkansas College of Medicine, Little Rock, Arkansas
1980-present	Professor of Pediatrics, Department of Pediatrics, University of Arkansas College of Medicine, Little Rock, Arkansas
1987-1994	Vice-Chairman, Department of Pediatrics, University of Arkansas College of Medicine, Little Rock, Arkansas
1990-May 1992	Director of Human Services, State of Arkansas, Little Rock, Arkansas
1988-1992	Associate Dean, College of Medicine, University of Arkansas for Medical Sciences, Little Rock, Arkansas
1988-1992	Director, Continuing Education for Physicians, University of Arkansas for Medical Sciences, Little Rock, Arkansas
1987-1990	Section Head, Infectious Diseases and Clinical

	Pharmacology, University of Arkansas College of Medicine, Little Rock, Arkansas
1980-1989	School Physician, Little Rock Public Schools, Little Rock, Arkansas
1975-1989	Chief, Pediatric Infectious Diseases, University of Arkansas College of Medicine Little Rock, Arkansas
1975-1980	Director, Pediatric Ambulatory Medicine, Arkansas Children's Hospital, Little Rock, Arkansas
1975-1980	Associate Professor of Pediatrics, University of Arkansas College of Medicine, Little Rock, Arkansas
1975-1979	Consultant, Virology Section, National Center for Toxicological Research, Jefferson, Arkansas
1972-1975	Assistant Chief, Receiving-Emergency Department, Harbor General Hospital, Torrance, California
1972-1975	Assistant Professor of Pediatrics, UCLA School of Medicine, Los Angeles, California

CONSULTANT:

1980-1990	School Physician, Little Rock Public Schools, Little Rock, Arkansas

1981-1990	Hospital Infections Branch, Center for Disease Control, Atlanta, Georgia

HONORS AND AWARDS:

1959	Oregon State Scholarship
1965	State Scholarship
1966	Pfizer Scholarship Award
1967	Alpha Omega Alpha Honor Society
1967	Nominee, Gold-Headed Cane Award
1975	Outstanding Young Men of California
1976	Outstanding Teacher Award - Pediatric House Staff
1977	Outstanding Young Men of America
1976, '77, '78, '79 '80, '81, '82, '83 '84, '85, '86, '87 '88, '89, '90	Most Honored Faculty
1987	Golden Apple Award - First Runner-up
1987	Arkansas Chapter, American Academy of Family Physicians
1988-93	Editorial Board - American Journal of Infection Control
1989	Nominated by Portland State University for NCAA Silver Anniversary Award
1990-present	Editorial Board - Pediatrics in Review

1990-1991	Who's Who in Health and Medical Services
1990-1991	Who's Who in U.S. Executives
May 3-14, 1993	Adviser to World Health Assembly (World Health Organization), Geneva, Switzerland
May, 1994	Faculty Volunteer Service Award, University of Arkansas for Medical Sciences

SPECIAL COURSES:

November 1974	Co-Director, Post-graduate Course - "Emergency Department of Medicine in Practice", UCLA Harbor General Hospital - The American College of Emergency Physicians, Torrance, California
May 1978	Director, Postgraduate Course - "Fundamentals of Hospital Infection Control", Association of Practitioners in Infection Control, Arkansas Chapter and University of Arkansas for Medical Sciences, Little Rock, AR
November 1979-1989	Staff, "Surveillance, Prevention and Control of Nosocomial Infections", (Course #1200-G), Centers for Disease Control, Atlanta, Georgia
January 1980	Principal Speaker, Post-graduate Course - "The Child in an Emergency: Immediate Management and Prevention of Pediatric Injuries and Illnesses",

	Mississippi University for Women - Meridian, Columbus, Corinth and Cleveland, Mississippi
November 1980	Director, Postgraduate Course - "Beyond the Basics: An Advanced Program in Infection Control" - Association of Practitioners in Infection Control/ Arkansas Chapter and University of Arkansas for Medical Sciences, Little Rock, AR
February 1983-1989	Staff, "Infection Control in Small Hospitals and Extended Care Facilities", (Course #1800-G), Centers for Disease Control, Atlanta, Georgia
March 1984	Director, "Infectious Diseases Update", Continuing Education for Physicians, University of Arkansas Medical College and Arkansas Children's Hospital, Hot Springs, AR
June 1984	Staff, "Bermuda CE Seminar", Continuing Education for Physicians, University of Arkansas Medical College and Arkansas Children's Hospital, Bermuda
November 1984	Director, "Infectious Diseases for the Practicing Physician", Continuing Education for Physicians, University of Arkansas for Medical Sciences and Arkansas Children's Hospital, Cancun, Mexico

February 1985	Director, "Infectious Diseases: Update", Continuing Education for Physicians, University of Arkansas for Medical Sciences and Arkansas Children's Hospital, Hot Springs, AR
November 1985	Director, "Office Management of Infectious Diseases", University of Arkansas for Medical Sciences and Arkansas Children's Hospital, London, England
February 1986	Director, "Infectious Diseases: Update", Continuing Education for Physicians, University of Arkansas for Medical Sciences and Arkansas Children's Hospital, Hot Springs, AR
October 1986	Director, "Clinical Correlations of Infectious Diseases", Continuing Education for Physicians, University of Arkansas for Medical Sciences and Arkansas Children's Hospital, Owahu and Maui, Hawaii
February 1987	Director, "Clinical Correlations of Infectious Diseases", Continuing Education for Physicians, University of Arkansas for Medical Sciences and Arkansas Children's Hospital Hot Springs, Arkansas
October 1987	Director, "Management of Infectious Diseases", Continuing Education for Physicians, University

	of Arkansas for Medical Sciences and Arkansas Children's Hospital, Puerto Vallarta, Mexico
November 1987	Director, "Clinical Focus on AIDS", Continuing Education for Physicians, University of Arkansas for Medical Sciences and Arkansas Children's Hospital Little Rock, Arkansas
February 1988	Director, "Infectious Disease Update", Continuing Education for Physicians, University of Arkansas for Medical Sciences and Arkansas Children's Hospital, Hot Springs, Arkansas
March 1988	Director, "Educating and Caring for Young Children", Continuing Education for Physicians, University of Arkansas for Medical Sciences and Arkansas Children's Hospital Little Rock, AR
September 1988	Director, "Infectious Disease Update", Continuing Education for Physicians, University of Arkansas for Medical Sciences and Arkansas Children's Hospital, Toronto, Canada
December 1988	Director, "AIDS Issues in the Public Schools" Arkansas Children's Hospital, Little Rock, AR
March 1989	Director, "AIDS and Children: Issues and Dilemmas", Continuing Education for Physicians, University of Arkansas

	for Medical Sciences and Arkansas Children's Hospital, Little Rock, AR
March 1989	Director, "Infectious Disease Update", Continuing Education for Physicians, University of Arkansas for Medical Sciences and Arkansas Children's Hospital, Hot Springs, Arkansas
March 1989	Co-Director, "Symposium On Critical Care Medicine", University of Arkansas for Medical Sciences, Office of Continuing Medical Education and The University of Tennessee, Memphis, College of Medicine, Dept. of Family Medicine, Hot Springs, Arkansas
March and November 1989 - present	Speaker, "The Fundamentals of Surveillance, Prevention and Control of Nosocomial Infections (Basic Training Course,) Chicago, Illinois
March 1990	Co-Director, "Symposium On Critical Care Medicine, University of Arkansas for Medical Sciences, Office of Continuing Education for Physicians and The University of Tennessee, Memphis College of Medicine, Department of Family Medicine, Hot Springs, Arkansas
April, 1990	Co-Director, "Infectious Disease Update", Continuing Education for Physicians, University of Arkansas for Medical Sciences and Arkansas

	Children's Hospital, Hot Springs, AR
July, 1990	Co-Director,"Symposium on Maternal and Fetal Infections", The Department of Obstetrics and Gynecology and The Office of Continuing Education for Physicians, University of Arkansas for Medical Sciences and The Arkansas Chapter of NAACOG, Hot Springs, AR
April, 1991	Co-Director,"Symposium on Critical Care and Emergency Medicine", Continuing Education for Physicians, University of Arkansas for Medical Sciences and The University of Tennessee, Memphis,Tennessee Hot Springs, Arkansas
September, 1991	Director, "Treatment of Infectious Diseases", Continuing Education for Physicians, University of Arkansas for Medical Sciences and Arkansas Children's Hospital, Little Rock, AR
September, 1991	Director, "Symposium on Treatment of Infectious Diseases", Continuing Education for Physicians, University of Arkansas for Medical Sciences and Arkansas Children's Hospital, Little Rock, AR
March, 1992	Director, "Symposium on Critical Care and Emergency Medicine", Continuing Education for Physicians, University of

	Arkansas for Medical Sciences and The University of Tennessee, Memphis, Tennessee,
April, 1993	Hot Springs, Arkansas Director, "Symposium on Critical Care and Emergency Medicine", Continuing Education for Physicians, University of Arkansas for Medical Sciences and The University of Tennessee, Memphis, Tennessee, Hot Springs, Arkansas
July, 1993	Speaker, "The Fundamentals of Surveillance, Prevention and Control of Nosocomial Infection (Basic Training Course), Dallas, Texas

SOCITIES:

American Academy of Pediatrics

American Society of Magicians,

American Association for the Advancement of Science,

Association of Practitioners in Infection Control,

American Academy of Pediatrics,

American Federation for Clinical Research,

American Pediatric Society,

American Society for Microbiology,

American Institute of Biological Science,

American Venereal Disease Association,

Los Angeles Pediatric Society,

Infectious Diseases Society of America,

International Pediatrics Association

Western Society of Pediatric Research,

Southern Society for Pediatric Research,

Society for Pediatric Research,

Ambulatory Pediatric Association,

Central Arkansas Pediatric Society,

Southern Perinatal Association,

Arkansas Society of Clinical Microbiolgy,

Arkansas School Health Association,

South Central Society for Microbiology,

Society for Epidemiologic Research,

Society of Hospital Epidemiologists of America,

Pediatric Infectious Diseases Society,

Southwest Association of Clinical Microbiologists,

Sigma XI - The Research Society

Alliance for Continuing Medical Education

NATIONAL COMMITTEES AND COUNCILS:

National Committee of Child Abuse - 1975,

National Institute of Health - Study Section - 1978,

American Society for Microbiology, Nosocomial Infections Division - Nominating Committee-Co-Chairman - 1980,

National Center for Toxicological Research Peer Review Committee - 1975-79,

Association for Practitioners in Infection Control Education Committee - 1981-1984; Board of Directors, 1985-1991;

Chairman of Awards Committee 1987-1988; Committee on AIDS,

Centers for Disease Control - Committee on Infectious Diseases for Physicians - 1984; Committee on Vaccination Practices - 1983-1987,

National Association of Governors - Task Force on AIDS - 1987,

National Immunization

Advisory Committee - 1987-1990

National Vaccine Advisory Committee-1987

Southwestern Association for Clinical Microbiologists - Board of Directors-1987-1994

Nominated to FDA Advisory Committee on Anti-infectives and Vaccines - 1988

Alliance for Continuing Medical Education - Membership Committee 1989-present

Rx Management's National Pharmacy and Therapeutics Committee 1992-present

Oral Anti-Infective National Advisory Board - Bristol Myers Squibb 1992 - present

EDITORIAL BOARDS:

American Journal of Infection Control

Pediatrics in Review

STATE COMMITTEES:

American Academy of Pediatrics - Arkansas Chapter - Immunizations and Infectious Diseases Chairman - 1980-present

American Diabetes Association - Arkansas Affiliate - Advisory Board - 1977-79, 1982-1987

Association for Practitioners in Infection Control, Arkansas Chapter Advisory Board - 1980-84; Board of Directors - 1986

Arkansas Action for Foster Children - Steering Committee - Board of Directors - 1980-1985

Governor's Council for School Health - Subcommittee Chairman - 1980-1983

Arkansas Advocates for Children and Families - Board of Directors - 1981-1987

Arkansas AIDS Foundation-Nominating Committee, Chairman, 1984; Board of Directors - 1986-1987

Committee on Health and Nursing Services, Arkansas Department of Health - 1986

Little Rock Public School Scientific Advisory Board, 1985-1986

Arkansas Educational Department - Task Force on AIDS - 1986-present

Arkansas Health Department - Special Committee on AIDS - 1986-present

Health Care Access Council, 1990-present

State Job Training Coordinating Council, 1990-1992

Vision 2000 Task Force, 1990-present

Children's Medical Services Advisory Council, 1990-1992

Hot Springs Rehabilitation Center Board, 1990-1992

AIDS Advisory Council, 1990-present

National Council of State Human Services Administrators, 1990-1992

Red Ribbon Campaign Advisory Council, 1990-1992

Governor's Quality Management Team, 1990-1992

Arkansas Activity Association - Medical Advisory Committee 1993-present

Governor's Commission on People with Disabilities, 1990-1992

UNIVERSITY COMMITTEES:

Infection Control - 1979-1980

Research Council - 1977-1979

House Staff - 1977

Child Protection - 1978-1989

Medical College Physician's Group - 1978

Continuing Education for Physicians - 1980-present

Curriculum Committee - 1987-1992

Promotions Committee - 1988-1991

Dean's Cabinet - 1988-1991

Chairman - Committee for Continuing Medical Education for Physicians-1988-1991

Distinguished Faculty Lectureship Committee - 1994 - present

Medical College Physician's Group Executive Committee - 1994 - present

HOSPITAL COMMITTEES:

Infection Control - Chairman - 1978-present

Joint Conference Committee - 1994-present

Medican Staff Executive Committee - 1994-present

Pharmacy and Therapeutics - 1979

Clinical Training - 1977

Ambulatory Clinics - Chairman - 1980

Parking - 1986-1989

Executive - 1986-1988

Promotions and Tenure -

1987-1991

Child Protection - 1985-1990

CERTIFICATION:

1966	Oregon State Board of Basic Science
1968	Diplomat, National Board of Medical Examiners
1972	Diplomat, American Board of Pediatrics
1976	Arkansas State Board of Healing Arts

LICENSURE:

1967	State of California
1970	State of Oregon
1976	State of Arkansas

AUDIO VISUAL TAPES:

Audio-Digest Foundation
Family Practice
Vol. 41, Number 37
October 4, 1993
Pneumonia

Audio-Digest Foundation
Family Practice
Vol. 42, Number 14,
April 11, 1994
Immunizations

Audio-Digest Foundation
Family Practice
Vol. 42, Number 48
December 19, 1994
Emerging Communicable Diseases

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Published Material:

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2. Lachman, R. S., Yamauchi, T., and Klein, J.D.: Neonatal systemic candidiasis and arthritis. Radiology, 105:631, 1972.

3. Yamauchi, T., Klein, J. D. and Farrell, W. F.: Tuberculosis of the skin: A case report. Am. J. Dis. Child., 125:855, 1973.

4. St. Geme, J. W., Davis, C. W. C., Peralta, H. J., Gavrias, N. E., Yamauchi, T., and Cooper, M. D.: The biologic perturbations of persistant embryonic mumps virus infection. Pediatr. Res., 7:541, 1973.

5. Yamauchi, T. and Klein, H. D.: Osteomyelitis of the rib. Pediat. Digest, 15:9, 1973.

6. Yamauchi, T., Wilson, C. and St. Geme, J. W., Jr.: Transmission of the live, attenuated mumps virus to the human placenta. N. Engl. J. Med., 290:710, 1974.

7. Anthony, B. F., Yamauchi, T., Penso, J. S., Kamei, K. and Chapman, S. S.: Classroom outbreak of scarlet fever and acute glomerulonephritis related to type 1 (M-2, T-2) group A Streptococcus. J. Infect. Dis., 129:335, 1974.

8. Chow, A. W., Leake, R. D., Yamauchi, T., Anthony, B. F., Rosenblatt, R. M. and Guze, L. B.: Neonatal bacteriodaceae bacteremia: Incidence and clinical experience. Pediatr., 54:736, 1974.

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infants, children, and adults. Am J. Epidemiol., 101:253, 1975.

11. Yamauchi, T., St. Geme, J. W., Jr., Oh, W., and Cavid, C. W. C.: The biologic and biochemical pathogenesis of mumps virus induced embryonic growth retardation. Pediatr. Res., 9:30, 1975.

12. Schofferman, J., Yamauchi, T.: Overdose: The early treatment. West. J. Med., 123:160, 1975.

13. Seidel, J., Yamauchi, T., and Fong, C.: Septic arthritis caused by Eikenella corrodens. Pediatr., 87:491, 1975.

14. Fiser, R. H., Jr., Yamauchi, T., and Martin, S.: Hypoglycemia associated with congential syphilis. J. Ark. Med. Soc., 73:494, 1977.

15. Oill, P. A., Yoshikawa, T. T., and Yamauchi, T.: Infectious disease emergencies - Part I: Patients presenting with an altered state of consciousness, in infectious disease emergencies - Teaching Conference, University of California, Los Angeles, and Harbor General Hospital, Torrance, California (Specialty Conference) West. J. Med., 125:36, July, 1976.

16. Yamauchi, T., St. Geme, J. W., Jr., Martin, H. L., Heiner, D. C., and Cooper, M. D.: Induction of abnormal immunoglobulin maturation and antibody production by persistent embryonic mumps virus infection. Pediatr. Res., 10:957, 1977.

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19. Redman, J. F., Yamauchi, T., and Higginbotham, W. E.: Fournier's gangrene of the scrotum occurring in a child. J. Urol., 121:827, 1979.

20. Jacobs, R. F., Yamauchi, T., and Eisenhach, K.: Update on ampicillin resistant Hemophilus influenzae in Arkansas. J. Ark. Med. Soc., 75:345, 1979.

21. Yamauchi, T., Jimenez, J. F., McKee, T. W., Euler,

A. R., and White, P. C.: Amebic meningitis in Arkansas. J. Ark. Med. Soc., 76:164, 1979.

22. Nolan, C. M., Chalhub, E. G., Nash, D. B., and Yamauchi, T.: Treatment of bacterial meningitis with intravenous amoxicillin. Antimicrob. Agents Chemo., 16:171, 1979.

23. Jacobs, R. F. and Yamauchi, T.: Recurrent meningococcal meningitis caused by poly groups X-W135: Importance of chemoprophylaxis. J. Infect. Cont., 2:312-314, 1981.

24. Jacobs, R. F., Yamauchi, T., and Eisenach, K.: Streptococcal antigen detection by CIE. Am. J. Clin. Pathol., 75:203, 1981.

25. Jacobs, R. F., Eisenach, K., and Yamauchi, T.: Monitoring antibiotic resistance in Arkansas. J. Ark. Med. Soc., 76:502, 1980.

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tions in children. Am. J. Med., 79:188-191, 1985.

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44. Yamauchi, T.: Seminars in Respiratory Infections. Antiviral Chemotherapy for Pneumonia. Seminars in Respiratory Infections, Sept. 1987.

45. Graham, C. J., Yamauchi, T., and Roundtree, P.: Q

Fever in Animal Laboratory Workers: An Outbreak and its Investigation. Am J Infec Con 17:345-348.

46. Yamauchi, T.: A guide to controlling infectious diseases in day care. Infect Dis and Primary Care Phys., 4-8, 1990.

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Newsletter:

Dr. Yamauchi is senior editor of Nosocomial News, an infectious disease newsletter published bimonthly.

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E X E C U T I V E O F F I C E O F T H E P R E S I D E N T

26-Mar-1995 11:57pm

Rosalyn Miller
(202) 456-2216

TO: (See Below)

FROM: Julie E. Demeo
Domestic Policy Council

SUBJECT: Immigration Tour

I spoke to Carol tonight (Sun), about timing for the various events in San Diego.

1. INS should pick her up at the hotel (Town & Country Hotel, 500 Hotel Circle North) at 1:00pm, and return her at 4:00pm.

2. She needs one hour to get ready for the reception and return phone calls, etc. (4:00-5:00pm)

3. Then allot travel time to reception (5:00-5:30pm)

4. Then reception from 5:30-6:30pm. Carol would like to bring Dr. Yamauchi with her to the reception (Dr. Yamauchi is a friend of the Clinton's and is the one who asked her to give the speech in San Diego on Mon morning) --- Karen, can you coordinate with Roz and invite Dr. Yamauchi to the reception, first call Ben Austin (reception contact) and make sure it is okay with him (x65239).

5. Extra time in case reception goes over. Travel time back to hotel. Changing time. etc. (6:30-7:45)

6. 7:45 or 8:00pm, -- Pick up at hotel by INS

7. INS should drop Carol back off at hotel by 11:15 pm

8. 8:40 am: Carol's speech at hotel.

9. 11:36 am Carol's flight back to DC.

NOTES: Steve, please work with Roz & BEN AUSTIN if there are any problems with these times.

BEN: Please try to find a reception site that is no more than 30 minutes from her hotel. Also, please see if there is someone going to the reception that can pick Carol and Dr.

Yamauchi up at the Hotel and drop them back off there.

THANKS

Distribution:

TO: Stephen C. Warnath
TO: Benjamin B. Austin
TO: Karen R. Guss
TO: Rosalyn A. Miller

CC: Carol H. Rasco
CC: Jeremy D. Benami
CC: Thomas S. Epstein

NIOSH - certifies respirators

OSHA - ok by NIOSH

- "papper" - wear when in contact w/ TB patients.
  - big + expensive ($9) → HEPA
- other certifieds leak
- NIOSH wanted to put in new way of testing
  - 99% effective v. 100% effective
    but would be used alot more
  - will be cheaper ($3)

ocal testing methodology → we need new methodology

proposed rules changing!

Kevin Thurm