Withdrawal/Redaction Sheet
Clinton Library

DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
001. talking points	Personal (Partial) (1 page)	ca. 1995	P6/b(6)

COLLECTION:
Clinton Presidential Records
First Lady's Office
Domestic Policy Council (Karen Guss)
OA/Box Number: 5931

FOLDER TITLE:
Epidemiology [2]

2012-0820-S
ms480

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

P1 National Security Classified Information [(a)(1) of the PRA]
P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
P3 Release would violate a Federal statute [(a)(3) of the PRA]
P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [a)(5) of the PRA]
P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

C. Closed in accordance with restrictions contained in donor's deed of gift.
PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).
RR. Document will be reviewed upon request.

Freedom of Information Act - [5 U.S.C. 552(b)]

b(1) National security classified information [(b)(1) of the FOIA]
b(2) Release would disclose internal personnel rules and practices of an agency [(b)(2) of the FOIA]
b(3) Release would violate a Federal statute [(b)(3) of the FOIA]
b(4) Release would disclose trade secrets or confidential or financial information [(b)(4) of the FOIA]
b(6) Release would constitute a clearly unwarranted invasion of personal privacy [(b)(6) of the FOIA]
b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

AHCPR

Article Reprint

Agency for Health Care Policy and Research

Methodological Challenges and Innovations in Patient Outcomes Research

U.S. Department of Health and Human Services
Public Health Service
Agency for Health Care Policy and Research

MEDICAL CARE
Volume 32, Number 7, pp JS13–JS21, *Supplement*

Methodological Challenges and Innovations in Patient Outcomes Research

CLAIRE W. MAKLAN, PHD, MPH, RICHARD GREENE, MD, PHD, AND MARY A. CUMMINGS, DRPH, RN

Between 1989 and 1992, the Agency for Health Care Policy and Research (AHCPR) awarded funding to 14 special projects known as Patient Outcomes Research Teams (PORTs). These large, complex projects form the centerpiece of the first generation of research under the Medical Treatment Effectiveness Program. In carrying out their individual 5-year research plans, and through collaborative work of six Inter-PORT Work Groups, PORTs have contributed to methodological advances related to their specific clinical focus and to outcomes research in general. Each of the PORTs has followed a standard research model, involving the application of: systematic literature review, measurement of outcomes, analysis of cost and claims data, decision analysis, and strategies for disseminating findings. This article reports what has been learned by individual PORTs, and by AHCPR, regarding the usefulness of each of these methodologies, both for the ongoing projects and for the next generation of effectiveness research. Examples from individual PORTs and work groups illustrate some of the methodological gains that have been made in effectiveness research and provide a glimpse of the work that remains to be done. Key words: patient outcomes research; medical effectiveness research; effectiveness research methods.

This supplement addresses some of the major methodological challenges in patient outcomes/medical effectiveness research as carried out under the auspices of the Agency for Health Care Policy and Research (AHCPR). It presents an inside look at collaborative activities that have helped pioneers in outcomes research grapple with the difficult issues that they faced in common.

Many AHCPR investigators, and especially those involved in the projects known as Patient Outcomes Research Teams (PORTs), have been on the leading edge of methodological developments for health services research in general, and outcomes research in particular. In the case of PORTs, researchers have been challenged to explore, adapt, and sometimes invent methods for dealing with new concepts and complex data.

To address these challenges, while working on their individual PORTs, representatives of each PORT have participated in six "Inter-PORT Work Groups." These work groups are organized around research activities in which all PORTs are engaged, namely: the measurement of outcomes, analysis of the utilization and costs of health care, systematic literature review, decision modeling, and dissemination of research findings. The following six papers, by par-

From the Agency for Health Care Policy and Research, Center for Medical Effectiveness Research, Rockville, Maryland.

Address correspondence to: Claire W. Maklan, PHD, MPH, Agency for Health Care Policy and Research, CMER, Suite 605, 2101 East Jefferson St., Rockville, MD 20852.

ticipants in each work group, describe and discuss PORTs' collaborative deliberations on shared methodological problems and their individual solutions. The experience of PORTs is relevant to the next generation of medical effectiveness research and to ongoing discussions about the need to tie health care reform to a strong base of evidence regarding effective practice.

Medical Treatment Effectiveness Program

Under the Medical Treatment Effectiveness Program (MEDTEP), AHCPR carries out a significant program of clinically oriented extramural research. These studies break with both traditional health services research and with traditional clinical "efficacy" studies. As a result, they entail different types of data and methodological approaches. MEDTEP research shifts the focus of health services research from issues of organization and process to the outcomes of health care. Moreover, concern is with outcomes in the real world. MEDTEP research is expected to address questions about what clinical interventions work best for typical patients, cared for by typical health care providers. Another major new feature is MEDTEP's emphasis on outcomes that patients understand and care about. Thus, important outcomes include quality of life, functional capacity, symptom relief, and cost (in contrast to physiological measures and parameters that focus more on organs than their owners). Questions of cost effectiveness and appropriateness of treatment decisions are other basic themes in this research.

The substantive and methodological contributions of MEDTEP research have begun to emerge. The recognized potential for policy-relevant findings has been a major factor in the substantially increased federal support. From fiscal year 1990, the first full year of the program, the MEDTEP research budget has grown steadily from approximately $22 million to approximately $48 million in fiscal year 1994. To date, these funds have supported over 150 research projects.

PORTs are AHCPR's largest extramural research investments. The "PORTfolio" consists of 14 five-year projects (10 grants and 4 contracts) with average annual budgets of one million dollars. PORTs are multi-disciplinary, multi-faceted, multi-method, and multi-site. Each project focuses on a clinical condition or procedure(s) and tries to relate different patterns of clinical practice to different patient outcomes. The research teams include both academicians and practicing clinicians, with expertise in the clinical subject as well as other pertinent disciplines and methods, usually including epidemiology, statistics, economics, decision modeling, and outcomes assessment. PORTs are distinguished from other MEDTEP projects in part by their size and scope and in part by the expectation that each will carry out a series of activities that includes: systematic literature review and formal analysis; analysis of variations in practice patterns and patient outcomes; and dissemination of findings and evaluation of the effects.

Systematic Literature Review and Formal Analysis

PORTs carry out comprehensive reviews of the literature on the clinical condition or procedure(s) under study. If possible, one or more quantitative synthesis (or meta-analysis) is conducted. The literature review has multiple uses, including refinement of research hypotheses, testing hypotheses, input to decision models, and assessing quality of the evidence.

Analysis of Variations in Practice Patterns and Patient Outcomes

PORT investigators conduct extensive analyses of clinical, administrative, and patient-reported data. Secondary data, especially claims data from Medicare and other payors, are used to address questions of

practice patterns, costs of care, and selected outcomes. Primary data (usually prospective) are collected to provide details of clinical care and information about patient outcomes, including quality of life and physical and psychosocial functioning.

Dissemination of Findings and Evaluation of the Effects

MEDTEP places major emphasis on the importance of effective dissemination of research findings. Each PORT is expected to disseminate its findings to providers, patients and the public in a systematic and scientific manner. The effects of the dissemination are then evaluated in terms of change in practice patterns and, if possible within the funding period, in terms of patient outcomes.

Inter-PORT Work Groups

In fall 1989, soon after award of the first PORTs, AHCPR sponsored a meeting for investigators on the four new projects, i.e., the PORTs on acute myocardial infarction, cataract, low back pain, and prostate disease. Participants held in-depth discussions regarding the data and methods necessary to carry out their research. They concluded that it would be beneficial for the investigators, and helpful to AHCPR, for PORTs to maintain contact and exchange information across projects. To accomplish this, the PORTs proposed establishment of inter-PORT working groups. These committees would serve to augment the talent of the individual PORTs with additional expert resources and perspectives, to facilitate consultations to complement that expertise when necessary, and to provide forums for discussion of common issues.

Initially, five work groups were formed: Literature Review and Meta-Analysis, Use of Claims Data, Decision Modeling, Outcomes Assessment, and Cost of Care. In October 1990, the Dissemination Work Group was established. Each work group consisted of a primary and alternate representative from each of the PORT projects and two members of AHCPR staff. Over their more than 4-year history, the work groups have carried out their activities through periodic conference calls and occasional face-to-face meetings.

PORT and Inter-PORT work group experience is now considerable. Four of the 14 PORTs are in their fifth (and final) year of work; seven more are in their fourth year. In this supplement, they share their experience with the broader community of researchers, especially in terms of what has been learned about the adaptability and varied uses of "PORT methods" in effectiveness research and the contributions of PORTs to the development of these methods.

In considering these issues, we take the view of program administrators who can step back from the individual work groups and from individual PORTs and attempt to draw general conclusions that reflect our awareness of success and failure, competing objectives, hopes for the future, and the advantage of hindsight. We will discuss some of the accomplishments of individual work groups and relate these to the continuing evaluation and development of AHCPR's medical effectiveness research program.

Outcomes Assessment: Coming to Terms With the Terms of Effectiveness Research

At the heart of every PORT is the critical and difficult task of accurately identifying and measuring the outcomes in terms of which treatment effectiveness is to be assessed. All PORTs measure multiple outcomes, and they obtain these data from multiple sources, reflecting multiple perspectives. In general terms, PORT outcomes typically include survival, morbidity, complications, physical functioning, and resource use (cost, readmissions), as well as "softer" outcomes such as overall health status, symptom relief, role functioning, and satis-

faction with care. Some outcomes data are necessarily provided by physicians or payors and reflect their definition of the problem and their abstract experience of the patient's condition. Other important outcomes are known only by patients, so pertinent information must be obtained from them.

The Outcomes Assessment Work Group has focused its attention on these issues and the influence of the clinical condition being studied on selection of measures, study design, data collection method, and data interpretation, in particular. Underlying much of this group's activity is the early conclusion that none of the existing measures of general health status or quality of life is clearly the "best" measure, i.e., no one measure is useful in all outcomes research. The most widely used and tested general measures, the Sickness Impact Profile (SIP), the MOS Short-Form General Health Survey (SF-36), and indices of activities of daily living, all have both strengths and weaknesses. This conclusion "freed" the PORTs to create new condition-specific measures and new versions of existing measures for assessing outcomes in many clinical entities. However, it also provides further indication of the challenges that still lie ahead, especially in view of proposals for a "health care report card."

Claims Data Analysis and Cost of Care: Secondary Data Take Second Place

All PORTs that deal with inpatient conditions affecting adults (11 of the 14 PORTs) have utilized Medicare claims data to describe variations in practice and have tried to associate practice with outcomes. This approach is principally the result of optimism about the usefulness and relatively low cost of secondary data in general, and Medicare administrative data in particular, which is reflected in AHCPR's authorizing legislation. The fact that the Medicare databases represent essentially the entire U.S. population older than age 65, provide information about resource use for a vast array of clinical conditions, and permit longitudinal follow-up of individuals makes these data extraordinary. But, PORT experience has tempered early enthusiasm about the ability of claims data to answer effectiveness questions.

The problems and potential of administrative data, especially Medicare data, have been the focus of the Cost of Care and Claims Data Work Groups. Although their specific interests are different, the experience of both groups has been a similar mix of frustrations and accomplishments. A major problem affecting all PORTs is that the only outcomes addressed in Medicare data are survival, subsequent morbidity (especially in terms of subsequent admissions, diagnoses and procedures), and costs. Another general problem, the limited information about the patient's clinical condition, either at the time of treatment or subsequent to it, precludes accurate classification of patients with the same diagnosis by severity, procedure, or resource use. For example, the Medicare coding rules for acute myocardial infarction (AMI) lump together patients admitted as "rule out AMI," patients with small infarcts and normal cardiac function, and patients with massive AMIs who are in extremis. Because the patients may not be comparable, it is risky to draw conclusions about observed variations in the few outcomes that are captured.

PORTs quickly identified other serious limitations of the Medicare data, including the fact that bilateral anatomical structures (e.g., eyes, hips, knees) are not coded as left or right, and that for many important effectiveness questions, untreated patients cannot be identified at all. For example, although all Medicare patients who underwent gallbladder surgery can easily be identified for any given time period, there is no way to identify comparable patients who had symptoms of gallbladder disease, but who were treated conservatively or who were not treated at all. Similarly, Medicare

cost data only address Medicare-covered services, so there are no data, for example, on the use of outpatient drugs.

PORTs have developed substantial expertise in building and linking complex patient-specific administrative databases. Sharing of experience and expertise within the Claims Data Analysis and Cost of Care Work Groups has enabled PORTs to deal successfully with many tricky problems in these data: codes that change over time, idiosyncratic coding conventions, missing data, linking problems, and the logistics of managing enormous data sets. PORTs have taken these data to their limits and, although those limits have been disappointing in some cases, analyses of these data have also led to some very important findings.

The Cataract PORT provides a good illustration of innovation in the use of available data. The PORT's analyses of Medicare data suggested that the risk of retinal detachment, while remaining low, is significantly increased in cataract patients who subsequently undergo a procedure known as Nd:YAG laser capsulotomy.[1] The lack of detailed clinical information in the Medicare data precluded direct confirmation of this possibility, but these same data do afford a unique opportunity for examining some outcomes of treatment. First, the vast number of cases in the Medicare dataset enabled the PORT to identify individuals with this serious, but very rare complication. This, in turn, made it possible to obtain medical records for these patients. With these detailed clinical records, it will be possible to test directly the link between laser capsulotomy and elevated risk of retinal detachment.

Another very important use of Medicare claims data was developed by the Prostate Disease PORT when they created a representative sample of Medicare beneficiaries with early or localized prostate cancer who had undergone radical prostatectomy. The PORT surveyed this cohort 2- to 4-years post-surgery to ascertain the prevalence of serious adverse effects of surgery such as incontinence and impotence. The power of this technique is extraordinary, because it can elicit outcomes information from a sample of Medicare beneficiaries representative of whatever characteristics are reported in the Uniform Hospital Discharge Summary. The fact that the PORT was able to obtain a 92% response rate in their survey further argues for this use of Medicare claims data.[2]

Literature Review: You Can't Tell a Book (or a Journal) by Its Cover

PORT literature reviews brought several surprises. First, in carrying out systematic reviews of published (and, occasionally, unpublished) studies pertinent to their topics, PORTs found that studies often failed even the simplest tests of quality with regard to design. The Prostate Disease PORT performed a structured literature review to determine the clinical course of localized prostate cancer, the effectiveness of radical surgery and radiation therapy, and treatment complications. Although they could compare complications associated with different treatments, they were not able to determine the effectiveness of treatment for localized prostate cancer because of methodologic inadequacies in the reviewed literature.[3] Other PORTs that conducted formal assessments of the quality of the literature also found it very disappointing. PORT documentation of inadequacies in published studies are accompanied by specific recommendations regarding the design and reporting of research (that may contribute eventually to overall improvement in the literature).[4,5]

Another surprise for some would-be meta-analysts was the result of different research traditions within various clinical areas. In the entire English language literature, there exists only one randomized controlled trial comparing radical prostatectomy to watchful waiting in localized prostate cancer patients. The PORTs on Biliary Tract,* Total

* Personal communication with Jesse Berlin, Biliary Tract Disease PORT.

Knee Replacement† and Low Back Pain found no relevant randomized clinical trials for certain common procedures.[6] Thus, for some PORT conditions, statistical pooling of data from published clinical trials to produce new information could not be done, at least not in the conventional way. Although it is extremely important to define rigorously the limited knowledge on treatment effectiveness in some fields, clinical literature consisting mostly of descriptive studies does not support definitive conclusions about the effectiveness of treatment. The results of PORT systematic literature reviews challenge directly "the inevitable tendency to let sleeping dogmas lie."[7]

As described in the paper by the Literature Review/Meta-Analysis Work Group, PORTs have been innovative in their use of this relatively new research method. All PORTs have extended "formal" literature review approaches and criteria far beyond the narrow range of traditional meta-analysis. Although the specific features that distinguish the type of formal literature reviews being carried out by PORTs are numerous and subject to debate, several elements stand out. Unlike the reviews that preface most research reports (and grant applications), these reviews are distinguished by the fact that they are critical, systematic, usually quantitative and, at least theoretically, reproducible. A full record of the methods and decision criteria, as well as the identity of the studies that were reviewed and their place in the synthesis permits prospective users of the review to assess the comprehensiveness of the search and the validity of the conclusions.

Another innovative approach to literature review advanced through PORT work focuses on "cumulative" meta-analysis. Among PORTs, the literature review work of the Acute Myocardial Infarction PORT was distinguished by the existence of large numbers of clinical trials. After carrying out both traditional and cumulative meta-analyses, the investigators concluded that cumulative meta-analysis of a set of small therapeutic trials can produce statistically significant evidence of efficacy in advance of definitive large scale trial results.[8]

Decision Analysis: Healthy Decision Trees Provide More Light than Shade

Each of the PORTs has developed (or is developing) a decision model to help define the optimal path to the desired outcome, through a vast number of patient characteristics and treatment options, and modified by probabilities, patient utilities, risks, and costs. These complex models, which may incorporate data from literature reviews, claims data analysis, chart abstraction, and surveys, are designed to predict various outcomes and/or costs for patients with the same disease or clinical problem, but who present with different characteristics and who undergo different management strategies. For example, the model developed by the Ischemic Heart Disease PORT examines the treatment alternatives following cardiac catheterization, including medical management, percutaneous transluminal coronary angioplasty (PTCA), and coronary artery bypass graft (CABG) surgery; and predicts the outcomes of each.‡ The decision model of the Prostate Disease PORT focuses on the expected length of life for men older than 65 with early prostate cancer who have a radical prostatectomy. Projections based on this model can contribute to patient decisions relative to surgery vs. watchful waiting.[9] The decision analysis being done by the Cataract PORT will help to define strategies for managing cataract patients that optimize the tradeoff between effectiveness and cost. This model will project the impact of anticipated

† Personal communication with Chris Callahan, Total Knee Replacement PORT.

‡ Personal communication with John B. Wong, Ischemic Heart Disease PORT.

changes in the demographic distribution of the U.S. population on the cost-effectiveness of cataract care over the next 30 years.

The newness of applying decision modeling and analysis to effectiveness research prompted the Decision Modeling Work Group to develop a guide for selecting an appropriate model based on characteristics (*e.g., acute vs. chronic, linear vs. nonlinear* course of disease, anticipated outcomes, etc.) of the clinical problem being studied and for assessing critical elements within the model. Using each other's work as subjects of critique, PORT investigators compared and contrasted the benefits, strengths, limitations, and liabilities of alternative modeling strategies, including Markov models, decision trees, and simulations. The framework that they developed, and present in their paper, will assist reviewers in judging the adequacy of decision models and will aid other investigators in selecting an appropriate strategy for building new models.

Dissemination: Lost Findings Lead Nowhere

Exceeding the usual research expectation of preparing results for the academic community, PORTs are also actively disseminating their findings to community practitioners, patients, policymakers, and the public at large. Moreover, as described in the paper by the Dissemination Work Group, PORTs are using a variety of creative approaches to accomplish effective dissemination and assimilation, i.e., not merely to distribute materials.

The Prostate Disease PORT has pioneered the use of interactive video disk technology to inform patients of the risks and benefits of surgery and alternative treatments. Early results of the PORT's evaluation of this method of disseminating information indicate that patients with benign prostatic hypertrophy, who have seen the video, tend to choose watchful waiting or conservative medical treatment over surgery.[10]

The Low Back Pain PORT has designed a program of continuing medical education and "study groups" focused on informing primary care physicians, surgeons, and hospital administrators about variations in rates of surgery for low back pain. For patients, the PORT has developed an educational brochure and, in collaboration with investigators at Dartmouth Medical School, Massachusetts General Hospital, and the Foundation for Informed Medical Decision Making, an interactive video disk to provide information pertinent to treatment options. The effects of these dissemination strategies on practice patterns are being tested in a randomized community-based study in which five communities receive the intervention and five serve as controls.

Another avenue of PORT information dissemination is through involvement in the development of AHCPR-sponsored clinical practice guidelines. The PORTs on Prostate Disease, Low Back Pain, and Cataract have all made important contributions to AHCPR guideline work in their respective clinical areas.[11,12]

Conclusions

In applying similar methods to distinct research questions, each PORT has faced a unique set of challenges, and, in the end, each will have a different story to tell. A full evaluation of the PORT approach must await completion of the projects. Although the work has gone along smoothly, there have been some surprises and some disappointments. PORTs have dealt with these creatively, assisted in part by the Inter-PORT Work Groups. Moreover, we all stand to benefit from PORT and work group feedback: the clinical literature can improve, changes can be made in administrative data, and government programs can evolve to reflect experience and emerging needs.

The now ample evidence of the worth of the PORT approach can be illustrated by accomplishments of the Prostate Disease

PORT. The work that has been completed to date illustrates how the individual components of the PORT model fit together to build complementary evidence and how this multi-method approach can have enlarged impact. In its examination of localized prostate cancer treatment, the PORT has completed a comprehensive and critical review of the clinical literature; an analysis of Medicare data to reveal patterns of treatment in elderly males in the United States; a 2- to 4-year post-operative survey of a representative sample of men who were treated with radical prostatectomy; and a decision model that weighs risks and benefits of radical prostatectomy as a function of patient age. Each of these approaches has led to important findings, as follows:

- The scientific literature provides no hard evidence that radical prostatectomy is an effective treatment for localized prostate cancer.[3]
- (In spite of this lack of evidence for clinical effectiveness), Medicare data show that the rate at which U.S. men older than 65 underwent radical surgery for prostate cancer increased more than 500% between 1984 and 1990. There was a greater than 20-fold variation in radical prostatectomy by state.[13]
- PORT data from a national survey of men who underwent radical prostatectomy reveal a much higher rate of serious complications 2- to 4-years post-surgery (e.g., 63% incontinence and 89% impotence) than has been published in surgical case series.[2]
- The PORT decision model shows that, for men older than 70, even the most optimistic claims of benefit of radical prostatectomy treatment would not result in significant enhancement in survival. Yet, half the prostatectomies performed on Medicare patients are on men age 70 and older.[9]

Collectively, these powerful results have shaken complacent views about the effectiveness and appropriateness of radical surgery for prostate cancer. They have led to a consensus in the United States that a randomized trial is needed to compare radical surgery to watchful waiting for men with localized cancer. Although the PORT methods, by themselves, do not resolve the effectiveness question, they have uncovered an epidemic of radical surgical intervention that is not supported by scientific evidence of effectiveness.

The strengths and limitations of the PORT model have been analyzed by AHCPR in conjunction with PORT investigators, work group members, and outside methodologists. The methodological lessons, in particular our fuller understanding of the specific possibilities and problems inherent in individual PORT methods and the total PORT model, are reflected in our plans for the next generation of medical effectiveness research. A new set of grants, the "PORT-IIs" that will be funded starting in mid 1994, will continue the PORT tradition by tackling important clinical questions and breaking new methodological ground.[14,15] They will incorporate what has worked best in the original PORTs into new research strategies that are tailored to determining effective and ineffective therapies for a new set of common clinical conditions. PORT-IIs will make additional methodological advances by applying a broad set of research tools to measuring the effectiveness of different clinical strategies. The challenge for PORT II and for the effectiveness research field is to design research approaches that have both a high degree of internal validity and generalizability. We have learned from the first 14 PORTs that there is no simple formula for answering medical effectiveness questions and that research methods must be tailored to each specific problem.

As we eagerly await the final products of our original PORTs and look forward to PORT-IIs, we will continue to evaluate and refine the strategies for effectiveness research when warranted. Through this continuous, critical approach, we will build both the quantity and quality of evidence

on the effectiveness, appropriateness, and cost effectiveness of clinical interventions and, simultaneously, we will strengthen the methods and measures for additional research.

Acknowledgments

The authors thank Ira E. Raskin, PHD, and Risa J. Lavizzo-Mourey, MD, for their helpful comments.

References

1. Javitt JC, Vitale S, McBean AM, et al. National outcomes of inpatient cataract extraction. 1. Retinal detachment following inpatient surgery. Arch Ophthalmol 1991;98:896.

2. Fowler FJ Jr., Barry MJ, Lu-Yao G, et al. Patient-reported complications and follow-up treatment after radical prostatectomy, the national Medicare experience: 1988-1990. Urology 1993;42:622.

3. Wasson JH, Cushman CC, Bruskewitz RC, et al. A structured literature review of treatment for localized prostate cancer. Arch Family Med 1993;2:487.

4. Carson CA, Fine MJ, Smith MA, et al. Quality of published reports on the prognosis of community acquired pneumonia. J Gen Intern Med 1993;9:13.

5. Powe NR, Tielsch JM, Schein OD, et al. Rigor of research methods in studies of the effectiveness and safety of cataract extraction with intraocular lens implantation. Arch Ophthalmol 1994;112:228.

6. Turner JA, Ersek M, Herron L, et al. Patient outcomes after lumbar spinal fusion: A comprehensive literature synthesis. JAMA 1992; 268:907.

7. Grimes DA. Technology follies: The uncritical acceptance of medical innovation. JAMA 1993;269:3030.

8. Lau J, Antman EM, Jimenez-Silva J, et al. Cumulative meta-analysis of therapeutic trials for myocardial infarction. N Engl J Med 1992;327:248.

9. Fleming C, Wasson JH, Albertsen J, et al. A decision analysis of alternative treatment strategies for clinically localized prostate cancer, prostate patient outcomes research team. JAMA 1993;269:2650.

10. Kasper JF, Mulley AG, Wennberg JE. Developing shared decision-making programs to improve the quality of health care, QRB 1992;18:183.

11. Clinical Practice Guideline, No. 4., Cataract in Adults: Management of Functional Impairment, AHCPR Pub. No. 93-0542, Feb. 1993.

12. Clinical Practice Guideline, No. 8, Benign Prostatic Hyperplasia: Diagnosis and Treatment, Pub. No. 94-0582, Feb. 1994.

13. Lu-Yao GL, McLerran D, Wasson J, et al. An assessment of radical prostatectomy: Time trends, geographic variation, and outcomes. JAMA 1993;269:2633.

14. Agency for Health Care Policy and Research, Medical Treatment Effectiveness Research: PORT-II. Grant Announcement, August 1993.

15. Agency for Health Care Policy and Research, Medical Treatment Effectiveness Research: PORT-II. Grant Announcement, May 1994.

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 Pub. No. 94-0113
September 1994

AHCPR grant announcement

Agency for Health Care Policy and Research

August 1994 Executive Office Center, Suite 501, 2101 East Jefferson Street, Rockville, MD 20852, (301) 594-1360

Medical Treatment Effectiveness Research — Summary

Ongoing Announcement

Agency for Health Care Policy and Research

PA: PA-94-074
PT: 34; K.W. 0730021, 0408006

Purpose

The Agency for Health Care Policy and Research (AHCPR) has ongoing interest in research under the Medical Treatment Effectiveness Program (MEDTEP). This grant announcement outlines the common themes inherent in all MEDTEP projects and identifies major ongoing areas of research. MEDTEP research encompasses three main areas of emphasis: (1) determining what clinical interventions are most effective, cost effective, and appropriate; (2) methods and data to advance effectiveness research; and (3) dissemination and evaluation of the impact of research findings on clinical practice and outcomes. This announcement serves as a general reference for other publications and contacts regarding current MEDTEP research interests and award mechanisms.

Healthy People 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. AHCPR urges applicants to submit grant applications with relevance to the specific objectives of this initiative. Potential applicants may obtain a copy of "Healthy People 2000" (full report: stock No. 017-001-00474-0 or summary report: stock No. 017-001-00473-1) from the Superintendent of Documents, P.O. Box 371954, Pittsburgh, PA 15205-7954; or by contacting the Government Printing Office order desk at telephone: (202) 783-3238.

Eligibility Requirements

Applications may be submitted by domestic and foreign nonprofit organizations, public and private, including universities, clinics, units of State and local governments, nonprofit firms, and nonprofit foundations. Applications from minority and women investigators are encouraged. Foreign applicants are advised to contact the AHCPR Grants Management Officer regarding limitations and special requirements (see "Inquiries").

Mechanisms of Support

The research project grant (R01) mechanism is the principal mechanism of support for MEDTEP research. The small grant (R03) mechanism is available for projects that do not exceed 2 years and $50,000 in total direct costs for the entire project period. Responsibility for planning, direction, and execution of the proposed project is solely that of the applicant.

In addition, AHCPR may issue requests for applications (RFAs) and program announcement (PAs) that announce new MEDTEP program interests and/or the availability of other mechanisms of support for MEDTEP research. For further information, contact

Note: This grant announcement amplifies a program announcement that appeared in the "NIH Guide for Grants and Contracts," Vol 23, No. 22, on June 10, 1994. It supersedes the "Medical Treatment Effectiveness Research" announcement published in the "Federal Register" of August 14, 1990 (FR 55, 33170-33172).

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

the Center for Medical Effectiveness Research (CMER), the Center for Research Dissemination and Liaison (CRDL), and/or the Center for General Health Services Extramural Research (CGHSER). Please refer to the "Inquires" section for contact information (i.e., names, addresses, and telephone numbers).

Research Objectives

MEDTEP Research Themes

Medical effectiveness research is a major component of the health services research agenda of AHCPR. MEDTEP grew out of awareness of significant unexplained variations in clinical (medical, nursing, and allied health) practice and the inadequacy of scientific evidence to support many practices and procedures. MEDTEP projects assess the relative effectiveness, cost effectiveness, and appropriateness of available strategies for the prevention, diagnosis, treatment, and management of illness, in terms of patient outcomes. While MEDTEP research projects vary in focus, size, scope, methods, and complexity, all are expected to be:

Generalizable: "Effectiveness" research is concerned with the outcomes that can be expected in typical patients, receiving care in typical clinical situations, not with outcomes that can only be achieved in selected patients and in controlled clinical situations. Thus, a critical feature of all MEDTEP projects is that the questions have broad applicability and the research design supports wide generalization of the findings.

Pragmatic: MEDTEP projects address questions that have high clinical and policy significance and are designed with attention to the eventual implementation of findings. They obtain empirical evidence or strengthen the science base in ways that can directly contribute to improved patient outcomes and decisionmaking processes (including clinical practice guidelines), and to a more equitable and cost-effective health care system. The usefulness of MEDTEP research stems, in part, from MEDTEP's requirement that the clinical problems and practices addressed are common and costly, and from attention to the realities of clinical practice.

Patient-centered: MEDTEP research evaluates health care in terms of outcomes that emphasize the patient's experience and perspectives. In addition to survival, morbidity, and complications, MEDTEP studies consider patient-reported symptom relief, functional capacity, quality of life, satisfaction with care, and economic burden. Demographic, social and cultural characteristics, as well as personal preferences are important independent variables.

Multidisciplinary: MEDTEP research requires theoretical and practical understanding of a wide range of clinical and nonclinical variables that determine the structure, processes, and outcomes of health care. Studies typically involve a team of researchers who bring the knowledge and methodological expertise of both the clinical and social sciences, plus understanding of the perspectives of patients, providers, and policymakers.

Types of Studies

MEDTEP research encompasses three main areas of emphasis: (1) determining what clinical interventions are most effective, cost effective, and appropriate; (2) methods and data to advance effectiveness research; and (3) dissemination and evaluation of the impact of research findings on clinical practice and outcomes.

1. Clinical Studies

All MEDTEP clinical studies address the basic MEDTEP themes described above to obtain evidence for, or against, the effectiveness, cost effectiveness, and/or appropriateness of available interventions. Most focus on a particular disease or clinical condition and assess the outcomes associated with different interventions that are available for its prevention, diagnosis, treatment, and/or management. Some MEDTEP clinical studies focus on an established technology or procedure. Of interest are conditions or procedures that are common and costly, either in the general population or in a major subpopulation. Major categories of MEDTEP clinical studies are described below:

Patient Outcomes Research Teams (PORTs) and PORT-IIs. Between 1989 and 1992, AHCPR awarded 14 special MEDTEP projects known as Patient Outcomes Research Teams (PORTs). PORTs are distinguished from other MEDTEP clinical studies by their broad scope, multimethod approach to patient outcomes questions, and by the standard 5-year model they follow. AHCPR does not anticipate award of additional projects that use the PORT model.

In July 1993, AHCPR issued an RFA initiating a new generation of MEDTEP research, called "PORT-II," with the first of these grants awarded in summer, 1994. An ongoing PA, "Medical Treatment Effectiveness Research — PORT-II," was published in the *NIH Guide for Grants and Contracts*, Volume 23, Number 18, on May 13, 1994. PORT-IIs continue the PORT tradition by addressing important clinical questions and breaking new methodological ground. They are distinguished from the original PORTs by their individualized research strategies and from other

MEDTEP clinical projects by the expected direct impact of the empirical evidence they obtain on clinical practice, patient outcomes, and health care policy.

PORT-IIs are not feasible or desirable in all clinical areas. There must be sufficient existing information to permit the formulation of effectiveness questions and design of a research strategy tailored to the clinical problem and the population at risk, so that convincing evidence of optimal patient care can be realistically expected within the project period. PORT-IIs focus on the establishment of direct linkages between practice and outcomes and on research methods that facilitate direct comparisons of two or more distinct clinical strategies, e.g., medical vs. surgical treatment. For information on MEDTEP clinical studies, including PORT-IIs, contact CMER.

Other MEDTEP Clinical Studies. The majority of MEDTEP clinical studies are designed to build the science base in areas where a PORT-II is not currently feasible or desirable. This includes research designed to document patterns of practice, describe the natural history of diseases, synthesize the evidence for various clinical strategies, or answer relatively discrete effectiveness questions. Major ongoing program areas focus on pharmaceutical therapy, minority health, and primary care.

AHCPR's program of studies on pharmaceutical therapy, established in 1992, focuses on the effectiveness and cost effectiveness of available pharmaceutical interventions, especially the relationships among drug therapy, other pharmaceutical services, and patient outcomes. Studies address preventive, acute, or chronic treatment in inpatient, ambulatory, or long-term care settings. For further guidance, contact program staff in CMER (see "Inquiries").

In 1991, AHCPR established a research program focused on the effectiveness of current clinical practice for health conditions of special significance among racial and ethnic minorities. This program is highlighted by the 11 MEDTEP Research Centers on Minority Populations, which train minority investigators to develop and conduct effectiveness research. Although additional MEDTEP Minority Centers are not anticipated, AHCPR has continuing interest in studies of the effectiveness of care related to special problems in minority populations. For information, contact Dr. Miriam Kelly, CMER, telephone: (301) 594-1485; or the Associate Administrator for Minority Health, Dr. Morgan Jackson, telephone: (301) 594-6665.

AHCPR's program of primary care research includes, but is not limited to, effectiveness research topics. MEDTEP primary care studies focus on the effectiveness and cost effectiveness of care for conditions that are often undifferentiated, as they present in unselected or nonreferred populations, in primary care settings, and the role of primary care physicians in enhancing the effectiveness and cost effectiveness of care. For information, contact CGHSER, Division of Primary Care, Dr. Carolyn Clancy, Director, telephone: (301) 594-1357, ext. 137.

2. Methodological Studies

Effectiveness research frequently requires new kinds of data and analysis, and new applications of existing tools. MEDTEP supports projects that aim to strengthen or define the limits of existing data and develop or test measurement and data collection instruments, and analytic methods useful for outcomes research. For example, MEDTEP projects may develop new outcomes measures, methods for linking or enhancing existing databases, methods to assess patient preferences, or methods for cross-cultural or international comparisons of patient outcomes. Methodological work may be the main focus of a project or may be embedded in a larger project. For information on these studies, contact CMER or CGHSER.

3. Dissemination and Evaluation Studies

Some MEDTEP projects focus on approaches or technologies for achieving optimal dissemination and integration of new knowledge into practice. This includes research, demonstrations, and evaluations that examine issues of diffusion, awareness, acceptance, and adoption of research findings and clinical practice guidelines by health care providers and consumers. For example, projects may examine the role of opinion leaders and practitioner study groups in influencing practice, or various approaches to enhancing patient participation in health care decisions.

MEDTEP also supports studies to develop and evaluate clinical practice guidelines, information systems, and clinical evaluation tools designed to help practitioners and consumers make better health care decisions. Contact CRDL regarding dissemination studies. Contact CGHSER regarding evaluation studies.

Research Methods

MEDTEP studies draw on a wide range of research methods, especially those used in the clinical, evaluative, and social sciences. The research design may be experimental, quasi-experimental, observational, or a combination of designs. Any appropriate type(s) of statistical analysis, modeling, or synthesis may be proposed. Types and sources of data

may include: new, established, or adapted surveys of patients or providers; clinical data obtained prospectively, or from clinical registries, practice-based networks, or other health care providers; administrative data maintained by providers, insurers, or institutions; and published research findings. Laboratory-based studies are not appropriate.

Applications must be explicit and detailed in describing data, methods, and tools for data collection and analysis. The research plan must be justified in terms of potential for answering the research questions under study.

Applicants who propose to use Medicare or Medicaid data must specify the required data files and explore the availability and cost of obtaining these data with the Health Care Financing Administration (HCFA). The estimated cost must be presented, along with documentation from HCFA, as part of the grant application. This cost should not be included in the total budget request for the project. For more information about data budgets, contact AHCPR's Grants Management Officer (see "Inquiries").

Study Populations

Inclusion of Women and Minorities in Research Involving Human Subjects

It is the policy of AHCPR that women and members of minority groups must be included in all AHCPR-supported health services research projects involving human subjects, unless a clear and compelling rationale and justification are provided that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research.

A new National Institutes of Health (NIH) policy resulting from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43) supersedes and strengthens NIH's previous policies (concerning the inclusion of women and minorities in study populations), which were in effect since 1990 and which AHCPR had adopted. The new NIH policy contains some provisions that are substantially different from the 1990 policies. AHCPR plans to publish guidelines specific to AHCPR. In the interim, AHCPR will follow the NIH guidelines, as applicable.

All investigators proposing research involving human subjects should read the "NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research," published in the *Federal Register* on March 9, 1994 (FR 59, 11146-11151) and reprinted in the *NIH Guide for Grants and Contracts*, Volume 23, Number 11, on March 18, 1994.

Investigators also may obtain copies of the NIH policy from AHCPR program staff listed under "Inquiries." AHCPR program staff also may provide additional relevant information concerning this policy.

Application Procedures

Applications are to be submitted on the grant application form PHS 398 (rev. 9/91). They will be accepted at the standard application deadlines indicated in the application kit. (Until further notice, these dates are: February 1, June 1, and October 1.) State and local governments may use form PHS 5161 and follow accompanying requirements for copy submission.

Application kits are available at most institutional offices of sponsored research or from the Office of Grants Information, Division of Research Grants, NIH, Westwood Building, Room 449, Bethesda, MD 20892, telephone: (301) 594-7248. For AHCPR, applications may also be obtained from:

Global Exchange, Inc.
7910 Woodmont Avenue, Suite 400
Bethesda, MD 20814-3015
Telephone: (301) 656-3100
Fax: (301) 652-5264

To receive a copy of an announcement referred to above, please contact Global Exchange. Or, if you have a fax machine with a *telephone handset*, you may use the AHCPR InstantFAX system. Dial (301) 594-2800 and use the key pad on your receiver when responding to prompts from this system. The requested announcement will be faxed at the end of the ordering process.

The completed, signed, original application and five legible copies must be sent or delivered to:

Division of Research Grants*
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892

The Division of Research Grants (DRG) will not accept any application in response to this announcement that is essentially the same as one currently pending initial review, unless the applicant withdraws the pending application. The DRG will not accept any application that is essentially the same as one already reviewed. This does not preclude the submission of substantial revisions of applications already reviewed, but such applications must include an introduction addressing the previous critique.

**Note: This mailing address is the central mailing address for NIH. Applicants who use express mail or a courier service are advised to follow the carrier's requirements for showing a street address. The address for the Westbard Building is: 5333 Westbard Avenue, Bethesda, MD 20816.*

Review Procedures

Upon receipt, applications will be reviewed for completeness by the referral office, DRG. Incomplete applications will be returned to applicants without further consideration.

General review criteria for all grant applications are: significance and originality from a scientific and technical viewpoint; adequacy of the method(s); availability of data or adequacy of plan to collect required data; qualifications and experience of the principal investigator and proposed staff; adequacy of the plan for organizing and managing the project; reasonableness of the proposed budget; and adequacy of the facilities and resources available to the applicant.

An appropriate peer review group will evaluate applications for scientific/technical merit in accordance with the general criteria stated above, and any special review criteria applicable to an individual mechanism or as listed in specific announcements.

Applications requesting total direct costs in excess of $250,000 will be reviewed by AHCPR's National Advisory Council for Health Care Policy, Research, and Evaluation. The Council also may review applications requesting total direct costs in excess of $50,000.

Special Review Criteria

Applicants are advised to refer to individual announcements and to contact the staff offices listed in the next column regarding special review criteria.

Award Criteria

In making funding decisions, AHCPR will consider: quality of the proposed project as determined by peer review, program balance, and availability of funds.

Inquiries

As indicated above, several AHCPR offices are involved in MEDTEP extramural research. Those considering applying in response to this announcement are strongly encouraged to discuss their project with appropriate AHCPR program administrators. AHCPR welcomes the opportunity to clarify any issues or questions from potential applicants.

For MEDTEP clinical studies, including PORT-IIs, pharmaceutical outcomes, and other MEDTEP clinical studies; and related methodological studies, contact:

Richard J. Greene, M.D., Ph.D.
Director, Center for Medical Effectiveness Research (CMER)
Agency for Health Care Policy and Research
Executive Office Center, Suite 605
2101 East Jefferson Street
Rockville, MD 20852
Telephone: (301) 594-1485

Direct inquiries regarding primary care, methodological studies, and evaluation studies to:

Norman W. Weissman, Ph.D.
Director, Center for General Health Services Extramural Research (CGHSER)
Agency for Health Care Policy and Research
Executive Office Center, Suite 502
2101 East Jefferson Street
Rockville, MD 20852
Telephone: (301) 594-1349, ext. 106

Direct inquiries regarding dissemination studies to:

Phyllis M. Zucker
Director, Center for Research Dissemination and Liaison (CRDL)
Agency for Health Care Policy and Research
Executive Office Center, Suite 501
2101 East Jefferson Street
Rockville, MD 20852
Telephone: (301) 594-1360

Direct inquiries regarding fiscal matters, including budget justification for HCFA data, to:

Ralph L. Sloat
Grants Management Officer
Agency for Health Care Policy and Research
Executive Office Center, Suite 601
2101 East Jefferson Street
Rockville, MD 20852
Telephone: (301) 594-1447

Authority and Regulations

This program is described in the *Catalog of Federal Domestic Assistance*, Nos. 93.180 and 93.226. Awards are made under authorization of the Public Health Service Act, Title IX (42 U.S.C. 299-299c-6 and Section 1142 of the Social Security Act (42 U.S.C. 1320b-12). Awards are administered under the PHS Grants Policy Statement; and Regulations 42 CFR Part 67, Subpart A; and 45 CFR Part 74 (45 CFR Part 92 for State and local governments). This program is not subject to the intergovernmental review requirements of Executive Order 12372.

The Public Health Service (PHS) strongly encourages all grant recipients to provide a smoke-free workplace and promote the nonuse of all tobacco products. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

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 Pub. No. 94-0089
August 1994

Withdrawal/Redaction Marker
Clinton Library

DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
001. talking points	Personal (Partial) (1 page)	ca. 1995	P6/b(6)

COLLECTION:
Clinton Presidential Records
First Lady's Office
Domestic Policy Council (Karen Guss)
OA/Box Number: 5931

FOLDER TITLE:
Epidemiology [2]

2012-0820-S
ms480

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

P1 National Security Classified Information [(a)(1) of the PRA]
P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
P3 Release would violate a Federal statute [(a)(3) of the PRA]
P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [a)(5) of the PRA]
P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

C. Closed in accordance with restrictions contained in donor's deed of gift.
PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).
RR. Document will be reviewed upon request.

Freedom of Information Act - [5 U.S.C. 552(b)]

b(1) National security classified information [(b)(1) of the FOIA]
b(2) Release would disclose internal personnel rules and practices of an agency [(b)(2) of the FOIA]
b(3) Release would violate a Federal statute [(b)(3) of the FOIA]
b(4) Release would disclose trade secrets or confidential or financial information [(b)(4) of the FOIA]
b(6) Release would constitute a clearly unwarranted invasion of personal privacy [(b)(6) of the FOIA]
b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

Talking Points for American Academy of Otolaryngology - Head and Neck Surgery

[001]

Thank you. It is a pleasure to be here today. Leon Panetta asked me to let you know how sorry he is that he couldn't join you. P6/b(6) P6/b(6) I can tell you that there are few people in this world who appreciate your work more than I do. . .

THE CLINTON ADMINISTRATION CONTINUES TO FIGHT FOR REAL HEALTH CARE REFORM.

- As you know, last year the Clinton Administration fought hard for health care reform. While we could not reach agreement on legislation, there can be little disagreement that the problems remain. Nearly 40 million Americans have no health insurance and millions more are just one pink slip or illness away from losing it. Eighty-four percent of the uninsured in 1993 were in working families, and more that 55 percent lived in families headed by full-time workers. And while health care costs have begun to slow down, they are continuing to rise at three times the rate of inflation.

- As the President said in his State of the Union address and in his December letter to the Congressional Leadership, we remain firmly committed to guaranteeing health security to all Americans and to containing health care costs for families, businesses and Federal, state and local governments.

- The President believes that we should take a step-by-step approach. This year, we can take the first steps. The Congress can and should:

    - Reform the insurance market -- so that people don't lose their insurance when they lose their job or change jobs or a family member falls ill, and so that small businesses can afford to buy insurance for their workers.

    - Make coverage affordable for and available to children.

    - Help workers who lose their jobs keep their health insurance.

    - Level the playing field for the self-employed by giving them the same tax treatment as other businesses.

    - Help families provide long-term care for a sick parent or a disabled child.

- Because their constituents are demanding action, some Republicans have begun to respond to the President's challenge by coming forward with proposals and bills. We look forward to working with them to take the first steps this year.

- But as we continue to work toward health reform, we must continually remember that we have the highest quality of care, the most talented and dedicated health professionals, and the most advanced research institutions in the world. All health reform proposals must be measured by their ability *both* to fix what is wrong *and* to preserve what is right about our health care system.

THE CLINTON ADMINISTRATION IS FIGHTING BACK TO PROTECT DOCTORS AND PATIENTS FROM SEVERE CUTS IN MEDICARE AND MEDICAID.

- Unfortunately, for too many Republicans in Congress, "health reform" has turned into the code word for ~~slashing~~ cutting Medicare and Medicaid to pay for tax cuts for the wealthy. A number of Republicans in the House and the Senate have talked about cutting both Medicare and Medicaid by hundreds of billions of dollars.

  - ~~Republicans have signaled their intention to cut~~ Medicare by about $300 billion between now and 2002.

  - ~~Republicans have suggested cutting Federal~~ Medicaid spending by at least $180 to $190 billion in spending cuts between now and 2002.

- It's not hard to figure out what that means for the doctors and hospitals who treat patients receiving benefits under these programs, and for the patients themselves.

  - It means significant cuts in payments to hospitals, physicians and other providers.

  - It means shifting ~~a staggering~~ additional financial burdens to the elderly and disabled ~~Medicare beneficiaries~~. Or to small businesses and families who will pay higher premiums and fees if these programs are ~~slashed~~ cut without overall reform.

  - It means ~~dropping~~ forcing them to drop coverage or shrinking benefits for mothers and children on Medicaid. Or it means asking States to pick up the tab to preserve the Medicaid program, and in doing so, forcing them to raise taxes or ~~slash~~ cut spending for services like education and public safety.

  - As you have all said, spending cannot be ratcheted down without affecting access to and quality of care for mothers and children, and for the elderly and disabled.

- The President presented a responsible budget to Congress -- a budget that made tough choices to get our rising deficit under control, but a budget that protected hard-working Americans and investments in our children. Now it is Congress' turn to act. To detail where they will get the cuts they need to pay for their tax cuts for the wealthy. To step forward with *their* plan for deficit reduction.

- The President has consistently said that we cannot get a hold of the deficit without passing meaningful health reform. Over the next five years alone, almost 40 percent of the growth in total Federal spending will come from rising costs in Federal health care programs. We must contain costs in these programs. But we must do it as we reform our health care system as a whole -- not by arbitrarily cutting programs that serve the most vulnerable Americans.

- That is not to say that these programs cannot and should not be improved.

    - The Clinton Administration is committed to continuing to give States flexibility to reduce costs while maintaining coverage in their Medicaid programs.

    - And we are committed to continuing to reduce regulatory burdens, streamline administration, and improve cost effectiveness in the Medicare program while increasing choices for beneficiaries and ensuring that quality of care is protected.

    - These are the kind of changes that the Clinton Administration is doing now. And these are the kind of changes that we look forward to working with Congress on in the coming months.

To note at the end:

Unfortunately, I am on my way to another event so I will not be able to take questions.

Additional Notes for Speech

1. Anti-Smoking

As you know, more than 400,000 smokers die each year from smoking-related illnesses. Tobacco use kills more people each year in the United States than AIDS, car accidents, alcohol, homicides, illegal drugs, suicides and fires *combined.* And the real tragedy is that these deaths are preventable.

The Clinton Administration is committed to the nation's campaign against smoking and tobacco use. The Administration has a number of initiatives -- across a wide range of departments -- aimed at increasing awareness about the harmful effects of tobacco use and second-hand smoke and at preventing smoking.

- To take just a few examples. The Centers for Disease Control and the National Cancer Institute provide funds to States for education and prevention programs. The Environmental Protection Agency and HHS have united to voice support for the scientific evidence on the dangers of second-hand smoke. Armed with this evidence, the Public Health Service is working -- with health professionals -- to increase public awareness about the impact of second-hand smoke in the home on children's health. The Department of Labor is working against occupational exposure. The Department of Defense has banned smoking indoors in military installations. And, as I am sure you know, the Food and Drug Administration has undertaken a review to determine whether nicotine should be regulated as a drug.

- Perhaps most tragic is the epidemic of youth addiction to nicotine. A casual decision at a young age to use tobacco products can lead to addiction and serious disease. The Department of Education is spearheading efforts to educate children, particularly adolescents, about the dangers of tobacco use -- in order to prevent kids from smoking, hopefully before they start. In addition, our Goals 2000 legislation requires all schools to be smoke-free -- which will provide cleaner learning environments for all of our children.

Your concern and leadership on tobacco issues has been extremely important and I urge you to continue those efforts.

2. Regulatory Reform

- I thought that all you should say about regulatory reform is what I included on the second page under the part about improving the Medicare and Medicaid programs. You could add that this is part of the Administration's overall regulatory review initiative to reduce the burdens of government and make it more responsive to its customers -- in this case the doctors and patients who must manage the maze of Medicare and Medicaid -- while ensuring health and safety.

I am reluctant to include the specifics, because Elaine has been clear that this will be unveiled in a coordinated way. As you know, we are considering proposals to: (1) eliminate the physician attestation form; (2) change CLIA significantly; and (3) move to performance standards in reviewing and certifying hospitals, home health agencies and ESRD facilities (but not nursing homes).

3. Medical Liability Reform

- We have not changed our policy from last year on medical liability reform, but, as you know, we have not yet discussed our position going forward. This group was not satisfied with the "modest" reforms in the Health Security Act (especially because we did not include caps on damages). I would not raise this issue in light of the debate this week on the Republicans' Common Sense Legal Reform Act and our strong public position against it.

4. Antitrust Relief

- Physicians want clear antitrust exemptions so that they can better compete in a marketplace increasingly dominated by managed care organizations and other insurance companies. As with medical malpractice, we have not changed our position, but we have not yet developed a policy for the coming months. The Justice Department has shortened review times and released nine antitrust policy statements to guide physicians and hospitals (i.e., describing joint ventures that will not violate antitrust laws). The physician and hospital groups see these policy statements as a good first step but believe that we have not gone far enough. Last year, a number of Republicans supported stronger antitrust relief (best known was the Hatch-Archer bill which delineated safe harbors for certain activity and provided for streamlined antitrust review).

U.S. Department of Labor

Assistant Secretary for
Occupational Safety and Health
Washington, D.C. 20210

FACSIMILE TRANSMISSION

DATE: March 29, 1995

TO: Karen Goss

FAX NUMBER: 456-7431

TELEPHONE NUMBER: _____

NUMBER OF PAGES, INCLUDING COVER SHEET: 4

* *

FROM: Nelson Reyneri

TELEPHONE NUMBER: 202 219 6027

FAX NUMBER: 202 219 6064

* *

SPECIAL INSTRUCTIONS: _____

Susan Harwood
Adam Finkel
(202) 219-7075

Talking Points for Carol Rasco
Society for Healthcare Epidemiology of America
OSHA Regulations

SHEA was an active participant in the development of the Bloodborne Pathogens Standard, published in 1991, and they have been involved in OSHA's ongoing activities related to occupational exposure to tuberculosis. We should acknowledge their participation and active involvement.

Occupational Exposure to TB

The regulatory activities of primary concern to this group are those that relate to occupational exposure to **tuberculosis.** At present, OSHA has two parallel activities:

Ongoing enforcement activity Beginning in October of 1993, OSHA began nationwide enforcement activities to respond to the hazard of occupationally-acquired tuberculosis. This ongoing activity is based on OSHA's General Duty clause as well as other existing OSHA regulations. Guidance for many of the protective measures to be taken is found in the CDC guidelines for control of tuberculosis.

Development of a TB standard OSHA is currently developing a proposed standard for occupational exposure to tuberculosis. OSHA recognizes the significance of CDC's TB guidelines and anticipates that they will serve as one of the primary bases for the proposed standard. We anticipate that the proposed standard will be published in Octobere of this year if there is no regulatory moratorium.

Red Flag for TB

The type of respirator required is far and away the most controversial issue related to this hazard. Both CDC and OSHA say that respirators are necessary under certain circumstances when the employee has contact with a person who has active TB. For example, if an infectious TB patient is in a hospital isolation room, employees entering the room must wear a respirator.

Question: Why does OSHA require expensive, uncomfortable HEPA respirators when there is no scientific evidence that they are necessary and that lighter, less expensive respirators work just as well?

Answer: At present, the minimum respirator that meets the recommendations of the CDC TB guidelines is a high-efficiency particulate air (HEPA) respirator. This is currently the only respirator which is certified to filter out airborne particles in the size range of those which contain the tuberculosis organism. When the National Institute for Occupational Safety and Health (NIOSH) completes the revision of its respirator certification procedures, additional respirators may become available.

Question: When will the revised NIOSH certification regulations be published and go into effect?

Answer: (HHS will have to supply the answer.)

Occupational Hepatitis B

~~The following is information about a hazard that has been addressed by OSHA's standard for Bloodborne Pathogens. Since it is based on data from the CDC, it is important that we get agreement from HHS before this information is used by Carol Rasco in her speech. As soon as we have gotten agreement from HHS, we will let you know.~~

~~In 1986, there were approximately 12,500 hepatitis B infections in high risk healthcare workers (those with frequent blood exposure). This dropped to 8,700 in 1987, when CDC published its recommendations for the prevention of HIV transmission in the health care setting which included rigorous adherence to precautions designed to prevent exposure to blood. In 1987 and, to a greater extent, in 1988, OSHA began responding to complaints concerning occupational exposure to these hazards. In December of 1991, OSHA published the Bloodborne Pathogens standard that went into effect the following year. By 1993, the number of hepatitis B infections in this group had dropped to 1,460.~~

~~This approximately 90% decrease in occupationally related hepatitis B infections over a seven year period is the result of the combined efforts of all those involved, including the exposed healthcare workers, the committees and individuals responsible for implementing precautions in the workplace, as well as CDC and OSHA.~~

In 1993, the most recent year that statistics were available, the Center for Infectious Diseases at CDC reported that the number of cases of hepatitis B in occupationally exposed workers had been reduced to 727. The primary factor enabling the reduction of occupationally related hepatitis B was in promulgation of OSHA's Bloodborne Pathogens Standard. Clearly, individuals such as the

members of SHEA have made a significant contribution to this reduction through your implementation of and commitment to programs designed to reduce exposures and to intervene when accidental exposures take place. This is a result we can all be proud of.

Note: There will be individuals at this meeting who feel that OSHA's regulation had no impact, wasted money and they will get up and say so. The information above is taken directly from the revision from Health People 2000 and the individuals at CDC involved with this information are in agreement with the information.

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
(301) 594-1455

TO:	FAX number:	202 456-7431
	Name:	Karen Guss
	Organization:	Old Executive Office Building
	Telephone:	202 456-7431

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

Number of pages including this page: 5

MESSAGE: March 24, 1995

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Agency for Health Care Policy
and Research
Rockville MD 20852

NOTE TO: Karen Guss, Assistant to the First Lady

From: Irma Arispe, Evaluation Officer, Agency for Health Care Policy and Research

Date: March 24, 1995

This note responds to your request for information to assist in the preparation of a speech for the Society for Healthcare Epidemiology of America, Inc. (SHEA). If you have any questions about this information, please contact me or Jill Bernstein at 301 594-1455.

The Agency for Health Care Policy and Research (AHCPR), is an agency of the Public Health Service. Its primary mission is quality measurement and improvement. AHCPR works to improve quality of care by

- analyzing variations in current medical practice and examining the effectiveness of alternative treatments (through outcomes research, technology assessments, and the development of clinical practice guidelines) and
- developing measures of quality (clinical quality indicators for providers as well as quality measures for consumers and health care purchasers).

Claire Maklan has provided you with information on outcomes research. The remainder of this note provides information on AHCPR's quality measurement and improvement activities.

Defining Clinical Quality.

Clinical performance measures (also sometimes called clinical quality indicators) allow you to answer questions such as

- Was effective care provided to each patient?
- Was it provided safely and in an appropriate time frame for each patient?
- Was the outcome as good as could be expected given the patient's condition and personal characteristics and the current state of medical science?
- Was care delivered, outcomes achieved, and pertinent information communicated in a manner that meets patient's needs and expectations?

Understanding and Choosing Clinical Quality Indicators

AHCPR, working with the Center for Quality of Care Research and Education at the Harvard University School of Public Health and the Center for Health Policy Studies of Columbia, Maryland, has recently issued a report, "Understanding and Choosing Clinical Performance Measures for Quality Improvement: Development of a Typology." I enclosed a

copy of the report with the packet of information prepared for you by Claire Maklan. The first chapter of the report provides a nice overview.

The purpose of this project is to collect and analyze clinical performance measures currently used by public and private organizations. The federal government, and AHCPR in particular, has funded the development of many of the indicators and measurement tools used by public and private organizations to assess the quality of medical care. In addition, many private organizations have developed quality indicators. However, until now, there has been no single source of information on clinical quality measures, nor have there been any generally accepted criteria for evaluating the validity or usefulness of various measures. The "Measurement Typology Project" fills this gap.

This is a two step project:

1. to collect clinical performance measures currently in use and create a classification system for describing and evaluating the measures, and

2. to expand and validate the system to create a more comprehensive source of information on quality measures.

The first step, which is completed, tells us what measures exist and are in use and provides ways to assess the validity and usefulness of quality measures. The project has identified over 1200 clinical performance measures used by

- government organizations (such as HCFA, the Department of Veterans Affairs, and AHCPR),

- accrediting organizations (such as the Joint Commission on Accreditation of Healthcare Organizations and the National Committee on Quality Assurance), and

- private organizations such as the Bay Area Business Group on Health and United Health Care).

The project develops a standard method for describing the measures, and this will facilitate a uniform system of quality measures. (See incoming letter from the Society for Healthcare Epidemiology). This report is available from the AHCPR Clearinghouse at 1-800-358-9295. AHCPR will also make this report available through NTIS (the National Technical Information Service).

The next step, which will begin next month, will expand, validate, and refine this classification scheme. AHCPR will be working in partnership with organization like the Joint Commission on Accreditation of Healthcare Organizations (mentioned in the SHEA

letter) to identify and promote valid quality measures that permit systematic comparison of health care organizations.

Developing New Quality Indicators.

AHCPR is also sponsoring projects to develop clinical quality indicators. An important part of our research involves translating clinical practice guidelines into guideline-based measures of quality. AHCPR has contracted with the American Medical Review Research Center (AMRRC) to develop quality and utilization review criteria and performance measures based on three AHCPR-supported clinical practice guidelines (for urinary incontinence, acute postoperative pain, and benign prostatic hyperplasia or BPH).

These measures have been tested in random samples of medical records of Medicare patients and have successfully targeted quality improvement opportunities. For example, the acute pain guideline recommends

- the development of a preoperative pain management plan in collaboration with the patient so that the patient will understand the surgical procedure, the type of pain he or she is likely to experience, and the methods available for relieving pain and

- the use of a scaled pain assessment tool to regularly evaluate the patient's pain symptoms.

The project found that typically these recommendations were not followed, yet hospital length of stay was significantly lower among patients whose care complied with these two guideline recommendations. By examining clinical performance using these guideline based measures, health care providers can identify ways to improve care.

AHCPR is also working with Rand to develop clinical quality indicators based on the guidelines for cataract in adults and prediction and prevention of pressure ulcers.

Quality Indicators for Consumer Choice.

AHCPR's work has also shown that patients can provide information on the quality of care they receive. AHCPR has sponsored a number of consumer quality initiatives including

- **a model survey to assess consumer attitudes about the accessibility, quality and effectiveness of health care they receive.** Health Plans, employers, consumer advocacy groups, alliances, government agencies, and others will be able to use this survey to provide valid and comparable information from consumers about their health plans and providers.

- **a patient based tool to assess clinical quality, called "Patient Reports on System Performance" or PROSPER.** This project collects objective information from patients on time to receive services (access to care), communication between providers (coordination of care), and follow up after tests and treatment (continuity of care).

These projects, which create rates of consumer satisfaction, consumer access, and clinical performance will also facilitate clinical qualtiy improvement.

Contacts

Bob Irwin CDC - immunization cdc 6908598

Nelson Reyner, OSHA 2196064

Irma ~~Aspeu~~ Arispe AHCPR 301 ~~594~~ 5941455

NIOSH: Sharon Morse, Cathy Sykes

respirators Jill Hargas, HHS 6906133

Q & A

Q: You mentioned the Administration's response to the risk of occupational exposure to tuberculosis. Physicians and other health care professionals are extremely worried about the spread of tuberculosis in hospitals. To protect themselves, they are supposed to wear TB respirators. However, the respirators that are approved for use in hospitals today are unsatisfactory. HEPA respirators, or "pappers" are so cumbersome and expensive that few people actually use them. The other type of approved respirator has been shown to leak in laboratory tests.

The National Institute for Occupational Safety and Health has drafted regulations that will update the process by which TB respirators are tested. Under the proposed process, a new generation of respirators would be approved. These respirators will be extremely effective and less expensive than today's respirators. The health care industry, respirator manufacturers, and labor unions and other affected constituencies support the new regulations. Yet, due to the current anti-regulation climate, the Department of Health and Human Services and the Office of Management and Budget have failed to sign off on the new regulations so that they can go into effect. In the meantime, thousands of health care professionals are at risk of infection. What is being done to address this problem?

A: I fully understand your concerns about the TB respirator regulations. I can assure you that the Administration is working hard to get the new regulations finalized and ready to go.

Q: The Centers for Disease Control and Prevention are the world's leading authority on using epidemiology to improve public health. So why is CDC not involved the study of health care quality indicators, a very important aspect of epidemiology?

A: Of course, CDC is very interested in health care quality management as part of its mission to control and prevent disease. For example, as you know, the National Center for Infectious Disease can play an important role in controlling the spread of infections in hospitals and other health care settings. CDC is also working with other agencies within the Public Health Service to develop a uniform set of performance indicators to be used in assessing the quality of health care in programs currently funded through block grants.

However, healthcare quality management has aspects that go beyond control and prevention, so the agencies of the Department of Health and Human Services believe that spreading its healthcare quality management efforts around works best. Under the current system, AHCPR focuses on medical effectiveness and health services research. The Health Resources and Services Administration (HRSA), which is concerned with maternal and child health programs, rural and migrant health, and the care of persons with AIDS, focuses on the implementation of quality measures in health care settings

where these services are delivered. HRSA is also involved in the development of the health professions, and it concerns itself with integrating quality management into health education. The Substance Abuse and Mental Health Services Administration works on implementing quality measures related to the prevention and treatment of addictive and mental disorders. The Health Care Financing Administration applies quality indicators in its quality oversight and quality improvement efforts in the Medicaid and Medicare programs. And of course, all of these agencies are in communication with one another through Public Health Service workgroups.

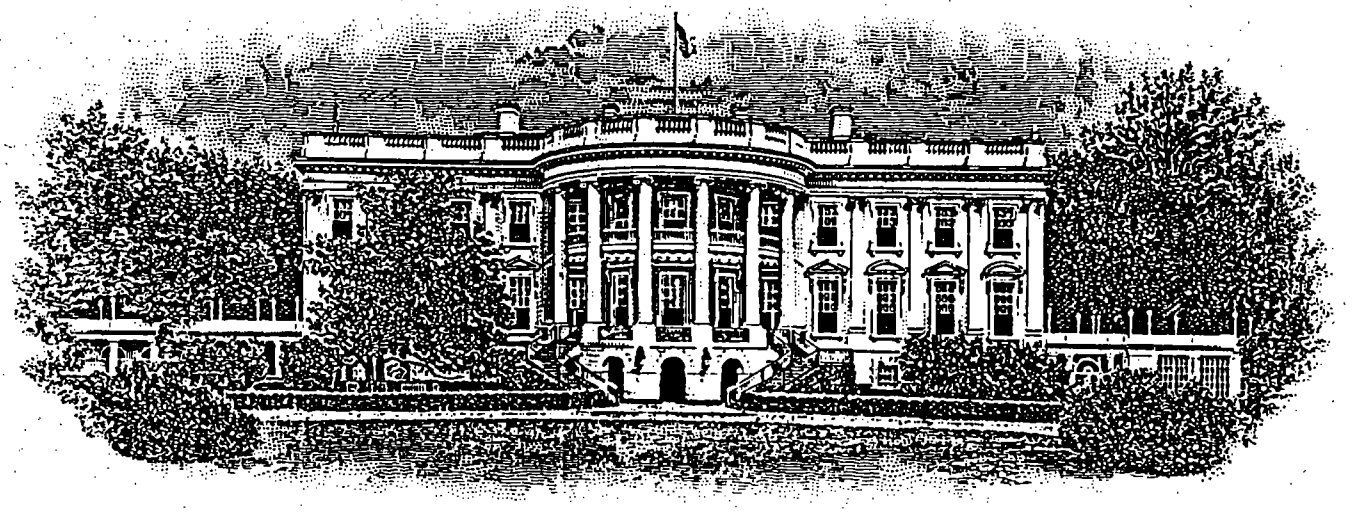
Q: I have heard that there have been many problems with the immunization program. Is this true, and if so, what is being done to fix the problems?

A: Most of the President's Childhood Immunization Initiative have progressed quite smoothly. As I mentioned before, we've helped states extend clinic hours and made it easier to keep parents and providers on the appropriate vaccination schedule.

The Vaccines for Children program has been attacked by some on Capitol Hill and by some vaccine manufacturers. But we are working out issues in the program including those related to the complaints of vaccine manufacturers that they must sell too much vaccine at a discounted price. At the same time, evidence of the program's effectiveness is becoming available -- a recent study revealed that the Vaccines for Children program in New York has allowed the state to provide more vaccinations to children in the primary care setting where they first receive care. And more and more public and private health care providers are getting involved. By January 1995, 20,000 private provider sites and 8,000 public provider sites were already enrolled. And 36 states have reported that they have centralized distribution systems in place to ship vaccines to public and private providers, with the remaining participating states and the District of Columbia distributing vaccines to a portion of enrolled providers.

We remain committed to this program, and we invite you all to get involved. So I want to remind you that National Infant Immunization Week -- a week of community outreach highlighting the role we can all play in protecting our children from disease -- is coming up at the end of April.

The White House



DOMESTIC POLICY

FACSIMILE TRANSMISSION COVER SHEET

TO: Dr. Yamauchi

FAX NUMBER: 501 320 3418

TELEPHONE NUMBER:

FROM: Karen Guss

TELEPHONE NUMBER: 202 456 5603

PAGES (INCLUDING COVER):

COMMENTS: Carol asked me to let you know how flattered we are that you are interested in having this speech!

Karen

Talking Points for Society for Healthcare Epidemiology of America, Inc.

Thank you for that kind introduction. It is truly a pleasure to be here and to visit with you all and with my dear friend Dr. Yamauchi. As I'm sure you all agree, Dr. Yamauchi is a credit to the medical profession and to this association. His tireless efforts in the areas of children's health and AIDS, the depth and breadth of his knowledge on a variety of topics, his dedicated public service, and his good humor have all been an inspiration to me at one time or another. Dr. Yamauchi and I spent a great deal of time working together -- and battling the state legislature together -- when we both worked for Bill Clinton in the Governor's office in Arkansas, and I can tell you, it would be wonderful to have him as an on-the-scene ally in Washington today. So thank you all for having me here.

I want to touch on about four different areas today that I think will be of interest to you. I am going to talk about health care reform, quality management research within the Clinton Administration, our efforts to fight the on-the-job infection of health care workers and the President's Childhood Immunization Initiative.

THE CLINTON ADMINISTRATION CONTINUES TO FIGHT FOR REAL HEALTH CARE REFORM.

- As you know, last year the Clinton Administration fought hard for health care reform. While we could not reach agreement on legislation, there can be little disagreement that the problems remain. Nearly 40 million Americans have no health insurance and millions more are just one pink slip or illness away from losing it. Eighty-four percent of the uninsured in 1993 were in working families, and more that 55 percent lived in families headed by full-time workers. And while health care costs have begun to slow down, they are continuing to rise at three times the rate of inflation.

- As the President said in his State of the Union address and in his December letter to the Congressional Leadership, we remain firmly committed to guaranteeing health security to all Americans and to containing health care costs for families, businesses and Federal, state and local governments.

- The President believes that we should take a step-by-step approach. This year, we can take the first steps. The Congress can and should:

    - Reform the insurance market -- so that people don't lose their insurance when they lose their job or change jobs or a family member falls ill, and so that small businesses can afford to buy insurance for their workers.

    - Make coverage affordable for and available to children.

    - Help workers who lose their jobs keep their health insurance.

- Level the playing field for the self-employed by giving them the same tax treatment as other businesses.

- Help families provide long-term care for a sick parent or a disabled child.

- Because their constituents are demanding action, some Republicans have begun to respond to the President's challenge by coming forward with proposals and bills. We look forward to working with them to take the first steps this year.

- But as we continue to work toward health reform, we must continually remember that we have the highest quality of care, the most talented and dedicated health professionals, and the most advanced research institutions in the world. All health reform proposals must be measured by their ability *both* to fix what is wrong *and* to preserve what is right about our health care system.

THE CLINTON ADMINISTRATION IS FIGHTING BACK TO PROTECT DOCTORS AND PATIENTS FROM SEVERE CUTS IN MEDICARE AND MEDICAID.

- Unfortunately, for too many Republicans in Congress, "health reform" has turned into the code word for cutting Medicare and Medicaid to pay for tax cuts for the wealthy. A number of Republicans in the House and the Senate have talked about cutting both Medicare and Medicaid by hundreds of billions of dollars.

  - It now appears that Medicare will be slated to be cut by about $300 billion between now and 2002.

  - It also appears that Medicaid is being targeted for at least $180 to $190 billion in spending cuts between now and 2002.

- It's not hard to figure out what that means for the doctors and hospitals who treat patients receiving benefits under these programs, and for the patients themselves.

  - It means significant cuts in payments to hospitals, physicians and other providers.

  - It means shifting additional financial burdens to the elderly and disabled. Or to small businesses and families who will pay higher premiums and fees if these programs are cut without overall reform.

  - In many states, it means being forced to drop coverage or shrink benefits for mothers and children on Medicaid. Or it means asking States to pick up the tab to preserve the Medicaid program, and in doing so, forcing them to raise taxes or cut spending for services like education and public safety.

- The President presented a responsible budget to Congress -- a budget that made tough choices to get our rising deficit under control, but a budget that protected hard-working Americans and investments in our children. Now it is Congress' turn to act. To detail where they will get the cuts they need to pay for their tax cuts for the wealthy. To step forward with *their* plan for deficit reduction.

- The President has consistently said that we cannot get a hold of the deficit without passing meaningful health reform. Over the next five years alone, almost 40 percent of the growth in total Federal spending will come from rising costs in Federal health care programs. We must contain costs in these programs. But we must do it as we reform our health care system as a whole -- not by arbitrarily cutting programs that serve the most vulnerable Americans.

- That is not to say that these programs cannot and should not be improved.

    - The Clinton Administration is committed to continuing to give States flexibility to reduce costs while maintaining coverage in their Medicaid programs.

    - And we are committed to continuing to reduce regulatory burdens, streamline administration, and improve cost effectiveness in the Medicare program while increasing choices for beneficiaries and ensuring that quality of care is protected.

    - These are the kind of changes that the Clinton Administration is doing now. And these are the kind of changes that we look forward to working with Congress on in the coming months.

THE CLINTON ADMINISTRATION'S EFFORTS TO IMPROVE THE HEALTH CARE SYSTEM ARE CONTINUING WITHIN THE HEALTH CARE AGENCIES. THIS WORK INCLUDES EFFORTS TO MAINTAIN AND IMPROVE THE <u>QUALITY</u> OF HEALTH CARE.

Developing Quality Measures

- As you know, the Agency for Health Care Policy and Research (AHCPR), an agency of the Public Health Service, works to improve the quality of care by developing measures of quality both for health care professionals and for consumers.

- More than 1200 clinical performance measures are now in use. However, as you know, there has been no single source of information on clinical quality measures. Nor has there been a generally accepted criteria for evaluating the validity or usefulness of the various measures. An important project now underway to fill this gap is AHCPR's "Measurement Typology Project."

- Working together with the Harvard School of Public Health and the Center for Health Policy Studies of Columbia, Maryland, AHCPR has collected the clinical performance measures being used by public and private organizations and has developed a standard method for describing them.

- Next, AHCPR will work with organizations like the Joint Commission on Accreditation of Healthcare Organizations to identify and promote the most valid of the quality measures they have found. This will facilitate the systemic and uniform comparison of health care organizations -- a vital task in today's changing health care industry.

- AHCPR is also developing new quality indicators based on adherence to clinical practice guidelines. Because practice guidelines are derived from scientific evidence of what really works for patients, these new quality indicators should prove to be extremely useful.

- In addition, AHCPR is working to help consumers make choices about health plans and providers by surveying consumers directly about the accessibility, quality, and effectiveness of the care they receive. Health plans, employers, consumer advocates, purchasing alliances and other consumers will be able to turn to this survey for information that will help them make their own informed decisions. By encouraging knowledgeable choices based on quality, these surveys will encourage clinical quality improvement.

Evaluating the Effectiveness of Clinical Practices

- Besides developing measures of quality, the Clinton Administration is working to improve quality of care by examining the effectiveness of different clinical practices that are now being used. AHCPR's Medical Treatment Effectiveness Program -- MEDTEP -- is looking at the effectiveness of differing treatments for a wide range of conditions including cancer, heart and kidney disease, cataracts, childbirth, and schizophrenia.

  - MEDTEP research is part of the shift in focus from issues of organization and process requirements to outcomes measures in health care. MEDTEP's concern is with outcomes in the real world -- what works best for typical patients cared for by real health care professionals.

  - A major feature of MEDTEP research is its emphasis on outcomes that patients understand and care about. These outcomes include quality of life, functional capacity, symptom relief and cost. Other basic themes in this research include cost effectiveness and appropriateness of treatment decisions.

- Learning what works from MEDTEP and other medical effectiveness research will continue to be important as we work to maintain and improve health care quality in the face of enormous health care cost pressures.

THE ADMINISTRATION IS WORKING TO PROTECT THE HEALTH AND SAFETY OF HEALTH CARE PROVIDERS

- SHEA has actively participated in the Administration's efforts to fight the occupational hazards you and your colleagues face. We appreciate your assistance and expertise in this area and we hope that you will continue to be involved.

- Alongside health care professionals, we have fought occupational hepatitis B -- and between 1987 and 1993, the number of cases contracted by health care workers exposed on the job fell 77%. Today, we are working to contain the threat of on-the-job exposure to tuberculosis.

  - The Occupational Safety and Health Administration (OSHA) has undertaken nationwide enforcement activities aimed at ensuring that employers are taking proper measures to protect their employees.

  - Currently, OSHA is working to develop a standard for occupational exposure to tuberculosis. One of the primary bases for this standard will be the tuberculosis guidelines issued by the Centers for Disease Control and Prevention (CDC). We hope to publish OSHA's proposed standard in October.

  - We are also continuing the process of finalizing for publication regulations that will change the method for testing TB respirators. As you know, under the new regulations, a new generation of better TB respirators are likely to become available.

THE PRESIDENT'S CHILDHOOD IMMUNIZATION INITIATIVE IS DESIGNED TO STRENGTHEN EFFORTS TO IMMUNIZE CHILDREN AND TO REDUCE OR ELIMINATE VACCINE-PREVENTABLE DISEASES

- Another Clinton Administration health care initiative that I know many of you are interested in is the Childhood Immunization Initiative. The Initiative's goal is to immunize at least 90 percent of the two-year-olds in this country with the initial and most critical doses by 1996 and at least 90 percent of all two-year-olds with the full series of vaccines by 2000.

- The Childhood Immunization Initiative will:

- **Improve the quality and quantity of vaccination services:**

  - In 1993, the Federal government sent $129 million to states and local health departments to improve existing services. Each local area uses its own discretion to allocate these funds to meet local needs -- whether that means extending clinic hours or automating records.

- **Reduce vaccine costs for parents:**

  - The Vaccines for Children program will reach more children with free vaccine than ever before, including many at their own doctor's offices. Sixty percent of our Nation's children will benefit, including the uninsured, those on Medicaid, Native American children, and children served by federally qualified health centers.

- **Increase participation, education, and partnerships in communities:**

  - The Administration's plan sends outreach coordinators around the country to increase awareness of the importance of vaccinating children and to encourage health care providers to use every opportunity to vaccinate children in their care. Community and business groups, religious and service organizations, schools, and the media are joining community-based networks to increase infant vaccination efforts. For example, Gerber Products Company put an immunization message on the back of baby cereal boxes, Kiwanis International created a national public awareness campaign, including public service announcements, billboards, and posters, and McDonalds featured an immunization message in its tray liners.

- Better monitor diseases and vaccinations:

  - We are creating a better system to monitor vaccine-preventable diseases so that we can spot problems early and prevent cases from escalating into epidemics. The Centers for Disease Control and Prevention are working to pinpoint the populations that are not receiving the benefits of infant vaccination.

- **Improve vaccines and how they are used:**

  - We developed a single childhood immunization schedule by working with the Advisory Committee on Immunization Practices, the American Academy of Pediatrics, and the American Academy of Family Physicians. This single schedule simplifies what parents and providers must know to ensure proper immunization.

- We are increasing applied research into new vaccines in an effort to reduce the number of shots children must receive and to ensure safe and effective vaccines. Finally, although available vaccines are very safe and effective, CDC is working with states and some providers to improve systems that detect those problems that do occur after a vaccination.

Org: Event file
xC: Klein & Rasco

F41

SHEA The Society for Healthcare Epidemiology of America, Inc.

April 5, 1995

Carol H. Rasco
Assistant to the President for Domestic Policy
The White House
1600 Pennsylvania Ave.
Washington, DC 20500

Dear Ms. Rasco,

On behalf of SHEA, I want to thank you for your wonderful presentation. I believe that you and President Clinton have an excellent healthcare strategy, especially the emphasis on children. Your talk was the highlight of SHEA's Annual Meeting. I will contact Terri Yamauchi shortly about the invitation to the White House to discuss a couple of items that are important to many involved in healthcare. I am eager to accept your invitation as soon as I can arrange a conference call with the SHEA Board, probably in the next 1-2 weeks.

Thanks again!

Sincerely,

Bryan Simmons, M.D.
President, SHEA

/ps

cc: Terri Yamauchi, M.D.

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

13-Apr-1995 03:52pm

TO: Karen R. Guss

FROM: Carol H. Rasco
Economic and Domestic Policy

SUBJECT: see attached

Anything you see in this based on your conversations with Tappan and others perhaps that raises red flags in your head?

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

13-Apr-1995 03:39pm

TO: Carol H. Rasco

FROM: Sally Katzen
Office of Mgmt and Budget, OIRA

SUBJECT: HHS/NIOSH Final Rule on Respirators

attached is an e-mail report from my staff on the briefing from HHS. Its generally positive. HHS will likely send the revised rule over by the end of next week and we should be able to conclude review in several weeks (it alway
s
takes longer when we have to coordinate with other agencies). Let me know if
you
need more. Sally

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

10-Apr-1995 06:02pm

TO: Sally Katzen

FROM: Daniel J. Chenok
Office of Mgmt and Budget, OIRA

CC: James B. MacRae Jr.
CC: John F. Morrall, III
CC: Shannah Koss
CC: Gary D. Rowe

SUBJECT: HHS/CDC/NIOSH Briefing on Respirator final rule

Linda Rosenstock, NIOSH Director, Claudia Cooley and their staff briefed Shannah and I today on their forthcoming respirator final rule. HHS expects to submit the rule within a week, and is asking for rapid action thereafter.

In general, HHS has made reasonable changes from those proposed in the NPRM. They have loosened requirements on manufacturers in a number of areas, and will do more in this regard as a result of today's discussion. They made a convincing case that this rule

will be welcomed by most of the affected parties, including workers using respirators, respirator manufacturers who currently live under a 1930s standard, and industrial users. They did indicate that some small firms may be disadvantaged, and will provide us with more data on employment effects in these firms.

They argue that the rule is a cost saver, though total costs will depend on how OSHA applies the standard in various industrial settings; NIOSH has not prepared an economic analysis that demonstrates cost effects. Also, they have not included risk analysis language in the rule. They argue, and may be justified in doing so, that the dose-response data for respirators is not sufficiently developed to use in full-blown risk assessment. They will add language to the rule that bolsters their risk arguments and provides a more convincing case for not conducting the full assessment.

They have coordinated the rule with OSHA, and we will follow up to ensure that OSHA is comfortable since OSHA will apply the NIOSH standard.

The advance draft included some disclosure requirements for which clearance would be covered under the new PRA; HHS is considering whether to issue those as a separate paperwork requirement to speed publication of the rule.

Last, HHS could publish two versions of the rule: a short version with only the new regulatory language, or a longer version with the whole rule. They say the Federal Register did not allow them to publish the short form for the NPRM, which would have incorporated by reference the existing language. Thought you would want to know this vis-a-vis you conversations with the Register.

Vol. 16 No. 9 INFECTION CONTROL AND HOSPITAL EPIDEMIOLOGY 1

Special Report

Special Update on Healthcare Reform From The White House

Keynote Address, SHEA Annual Meeting, April 1995

Carol H. Rasco

INTRODUCTION

I want to touch on four different areas today that I think will be of interest to you. I am going to talk about healthcare reform, quality management research within the Clinton Administration, our efforts to fight the on-the-job infection of healthcare workers, and the President's Childhood Immunization Initiative.

THE CLINTON ADMINISTRATION CONTINUES TO FIGHT FOR REAL HEALTHCARE REFORM

As you know, last year the Clinton Administration fought hard for healthcare reform. While we could not reach agreement on legislation, there can be little disagreement that the problems remain. Nearly 40 million Americans have no health insurance, and millions more are just one pink slip or illness away from losing their insurance. Eighty-four percent of the uninsured in 1993 were in working families, and more than 55% lived in families headed by full-time workers. And while healthcare costs have begun to slow down, they are continuing to rise at three times the rate of inflation.

As the President said in his State of the Union Address and in his December letter to the Congressional Leadership, we remain firmly committed to guaranteeing health security to all Americans and to containing healthcare costs for families, businesses, and federal, state, and local governments.

The President believes that we should take a step-by-step approach. This year, we can take the first steps. The Congress can and should:

- Reform the insurance market, so that people don't lose their insurance when they lose their job or change jobs or a family member falls ill, and so that small businesses can afford to buy insurance for their workers.
- Make coverage affordable for, and available to, children.
- Help workers who lose their jobs to keep their health insurance.
- Level the playing field for the self-employed by giving them the same tax treatment as other businesses.
- Help families provide long term care for a sick parent or a disabled child.

Because their constituents are demanding action, some Republicans have begun to respond to the President's challenge by coming forward with proposals and bills. We look forward to working with them to take the first steps this year. But, as we continue to work toward health reform, we must continually remember that we have the highest quality of care, the most talented and dedicated health professionals, and the most advanced research institutions in the world. All health reform proposals must be measured by their ability both to fix what is wrong and to preserve what is right about our healthcare system.

THE CLINTON ADMINISTRATION IS FIGHTING BACK TO PROTECT DOCTORS AND PATIENTS FROM SEVERE CUTS IN MEDICARE AND MEDICAID

Unfortunately, for too many Republicans in Congress, "health reform" has turned into the code word for cutting Medicare and Medicaid to pay for

From The White House, Washington, DC.
Address reprints to Carol H. Rasco, Assistant to the President for Domestic Policy, The White House, Washington, DC.
95-SR-107. Rasco CH. Special update on healthcare reform from the White House: keynote address, SHEA Annual Meeting, April 1995. Infect Control Hosp Epidemiol 1995;16:000-000.

tax cuts for the wealthy. A number of Republicans in the House and the Senate have talked about cutting both Medicare and Medicaid by hundreds of billions of dollars.

It now appears that Medicare will be slated to be cut by about $300 billion between now and 2002. It also appears that Medicaid is being targeted for at least $180 billion to $190 billion in spending cuts between now and 2002. It's not hard to figure out what that means for the doctors and hospitals who treat patients receiving benefits under these programs and for the patients themselves.

- It means significant cuts in payments to hospitals, physicians, and other providers.
- It means shifting additional financial burdens to the elderly and disabled or to small businesses and families who will pay higher premiums and fees if these programs are cut without overall reform.
- In many states, it means being forced to drop coverage or shrink benefits for mothers and children on Medicaid. Or it means asking states to pick up the tab to preserve the Medicaid program, and in doing so, forcing them to raise taxes or cut spending for services like education and public safety.

The President presented a responsible budget to Congress—a budget that made tough choices to get our rising deficit under control, but a budget that protected hardworking Americans and investments in our children. Now it is Congress' turn to act to detail where they will get the cuts they need to pay for their tax cuts for the wealthy and to step forward with *their* plan for deficit reduction.

The President consistently has said that we cannot get ahold of the deficit without passing meaningful health reform. Over the next 5 years alone, almost 40% of the growth in total federal spending will come from rising costs in federal healthcare programs. We must contain costs in these programs. But we must do it as we reform our healthcare system as a whole—not by arbitrarily cutting programs that serve the most vulnerable Americans, (which is not to say that these programs cannot and should not be improved).

The Clinton Administration is committed to continuing to give states flexibility to reduce costs while maintaining coverage in their Medicaid programs. And, we are committed to reduce regulatory burdens, streamline administration, and improve cost effectiveness in the Medicare program while increasing choices for beneficiaries and ensuring that quality of care is protected. These are the kind of changes that the Clinton Administration is doing now, and these are the kind of changes that we look forward to working with Congress on in the coming months.

THE CLINTON ADMINISTRATION'S EFFORTS TO IMPROVE THE HEALTH-CARE SYSTEM ARE CONTINUING WITHIN THE HEALTHCARE AGENCIES. THIS WORK INCLUDES EFFORTS TO MAINTAIN AND IMPROVE THE *QUALITY* OF HEALTH CARE.

Developing Quality Measures

As you know, the Agency for Health Care Policy and Research (AHCPR), agency of the Public Health Service, works to improve the quality of care by developing measures of quality both for healthcare professionals and for consumers.

More than 1,200 clinical performance measures are now in use. However, as you know, there has been no single source of information on clinical quality measures, nor have there been generally accepted criteria for evaluating the validity or usefulness of the various measures. An important project now underway to fill this gap is AHCPR's "Measurement Typology Project."

- Working together with the Harvard School of Public Health and the Center for Health Policy Studies of Columbia, Maryland, AHCPR has collected the clinical performance measures being used by public and private organizations and has developed a standard method for describing them.

Next, AHCPR will work with organizations like the Joint Commission on Accreditation of Healthcare Organizations to identify and promote the most valid of the quality measures they have found. This will facilitate the systemic and uniform comparison of healthcare organizations—a vital task in today's changing healthcare industry.

AHCPR also is developing new quality indicators based on adherence to clinical practice guidelines. Because practice guidelines are derived from scientific evidence as to what really works for patients, these new quality indicators should prove to be extremely useful.

In addition, AHCPR is working to help consumers make choices about health plans and providers by surveying consumers directly about the accessibility, quality, and effectiveness of the care they receive. Health plans, employers, consumer advocates, purchasing alliances, and other consumers will be able to turn to this survey for information that will help them make their own informed decisions. By encouraging knowledgeable choices based on quality, these surveys will encour

Vol 16 No.9 INFECTION CONTROL AND HOSPITAL EPIDEMIOLOGY 3

age clinical quality improvement.

Evaluating the Effectiveness of Clinical Practice

Besides developing measures of quality, the Clinton Administration is working to improve quality of care by examining the effectiveness of different clinical practices that are now being used. AHCPR's Medical Treatment Effectiveness Program—MEDTEP—looks at the effectiveness of differing treatments for a wide range of conditions including cancer, heart and kidney disease, cataracts, childbirth, and schizophrenia.

MEDTEP research is part of the shift in focus from issues of organization and process requirements to outcomes measures in health care. MEDTEP's concern is with outcomes in the real world—what works best for typical patients cared for by real healthcare professionals.

A major feature of MEDTEP research is its emphasis on outcomes that patients understand and care about. These outcomes include quality of life, functional capacity, symptom relief, and cost. Other basic themes in this research include cost-effectiveness and appropriateness of treatment decisions.

Learning what works from MEDTEP and other medical effectiveness research will continue to be important as we work to maintain and improve healthcare quality in the face of enormous healthcare cost pressures.

THE ADMINISTRATION IS WORKING TO PROTECT THE HEALTH AND SAFETY OF HEALTHCARE PROVIDERS

SHEA has participated actively in the Administration's efforts to fight the occupational hazards you and your colleagues face. We appreciate your assistance and expertise in this area, and we hope that you will continue to be involved.

Alongside healthcare professionals, we have fought occupational hepatitis B—and between 1987 and 1993, the number of cases contracted on the job by healthcare workers fell 77%. Today, we are working to contain the threat of occupational exposure to tuberculosis.

The Occupational Safety and Health Administration (OSHA) has undertaken nationwide enforcement activities aimed at ensuring that employers are taking proper measures to protect their employees.

Currently, OSHA is working to develop a standard for occupational exposure to tuberculosis. One of the primary bases for this standard will be the tuberculosis guidelines issued by the Centers for Disease Control and Prevention (CDC). We hope to publish OSHA's proposed standard in October.

We also are continuing the process of finalizing for publication regulations that will change the method for testing TB respirators. As you know, under the new regulations, a new generation of better TB respirators likely will become available.

THE PRESIDENT'S CHILDHOOD IMMUNIZATION INITIATIVE IS DESIGNED TO STRENGTHEN EFFORTS TO IMMUNIZE CHILDREN AND TO REDUCE OR ELIMINATE VACCINE-PREVENTABLE DISEASES

Another Clinton Administration healthcare initiative that I know many of you are interested in is the Childhood Immunization Initiative. The Initiative's goal is to immunize at least 90% of the two-year-olds in this country, with the initial and most critical doses by 1996, and at least 90% of all two-year-olds with the full series of vaccines by 2000. The Childhood Immunization Initiative will:

Improve the quality and quantity of vaccination services.

- In 1993, the Federal government sent $129 million to state and local health departments to improve existing services. Each local area uses its own discretion to allocate these funds to meet local needs—whether that means extending clinic hours or automating records.

Reduce vaccine costs for parents.

- The Vaccines for Children program will reach more children with free vaccine than ever before, including many at their own doctors' offices. Sixty percent of our nation's children will benefit, including the uninsured, those on Medicaid, Native American children, and children served by federally qualified health centers.

Increase participation, education, and partnerships in communities.

- The Administration's plan sends outreach coordinators around the country to increase awareness of the importance of vaccinating children and to encourage healthcare providers to use every opportunity to vaccinate children in their care. Community and business groups, religious and service organizations, schools, and the media are joining community-based networks to increase infant vaccination efforts. For example, Gerber Products Company put an immunization message on the back of baby cereal boxes; Kiwanis International created a national public awareness campaign, including public service announcements, billboards, and posters; and McDonald's featured an immunization message in its tray liners.

Better monitor diseases and vaccinations.

· We are creating a better system to monitor vaccine-preventable diseases so that we can spot problems early and prevent cases from escalating into epidemics. The Centers for Disease Control and Prevention is working to pinpoint the populations that are not receiving the benefits of infant vaccination.

Improve vaccines and how they are used.

· We developed a single childhood immunization schedule by working with the Advisory Committee on Immunization Practices, the American Academy of Pediatrics, and the American Academy of Family Physicians. This single schedule simplifies what parents and providers must know to ensure proper immunization.

We are increasing applied research into new vaccines in an effort to reduce the number of shots children must receive and to ensure safe and effective vaccines. Finally, although available vaccines are very safe and effective, CDC is working with states and some providers to improve systems that detect those problems that do occur after a vaccination.

AUTHOR'S PROOF

IMPORTANT
Please review the enclosed proof carefully for any typographical errors. If proofs of photos and figures are included, review for correct orientation and compare with legends. Also check authors' names and affiliations and proofread tables carefully.

Approval of the attached must be indicated by your signature below. Return one set of these galleys with your corrections no later than 2-20 or phone your corrections in to the number indicated below. Keep the second copy for your files.

If your corrections are not received by mail or phone by the above date, your article will be printed as attached. The Publisher and Editor are not responsible for corrections not made because of the author's failure to meet this deadline.

RETURN PROOFS TO:

Susan Cantrell

INFECTION CONTROL AND HOSPITAL EPIDEMIOLOGY Editorial Offices
Vanderbilt University
School of Medicine
A-1131 Medical Center North
Nashville, Tennessee 37232-2637

615-343-1095
Fax 615-343-1582

Author's Signature _____ Date _____

AGENCY FOR HEALTH CARE POLICY AND RESEARCH

Center for Medical Effectiveness Research
2101 East Jefferson Street - Suite 605
Rockville, Maryland 20852

Phone: (301) 594-1485
Fax: (301) 594-3211

Date/Time: 7/19 10:55 AM

To: Karen Guse

Fax: (202) 456-~~7437~~ 7028

Phone:

From: *Claire W. Maklan, Ph.D., M.P.H.*

Message: as requested Please see "attached."

Number of Pages (Excluding Cover Sheet): 3

July 19, 1995

NOTE TO KAREN GUSS, from Claire Maklan and Irma Arispe, AHCPR

re: Requested comments on galleys

AHCPR's emphasis on the need for good evidence of effectiveness as a scientific basis for valid and reliable measures of quality suggests the need to reverse the order of the two sections about AHCPR work. This could be done with only a few wording changes that should fit within the current space limits. Suggested modifications follow, with insertions and changes in bold:

Under the existing heading, THE CLINTON ADMINISTRATION'S EFFORTS TO IMPROVE...p. 2, start with:

Evaluating the Effectiveness and Quality of Health Care (delete: Clinical Practice)

DELETE: "Besides developing measures of quality,"

The Clinton Administration is working to improve the quality of health care by examining the effectiveness **and relative effectiveness** of different clinical practices that are now being used. **Responsibility for this rests with the Agency for Health Care Policy and Research (AHCPR), an agency of the Public Health Service, through its Medical Treatment Effectiveness Program (MEDTEP).** MEDTEP looks at the effectiveness of different treatments for a wide range of common conditions **and procedures**, including cancer, heart and kidney disease, cataract, childbirth, schizophrenia, and **hysterectomy**.

MEDTEP research **reflects** a shift in focus from issues of organization and process to evaluation in terms of **patient outcomes**. MEDTEP's concern is with .... and appropriateness of treatment decisions.

Learning what works from MEDTEP and other medical effectiveness research will continue to be important as we work to define, maintain, and improve healthcare quality in the face of enormous health care cost pressures.

NOTE TO CLAIRE MAKLAN

FROM: Irma Arispe

DATE: July 19, 1995

RE: Comments on White House article for Infection Control and Hospital Epidemiology.

Thank you for the opportunity to review this section of the article. Here are a few comments. All comments pertain to the section called "Developing Quality Measures", in which there is discussion of the typology project.

1. Page 2, First paragraph.

Suggested Change: **In addition to examining the medical effectiveness of various clinical practices,** AHCPR works to improve the quality of health care **by coordinating existing measures of clinical quality and by developing new science based measures of quality** for both health care professionals and consumers.

Rationale: This change assumes that the medical effectiveness section will precede the section on quality measures.

2. Page 2, Second paragraph under this section.

Suggested Change: Change first sentence to, "**There are literally hundreds** of clinical performance measures now in use."

Rationale: We identified over 1200 but we know there are hundreds (if not thousands) out there.

3. Page 2, Third paragraph

Suggested Change: "Working together with...AHCPR has collected a **sample of** clinical performance measures **most frequently used by** public and private organizations....

Optional Additional Change: After this sentence you may want to add the following, "**The project has identified more than 1200 such measures.**"

Rationale: The project focused on the most frequently used measures, but we know that many other measures exist. AHCPR is currently augmenting this inventory.

4. Page 2, Fourth paragraph, first sentence

Suggested Change: Next AHCPR is working with organizations such as the Joint Commission on Accreditation of Health Care Organizations, **the National Committee on Quality Assurance, private health care organizations such as United Health Care, and**

(2)

government organizations such as the Health Care Financing Administration and the Department of Veterans Affairs to identify and centralize information on clinical performance measures. This will facilitate the **systematic** and uniform comparison....

Rationale: The project seeks to coordinate federal and private efforts at clinical quality measurement (to avoid duplication and to encourage public private partnership). By mentioning only the Joint Commission, one might misconstrue the paragraph as being a government and regulatory effort to impose certain types of measures. I suggest not using the word "promote" because the project does not impose a certain type of measure. It is a tool to provide information that will inform or assist in the selection of measures.

5. Page 2, Fifth paragraph, first sentence.

Suggested Change: Delete the word adherence. Change sentence to: **"AHCPR is also developing new quality indicators based on clinical practice guidelines...."**

Additional Suggested Change: After the second sentence, add: **"The typology will include these new guideline based quality measures as they become available and this will health care providers, purchasers, and consumers in seeking better information on quality."**

Rationale: The word "adherence" connotes a very regulatory meaning to providers. The last sentence is intended to convey that the value of this government sponsored project is to coordinate information and develop tools that will assist in making this information available to health care providers, purchasers, and ultimately consumers.

The Official Journal of The Society for Healthcare Epidemiology of America

INFECTION CONTROL AND HOSPITAL EPIDEMIOLOGY

FAX COVER SHEET

Date: 8-22-95

To: Carol Rasco Karen Guss

Fax No: (202) 456-2878

From: Susan Cadwell

Number of Pages Following This Page: 4

Comments: Per our previous fax (7-25-95) these are second page proofs. These proofs are due back in our offices at 2 pm (our time) tomorrow. As we mentioned, this is NOT a time to make changes. Normally, we do not send 2nd proofs to authors. Since your changes were so extensive, we are sending these proofs for you to make sure that the changes called in by Karen Guss are on the proofs. Thank you for your kind attention to this important matter.

If you do not receive the entire fax or have other transmission problems, please call (615) 343-1095.

Michael D. Decker, MD, MPH
Editor

Editorial Offices
Vanderbilt University
School of Medicine
A-1131 Medical Center North
Nashville, TN 37232-2637

Telephone (615) 343-1095
FAX (615) 343-1882

Special Report

Special Update on Healthcare Reform From The White House

Keynote Address, SHEA Annual Meeting, April 1995

Carol H. Rasco

INTRODUCTION

Today, I want to touch on four different areas that I think will be of interest to you. I am going to talk about healthcare reform, quality management research within the Clinton Administration, our efforts to fight on-the-job infection of healthcare workers, and the President's Childhood Immunization Initiative.

THE CLINTON ADMINISTRATION CONTINUES TO FIGHT FOR REAL HEALTHCARE REFORM

As you know, last year the Clinton Administration fought hard for healthcare reform. While we could not reach agreement on legislation, there can be little disagreement that the problems remain. Nearly 40 million Americans have no health insurance, and millions more are just one pink slip or illness away from losing their insurance. Eighty-four percent of the uninsured in 1993 were in working families, and more than 55% lived in families headed by full-time workers. While healthcare costs have begun to slow down, they are continuing to rise at three times the rate of inflation.

As the President said in his State of the Union Address and in his December letter to the Congressional Leadership, we remain firmly committed to guaranteeing health security to all Americans and to containing healthcare costs for families, businesses, and federal, state, and local governments.

The President believes that we should take a step-by-step approach. This year, we can take the first steps. Congress can and should:

- Reform the insurance market, so that people don't lose their insurance when they lose their jobs or change jobs or a family member falls ill, and so that small businesses can afford to buy insurance for their workers.
- Help workers who lose their jobs to pay for their health insurance.
- Level the playing field for the self-employed by giving them the same tax treatment as other businesses.
- Help families provide long-term care for a sick parent or a disabled child.

As we continue to work toward healthcare reform, we must continually remember that we have the highest quality of care, the most talented and dedicated health professionals, and the most advanced research institutions in the world. All healthcare reform proposals must be measured by their ability both to fix what is wrong and to preserve what is right about our healthcare system.

PROTECTING MEDICARE AND MEDICAID

The Clinton Administration is fighting back to protect doctors and patients from severe cuts in Medicare and Medicaid. Unfortunately, for too many Republicans in Congress, "health reform" has turned into the code word for cutting Medicare and Medicaid to pay for tax cuts for the wealthy.

Medicare will be cut by approximately $270 billion between now and 2002. Medicaid is being targeted for $182 billion in spending cuts between now and 2002. It's not hard to figure out what that means for the doctors and hospitals who treat patients

From The White House, Washington, DC.
Address reprint requests to Carol H. Rasco, Assistant to the President for Domestic Policy, The White House, Washington, DC.
95-SR-107. Rasco CH. Special update on healthcare reform from the White House: keynote address, SHEA Annual Meeting, April 1995. Infect Control Hosp Epidemiol *1995;16:526-529*

receiving benefits under these programs and for the patients themselves.

- It means significant cuts in payments to hospitals, physicians, and other providers.
- It means shifting additional financial burdens to the elderly and disabled or to small businesses and families who will pay higher premiums and fees if these programs are cut without overall reform.
- In many states, it means being forced to drop coverage or shrink benefits for mothers and children on Medicaid. Or it means asking states to pick up the tab to preserve the Medicaid program, and in doing so, forcing them to raise taxes or cut spending for services like education and public safety.

The President consistently has said that we cannot get ahold of the deficit without passing meaningful health reform. Over the next 5 years alone, almost 40% of the growth in total federal spending will come from rising costs in federal healthcare programs. We must contain costs in these programs. But we must do it as we reform our healthcare system as a whole—not by arbitrarily cutting programs that serve the most vulnerable Americans.

The Clinton Administration is committed to continuing to give states flexibility to reduce costs while maintaining coverage in their Medicaid programs. And, we are committed to reduce regulatory burdens, streamline administration, and improve cost-effectiveness in the Medicare program while increasing choices for beneficiaries and ensuring that quality of care is protected. These are the kind of changes that the Clinton Administration is doing now, and these are the kind of changes that we look forward to working with Congress on in the coming months.

QUALITY

The Clinton Administration's efforts to improve the healthcare system are continuing within the healthcare agencies. This work includes efforts to maintain and improve the *quality* of health care.

Developing Quality Measures

As you know, the Agency for Health Care Policy and Research (AHCPR), an agency of the Public Health Service, works to improve the quality of care by coordinating existing quality measures and by developing new science-based measures of quality both for healthcare professionals and for consumers.

More than 1,200 clinical performance measures are now in use. However, as you know, there has been no single source of information on clinical quality measures, nor have there been generally accepted criteria for evaluating the validity or usefulness of the various measures. An important project now underway to fill this gap is AHCPR's "Measurement Typology Project."

- Working together with the Harvard School of Public Health and the Center for Health Policy Studies of Columbia, Maryland, AHCPR has collected a sample of the clinical performance measures most frequently used by public and private organizations and has developed a standard method for describing them.
- Next, AHCPR will work with organizations such as the Joint Commission on Accreditation of Healthcare Organizations, the National Committee on Quality Assurance, United Healthcare, and the Healthcare Financing Administration to identify and centralize information on the quality measures they have found. This will facilitate the systemic and uniform comparison of healthcare organizations—a vital task in today's changing healthcare industry.

AHCPR also is developing new quality indicators based on clinical practice guidelines. Because practice guidelines are derived from scientific evidence as to what really works for patients, these new quality indicators should prove to be extremely useful.

In addition, AHCPR is working to help consumers make choices about health plans and providers by developing a consumer survey that can assess the accessibility, quality, and effectiveness of the care they receive. Health plans, employers, consumer advocates, purchasing alliances, and other consumers will be able to use this survey to collect information that will help them make their own informed decisions. By encouraging knowledgeable choices based on quality, these surveys will encourage clinical quality improvement.

Evaluating the Effectiveness of Health Care

Besides developing measures of quality, the Clinton Administration is working to improve quality of care by examining the effectiveness of different clinical practices that are now being used. AHCPR's Medical Treatment Effectiveness Program—MEDTEP—looks at the effectiveness of differing treatments for a wide range of conditions including cancer, heart and kidney disease, cataracts, childbirth, and schizophrenia.

MEDTEP research is part of the shift in focus from issues of organization and process requirements to outcomes measures in health care. MEDTEP's concern is with outcomes in the real

world—what works best for typical patients cared for by real healthcare professionals.

A major feature of MEDTEP research is its emphasis on outcomes that patients understand and care about. These outcomes include quality of life, functional capacity, symptom relief, and cost. Other basic themes in this research include cost-effectiveness and appropriateness of treatment decisions.

Learning what works from MEDTEP and other medical effectiveness research will continue to be important as we work to define, maintain, and improve healthcare quality in the face of enormous healthcare cost pressures.

HEALTH AND SAFETY

The Administration is working to protect the health and safety of healthcare providers. SHEA has participated actively in the Administration's efforts to fight the occupational hazards you and your colleagues face. We appreciate your assistance and expertise in this area, and we hope that you will continue to be involved.

Alongside healthcare professionals, we have fought occupational hepatitis B—and between 1987 and 1993, the number of cases contracted on the job by healthcare workers fell 77%. Today, we are working to contain the threat of occupational exposure to tuberculosis.

The Occupational Safety and Health Administration (OSHA) has undertaken nationwide enforcement activities aimed at ensuring that employers are taking proper measures to protect their employees.

Currently, OSHA is working to develop a standard for occupational exposure to tuberculosis. One of the primary bases for this standard will be the tuberculosis guidelines issued by the Centers for Disease Control and Prevention (CDC). We hope to publish OSHA's proposed standard in October.

We also are continuing the process of finalizing for publication regulations that will change the method for testing TB respirators. As you know, under the new regulations, a new generation of better TB respirators likely will become available.

CHILDHOOD IMMUNIZATION INITIATIVE

Another Clinton Administration healthcare initiative that I know many of you are interested in is the Childhood Immunization Initiative. The President's childhood immunization initiative is designed to strengthen efforts to immunize children and to reduce or eliminate vaccine-preventable diseases. The initiative's goal is to immunize at least 90% of the 2-year-olds in this country, with the initial and most critical doses by 1996, and at least 90% of all 2-year olds with the full series of vaccines by the year 2000. The Childhood Immunization Initiative will:

Improve the quality and quantity of vaccination services.

- In 1993, the federal government sent $129 million to state and local health departments to improve existing services. Each local area uses its own discretion to allocate these funds to meet local needs—whether that means extending clinic hours or automating records.

Reduce vaccine costs for parents.

- The Vaccines for Children program will reach more children with free vaccine than ever before, including many at their own doctors' offices. Sixty percent of our nation's children will benefit, including the uninsured, those on Medicaid, Native American children, and children served by federally qualified health centers.

Increase participation, education, and partnerships in communities.

- The Administration's plan sends outreach coordinators around the country to increase awareness of the importance of vaccinating children and to encourage healthcare providers to use every opportunity to vaccinate children in their care. Community and business groups, religious and service organizations, schools, and the media are joining community-based networks to increase infant vaccination efforts. For example, Gerber Products Company put an immunization message on the back of baby cereal boxes; Kiwanis International created a national public awareness campaign, including public service announcements, billboards, and posters; and McDonald's featured an immunization message on its tray liners.

Better monitor diseases and vaccinations.

- We are creating a better system to monitor vaccine-preventable diseases so that we can spot problems early and prevent cases from escalating into epidemics. The Centers for Disease Control and Prevention is working to pinpoint the populations that are not receiving the benefits of infant vaccination.

Improve vaccines and how they are used.

- We developed a single childhood immunization schedule by working with the Advisory Committee on Immunization Practices, the American Academy of Pediatrics, and the American Academy of Family Physicians. This single schedule simplifies what parents and providers must know to ensure proper immunization.

We are increasing applied research into new vaccines in an effort to reduce the number of shots children must receive and to ensure safe and effective vaccines. Finally, although available vaccines are very safe and effective, CDC is working with states and some providers to improve systems that detect those problems that do occur after a vaccination.