MEDICAL TECHNOLOGY AND PRACTICE PATTERNS INSTITUTE, Inc.
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February 1, 1995

Gaynor McCown
Senior Policy Analyst
Domestic Policy Council
Old Executive Office Building
The White House
Washington, DC

Dear Ms. McCown,

It was a pleasure talking with you on Tuesday about our plans to convene a conference on child abuse. As an indication of eroding family values, the increasing reports of child abuse are troubling and recent incidents have captured the attention of the American public and the media. In light of the prevalence of child abuse, with all its attendant social costs, and because early identification of child abuse is critical to its intervention, Medical Technology and Practice Patterns Institute (MTPPI) is planning to convene a conference on "Identifying Child Abuse: The Changing Role of Imaging Technology." I have enclosed a concept paper outlining our proposal for the conference as well as information about the Institute.

The conference, to be held in Washington, DC, in late spring 1995, will address the medical, social, economic, and ethical/legal issues surrounding the detection and identification of suspected cases of abuse with an emphasis on the role of imaging technologies in the child evaluation process. The purpose of the conference is to consider the roles various imaging technologies play in the identification and treatment of child abuse and to seek ways to improve professional guidelines when warranted by advances in the technologies.

We have been joined in the planning process by a number of public and private sector organizations, including representatives from the Department of Health and Human Services, the Justice Department, the Department of Defense, and key medical professional societies. Some initial funding has been obtained to support the conference. We have also contacted over 350 professional organizations and associations with a combined membership of more than 3 million people who are affected by and concerned with the problem of child abuse.

We recognize that child abuse is a significant social issue and believe that this conference can make an important contribution in aiding communication and advancing state-of-the-art technologies in detecting and confirming suspected cases of abuse. As we discussed in our telephone conversation, we would welcome the participation of the White House in planning the program and in participating in the conference.

If you have any questions or suggestions regarding the conference, please call me or Chuck Hamilton of my staff at 202-333-8841.

Sincerely,

Dennis J. Cotter
Executive Director

Imaging in Child Abuse: Technology Assessment Forum

Objectives

The purpose of this forum is to provide expert advice on scientific and technical matters to the community concerned with the detection and identification of suspected cases of child physical abuse. The recommendations are intended to help care givers and professional groups by providing expert advice on the implications of technology advances for 'best practice' guidelines.

Background

By various estimates, child abuse affects one and a half million to nearly three million U.S. infants and children each year. More than a decade ago, it was estimated that between 2,000 and 5,000 children are fatally abused every year in the United States. Other statistics indicated that 1% of children seen on an unscheduled basis are victims of abuse and that child abuse is the most common cause of death between the ages of 6 and 12 months of age, and second only to sudden infant death syndrome from 30 days to 6 months of age. Since 1976, there has been a 331% growth in reports of child abuse per 1,000 children, up from 10 in 1976 to 43 children per 1,000 in 1992.

With the increase in the reported prevalence of child abuse in the past two decades — and its attendant costs and long-term consequences — both public agencies and private sector organizations have begun to view it as a public health issue and to hold medical and other professionals accountable for identifying and reporting suspected child abuse cases. Although both Federal and state laws mandating such reporting have been in force for more than 20 years, recent studies have found that health care professionals still fail to identify and report suspected cases of child abuse. Researchers have cited a variety of reasons for this failure, including technical difficulties of diagnosing and identifying cases of abuse as well as the consequences of a possibly incorrect judgment.

Because the identification and reporting of child abuse are crucial first steps to intervention processes, the best techniques, methods, and procedural expertise to accomplish this are warranted, especially in light of the fact that certain injuries are highly specific to intentional abuse and because both the social and medical costs increase with the failure to identify suspected cases.

The primary method of identifying child physical abuse is by discovering the history of the injury through interviews with the child and the child's adult caretakers. But studies have documented several problems inherent in the interview process which prevent accurate detection and identification of child abuse, including inability to achieve diagnostic certainty, possible negative consequences of a wrong judgment, and various sociological factors.

Recent advances in imaging technologies, however, may facilitate a more accurate diagnosis of child physical abuse by exposing more concrete evidence of abuse that, without the use of such

technologies, might not be detectable, thus allowing clinicians to identify suspected cases of child abuse with a higher degree of certainty. For example, improvements in X-ray film systems may allow radiologists to view internal structures in the chest cavity and subtle fractures in more detail with higher resolution. Advances and improvements in the use of such other imaging technologies as radionuclide bone scanning, magnetic resonance imaging, computed tomography and ultrasonography may also help clinicians better diagnose suspected cases of abuse.

Forum Goals

In an effort to examine the medical, social, economic, and ethical/legal issues surrounding child abuse and to seek consensus on the implications of recent advances in imaging technology for the detection and identification of suspected cases of child physical abuse, the Medical Technology and Practice Patterns Institute (MTPPI) proposes to conduct a 2½ day Technology Assessment Forum (TAF) in early 1995 to address the critical questions regarding the best practices to be followed in the diagnosis of suspected cases of child physical abuse. *The goal of the Forum will be to address these broad questions:*

1) What is the current standard of practice for the clinical detection and management of child abuse?

2) What is the role of imaging technology in the detection of child abuse and in defining the extent of abuse and what is the impact of recent advances on standards of practice?

3) Are there information gaps in the clinical detection of child abuse and, if so, how can they be filled?

4) What further imaging technology research is needed to improve the detection and management of victims of child abuse?

Forum Facilitator

MTPPI is a non-profit research institute established in 1986 and located in Washington, DC, which engages in technology assessment, health services research, and health policy analysis. In the conduct of technology assessments, MTPPI does not promote a particular technology; instead, its principal interest lies in acting as a catalyst and in designing a format where relevant research will be discussed and assessed.

Forum Format

In preparation for the Forum, MTPPI will commission a review of the relevant literature on identifying child physical abuse to develop a summary "White Paper" highlighting the medical, social, economic, and ethical/legal aspects of this health issue, as well as the role of imaging technology in the diagnosis of child abuse. MTPPI also will establish a Planning Committee and

convene meetings to identify key issues, develop the conference format and logistics, draft a tentative forum agenda and identify potential speakers and participants. Selected participants with an interest in the identification, treatment, and prevention of child abuse will be invited to make presentations to the panel. These participants may include, but will not be confined to: pediatricians, radiologists, pediatric radiologists, social workers, lawyers, and child advocacy groups.

The distinguishing feature of this TAF will be the use of an expert "Blue Ribbon Panel" that will assess the available evidence presented, write a final report, and make any recommendations. Assembled by MTPPI, the Blue Ribbon Panel will consist of people without known bias and with the necessary expertise to evaluate the clinical effectiveness and appropriate use of state-of-the-art imaging technology in the diagnosis of child physical abuse. The panel should include specialists from the following fields: Pediatrics, Radiology, Psychiatry/Psychology, Social Welfare, Law, and Child Advocacy. To maintain impartiality, the members will **not** have a direct interest or financial stake in the manufacture or use of imaging technology.

The product of the conference will be released in the form of a statement drafted by the Blue Ribbon Panel that will summarize the Panel's assessment of the effectiveness and appropriate use of state-of-the-art imaging technology in the diagnosis of child physical abuse. The statement will include the following: 1) a framework for broad guidelines on the appropriate use of imaging technology in the diagnosis of child abuse; and 2) identification of areas where further research is warranted. The final proceedings of the conference will be widely disseminated to target groups in the public, non-profit, and private sectors. In addition, MTPPI will compile and release a summary of the proceedings of the conference. MTPPI hopes the information disseminated from this conference will foster the earliest possible identification, intervention, and treatment of child abuse.

MTPPI Senior Project Management

Senior staff responsible for the MTPPI Technology Assessment Forum on Imaging in Child Abuse are identified below.

Overall Project Management:

DENNIS J. COTTER, M.S.E., Executive Director. Mr. Cotter has eighteen years of experience in technology assessment and applied health services research related to the global diffusion of medical technologies. Mr. Cotter developed his expertise through a long-standing tenure with Federal government agencies and as the founder and Executive Director of MTPPI.

In 1976, Mr. Cotter began his career at the U.S. Food and Drug Administration assessing medical device technologies. As a senior health policy analyst at the National Center for Health Care Technology (NCHCT), he directed the evaluation of medical technologies for the Medicare and State Medicaid programs. The results of those evaluations established specific recommendations for the introduction, adoption and coverage for new technologies. As the senior staff member of the Office of Health Technology Assessment, Mr. Cotter developed technology assessment guidelines which are still used by the government and the medical

community. Finally, he served as a senior staff member for the Prospective Payment Assessment Commission (ProPAC).

Mr. Cotter established MTPPI to address the challenges faced by health care providers, third-party payers and medical device and pharmaceutical manufacturers in providing appropriate and cost-effective health care.

Clinical Practice Issues:

SEYMOUR PERRY, M.D., FACP, Senior Scholar, is internationally recognized as a leader in technology assessment in health care. His expertise lies in the areas of evaluation of medical technologies for safety, efficacy and costs; health care delivery systems; and health policy issues in general. As an officer in the Public Health Service, Dr. Perry spent fourteen years in research and administration at the National Cancer Institute. He was the first Director of the Office of Medical Applications of Research at the National Institutes of Health and was instrumental in initiating the NIH Consensus Development Program in 1975. Three years later, Dr. Perry was appointed Assistant Surgeon General and served as the first Director of the National Center for Health Care Technology in the Department of Health and Human Services.

In 1983, Dr. Perry joined the Georgetown University (GU) faculty with dual appointments as Professor of Family Medicine and of Medicine and in 1990 was asked to chair the Department of Community and Family Medicine. In 1993, he joined MTPPI as a senior scholar and was named adjunct professor at Georgetown. He provides a valuable liaison between MTPPI and the resources at the University.

Dr. Perry was the founder and first President of the International Society of Technology Assessment in Health Care. He is a member of the Institute of Medicine of the National Academy of Sciences, a Fellow of the American College of Physicians and a Consultant on technology assessment to the World Health Organization.

International Activities

Cross-national comparisons of health status indicators, use of technologies, and provision and financing of health care, provide important models for health care decision-makers. Based on its long-standing collaborative relationships with the World Health Organization, the U.S. Agency for International Development, and ministries of health in Europe, Latin America, Africa and Asia, MTPPI has established a unique international health care research program. MTPPI's international health care research activities include:

- Assisting developing countries in establishing technology assessment capabilities
- Providing a database of existing health technology assessment models
- Establishing collaborative relationships with public and private sector individuals and organizations engaged in international health care research efforts
- Convening international conferences to examine such issues as the impact of trade agreements on the diffusion of health care technology and reuse of disposable medical devices

Senior Staff

Dennis J. Cotter, M.S.E., has eighteen years of federal and private sector experience in health care technology assessment and applied health services research related to the diffusion of medical technologies.

Mari Anne T. Hamilton, J.D., is a member of the District of Columbia and Maryland bars. She has federal government, medical law firm, and national public interest defense fund experience.

Seymour Perry, M.D., FACP, is recognized internationally as a leader in technology assessment in health care. His expertise lies in the areas of evaluation of medical technologies for safety, clinical effectiveness, and cost; health care systems; and health policy issues. Dr. Perry was the founder and first president of the International Society of Technology Assessment in Health Care. He is a member of the Institute of Medicine of the National Academy of Sciences and the consultant on technology assessment to the World Health Organization.

Nancy Fox Ray, M.S., has nine years of experience in using primary and secondary databases in health services research and health economic analyses of medical technologies. She directs epidemiologic and pharmacoeconomic studies and provides a structural framework within which research is conducted.

Mae Thamer, Ph.D., directs the medical and scientific analyses of emerging technologies, including cost-effectiveness and quality-of-life analyses, as well as medical practice pattern variations and patient outcome studies. Additionally, she collects and analyzes primary and secondary data relating to the adoption, diffusion, appropriate use, and payment for medical technologies.

For further information, contact:

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Executive Director

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MEDICAL TECHNOLOGY & PRACTICE PATTERNS INSTITUTE

MTPPI

A nonprofit organization dedicated to research, education, and the dissemination of information regarding current and emerging medical technologies

Medical technology includes the drugs, devices, and medical and surgical procedures used in medical care, and the organizational and supportive systems within which such care is provided.

— Office of Technology Assessment

Medical Technology & Practice P tterns Institute (MTPPI) is a nonprofit organization established in 1986 to conduct research on the clinical, economic, and social implications of new and emerging health care technologies. MTPPI's research is directed toward the formulation and implementation of local, national, and international health care policies.

With extensive investigator experience in both the public and private sectors, MTPPI's staff designs, implements, and conducts a full range of health services research activities. The staff includes clinicians, biomedical engineers, economists, statisticians, lawyers, and policy analysts.

Located in Washington, DC, MTPPI has longstanding contacts with numerous governmental agencies, medical professional associations, medical industry and provider organizations. The Institute also collaborates with academic institutions and international health organizations, as well as other research groups.

Research Policy

As a nonprofit independent research institute, MTPPI conducts its studies in a scientifically rigorous manner using state-of-the-art methodologies. Furthermore, MTPPI ensures that project sponsorship does not influence the cc lection, analysis, and interpretation of the data or its subsequent dissemination. MTPPI seeks to publish its findings in peer-reviewed journals.

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MTPPI's research includes patient outcomes, pharmacoeconomics, q lity-of-life, technology assessment, and international health care studies.

Patient Outcomes

Increasing medical innovation has led to the development of competing medical and surgical technologies to treat a given condition or illness. Furthermore, financial incentives may influence the adoption and use of these new technologies. Often, these technologies are not compared with the existing standard of practice prior to their approval and adoption. To address this gap, patient outcome studies examine the consequences of competing medical technologies on patients in terms of clinical outcome, including morbidity, mortality, and functional status. MTPPI's research includes:

- Assessing treatments including medical devices, pharmaceuticals, biotechnologies, and surgical and medical interventions
- Utilizing appropriate clinical measures to assess the differential impact of selected technologies on the risk of morbidity and mortality
- Identifying relevant sociodemographic and clinical variables to permit case-mix adjustment to standardize study findings
- Examining patient compliance with the recommended treatment program
- Identifying the effect of financial and nonfinancial barriers to access to health care
- Developing clinical practice guidelines for both providers and consumers

Ph rm coeconomic Studies

In this era of cost-containment, government regulators, third-party payers, medical providers, and patients increasingly demand that new technologies and medical practices demonstrate not only clinical effectiveness, but also cost effectiveness. MTPPI's studies, designed to meet FDA and other regulatory and peer review requirements, include:

- Quantifying cost of illness by examining the total economic impact of a disease, including direct medical and indirect costs
- Evaluating cost effectiveness by comparing competing technologies in terms of cost per unit of clinical outcome, such as cost per life saved or cost per hospitalization avoided
- Measuring outcomes in terms of their social value, expressed in incremental measures such as cost per quality-adjusted life-year or cost per healthy days of life gained to determine cost-utility

Quality of Life Assessment

Patient and family medical and lifestyle preferences have led to the development of quality-of-life assessments. MTPPI's research includes:

- Using disease- and treatment-specific quality-of-life instruments for inclusion in clinical trials
- Measuring specific parameters of health and disease impairment, including psychosocial functioning, physical fitness, functional status and pain

Technology Assessment

Technology innovation in health care often raises issues of safety, clinical effectiveness and access when devices and procedures are transferred from experimental settings into clinical practice. The careful evaluation of health care technologies is imperative to ensure their appropriate, rational and equitable adoption and use. MTPPI utilizes the following assessment approaches to examine these issues:

- Reviewing, summarizing, and interpreting findings reported in the literature using information synthesis and meta-analysis techniques
- Convening technology assessment forums using groups of experts to review published and unpublished data, formulate findings, and disseminate results and recommendations
- Conducting comparative analyses to evaluate the clinical and cost effectiveness of a technology compared with competing technologies, no treatment, or placebo
- Monitoring real-world effectiveness of a technology after its widespread diffusion and adoption

MTPPI

Medical Technology:

The drugs, devices, and medical and surgical procedures used in medical care, and the organizational and supportive systems within which such care is provided. *-Office of Technology Assessment, 1978*

In today's environment, access to and utilization of technologies is contingent upon demonstrating clinical benefit as well as cost effectiveness and improvement in quality of life. For this reason, studies of health economics, health services research and health policy analyses are necessary to evaluate the implications of technological innovation in a formal, comprehensive manner.

Medical Technology and Practice Patterns Institute (MTPPI) is a non-profit research institute established in Washington, D.C. in 1986. Specializing in the research and analysis of health care services and policies, MTPPI fulfills the needs of the medical community and policy makers by thoroughly examining the underlying factors associated with new and emerging medical technologies.
MTPPI's multidisciplinary staff has extensive experience in designing and conducting studies related to access, patient outcomes, quality of life, medical practice patterns, cost utility and cost-effectiveness. MTPPI draws on its expertise in health services research, health policy, biomedical engineering, epidemiology, economics, statistics and market research. Study sponsors include government agencies, third-party payers, hospital chains, medical specialty groups, as well as pharmaceutical, biotechnology and medical device manufacturers.

Unique to MTPPI is the dynamic environment established by its members, its extensive database library, and its use of state-of-the art computer technology. To enhance study design as well as the interpretation and dissemination of results, the Institute actively participates in the academic, health provider and health policy communities; in addition, MTPPI establishes relationships with relevant government agencies and health professional societies. MTPPI maintains a long standing, collaborative association with clinical and research professionals at Georgetown University and other academic institutions. These assets facilitate the ability to offer a full range of services and account for the Institute's far-reaching success.

The following pages contain information concerning these topics:

- Health Services Research
- Health Policy Analysis
- Technology Assessment
- Market Analysis
- Health Personnel Analysis
- Research Efforts
- Data Resources
- Technology Experience
- Special Programs

Facilities and Resources

Location

Located two miles from the center of Washington, D.C., MTPPI is within reach of the executive and legislative branches of government, including the National Institutes of Health and the Office of Technology Assessment. In addition, many medical specialty groups, patient advocacy organizations and pharmaceutical and medical device industry associations are headquartered in the Washington, D.C. area, thus increasing the opportunities for professional interaction.

MTPPI has access to numerous informational resources and has 24-hour on-line capabilities to over 150 medical and biomedical research and business-related databases. The ability to retrieve the most current and comprehensive information available facilitates the quickness, efficiency and comprehensiveness with which MTPPI's research is conducted.

MTPPI has an established collaborative relationship on a consultant basis with clinical and research professionals at local universities, including Georgetown University. Through these sources, MTPPI has developed associations with several hospitals, such as Georgetown University Hospital and D.C. General Hospital as well as a wide variety of affiliated outpatient clinics and facilities in the D.C. metropolitan area.

Information-Processing Facilities

The MTPPI data processing facility is centered around a network of two Unisys U6000/65 multi-processor minicomputer systems and three Dell desktop work stations. The central processing units within the five systems employ Intel 486 microchips. The operating system for these five hosts is Unix System V Release 4 with available disk space totaling more than thirty-two gigabytes. Raw data are read into the MTPPI computer systems using a combination of the Unix operating system and the C programming language. The programs used for creating analysis files are based on either the Statistical Program for the Social Sciences (SPSS) or ANSI Pascal.

Data Security Policy

Physical and electronic access to the computer and data facility is restricted *to ensure patient confidentiality and data security for all projects*. The computer room is protected by an alarmed keypad entry system, a halon fire detection and suppression system, and a room monitoring system. Backup tapes are rotated off-site and critical archives are maintained at a secure location. Procedures are in place for a disaster recovery system and a security system for electronic media. Finally, the systems meet commercial secure Level Two (C2) requirements, a federally-established high level electronic security standard.

Special Programs

The Senior Scholars Program and the Student Training Program were created to acknowledge the talents of special groups of people and to add those talents to the MTPPI team. The contributions of the senior scholars and student interns to services research and policy analysis augment various approaches to MTPPI's procedural investigations.

Senior Scholar Program

The Senior Scholar Program was established to recognize and promote the scholarly activities of leaders in the fields of health services research, technology assessment and health policy analysis. The three-year program enables the scholar, through financial and technical support, to pursue a research project of the individual's design.

MTPPI seeks nominations by department heads or deans of academic institutions of faculty who demonstrate exceptionally high levels of competence and integrity. The nominated faculty who compete for the position also share the characteristic of being nationally recognized for superior leadership in their respective fields; secured their doctoral degree (PhD or equivalent) awarded before January 1, 1975; hold a faculty position at their nominating institution at the time of application.

The exchange of fruitful ideas enhances the knowledge base of MTPPI as another member is added to the team. The information network expands for both the scholar and the Institute, creating a productive environment and enabling MTPPI to contribute a wider variety of approaches to the issues of health science.

Student Training Program

The Student Training Program at MTPPI was created to promote and stimulate interest in health services research. Paid training provides both graduate and undergraduate students from local universities the opportunity to acquire practical experience within a challenging and fast-paced environment.

For the students, the work experience serves the important purpose of developing skills in analytic thinking and clear, organized written communication. The trainees fulfill responsibilities which include statistical programming, research design and the writing and editing of publications.

After graduation, student trainees bring their expertise to long-term careers in health services research, public health, health policy and public policy. The diverse educational backgrounds have included the areas of public policy, labor economics, government studies, social psychology, international trade and quantitative business. Students from MTPPI are visible in a variety of organizations such as the Department of Health and Human Services, State Health Departments, non-profit corporations and private sector entities.

Health Policy Analysis

The rapid proliferation of technological advances in medicine often renders decision-makers unprepared to assess the ramifications of new and emerging technologies in a formal, comprehensive manner. MTPPI contributes valuable health policy analyses to both private and public sector organizations to assist them in identifying, evaluating and responding to a wide variety of health care financing and delivery issues. MTPPI assists clients with developing accurate, up-to-date information on access, costs and coverage of medical technologies.

National and International Analyses

Health Care Reform - MTPPI studies a broad range of health care issues, including major system reforms, for their potential impact on providers, patients, payers and suppliers. The effects of various health care reform proposals on Medicaid, Medicare and private sector health insurers are currently under examination by health policy experts at MTPPI.

Cost and Cost-Containment - MTPPI's staff assesses the cost implications of adopting new technologies and displacing established technologies as well as the impact of cost controls on technology adoption and use.

Access and Diffusion - Barriers to access and diffusion of technologies faced by specific patient populations, including women, minorities and the elderly, are critically examined. Moreover, the impact of organizational barriers have been evaluated in a variety of health care system segments, such as the Medicaid program, managed care organizations and private insurance markets.

Comparative International Analyses - MTPPI is in touch with health services researchers and government officials in numerous developed and developing countries. These relationships result in collaborative cross-national studies of health policies in various countries.

Manpower - Health manpower analyses include supply and demand studies, specialty plans of graduates, minority issues in graduate medical education, location patterns of recent medical school graduates and scope of practice among allied health professionals.

Market Analyses

Market Profiles - Using secondary databases, MTPPI profiles the utilization of pharmaceuticals, health care services and medical devices among specific populations. The present and projected demographic and clinical characteristics of these populations are also analyzed.

Coverage and Reimbursement - MTPPI serves private sector clients by developing coverage and reimbursement strategies for emerging technologies. For both private and public sector payers, MTPPI has formulated white papers, presentations and workshops that examine the potential impact of reimbursement policies on access, cost and quality of care.

Purchasing and Pricing - Private sector trends in group purchasing, competitive bidding and national accounts organization are analyzed. MTPPI also evaluates the impact of federal government purchasing and pricing programs, such as the Medicaid rebate program and the Medicare End Stage Renal Disease payment policy.

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Technology Experience

MTPPI staff have experience with a broad range of medical technologies, including:

Devices

Air-Fluidized Beds
Angelchik Anti-Reflux Prosthesis
Bone Growth Stimulators
Cardiac Event Recorders
Continuous Flow Centrifugation Devices
Home Oxygen Concentrators
Implantable Cardiac Defibrillators
Implantable Intravascular Stents
Intracranial Pressure Monitors
Intraocular Lenses
Left Ventricular Assist Devices
Penile Prostheses
Prosthetic Devices

Pharmaceuticals and Biotechnology

AIDS-Related Therapeutic Agents
Antacids and Antiflatulents
Anticonvulsants
Antiglaucoma Agents
Antibacterials
Antineoplastic Agents
Arthritis Medications
Autogenous Vaccines
Bacillus Calmette-Guerlin Vaccine
Biologic and Synthetic Burn Dressings
Cardiovascular Agents
Cephalosporins
Diabetes Agents
Hormonal Therapy for Advanced Prostate Cancer
Human Growth Hormone
Hypolipidemics
Hypocalcemia Agents
H_2 Antagonists
Influenza Virus Vaccines
Intra-Ocular Lens
Low-Osmolar Contrast Material
Monoclonal Antibody Imaging Agents
Opioid Analgesics
Oral Contraceptives
Orphan Drugs
Osteoporosis Drugs
Psychotropics
Recombinant Human Granulocyte-Macrophage Colony Stimulating Factors
Recombinant Human Erythropoietin
Respiratory Therapy Agents
Systemic Quinolones
Thrombolytics
Tissue Plasminogen Activator
Urinary Tract Agents

Diagnostic Procedures

Automated Ambulatory EEG Monitoring
Automated Ambulatory Esophageal pH Monitoring
Capnography
Continuous Arterial Blood Gas Monitoring
Digital Subtraction Angiography
Endoscopic, Diagnostic Techniques
Fully Auto Ambulatory Blood Pressure Monitoring
Hepatitis C Virus Antibody Testing
Magnetic Resonance Imaging
Photoplethysmography
Thermography
Translumination Light Scanning
Urodynamic Testing

Theraputic Procedures

Apheresis Therapy
Adhesiolysis
Bone Marrow Transplantation
Cochlear Implantation
Cochleostomy
Cryostatic Preamputation Preparation
Dialysis Treatment for End-Stage Renal Disease
Disease
Dynamic Splinting
Electromagnetic Treatment of Fractures
Electrotherapy
Endocardial Electrical Stimulation
Endoscopic, Theraputic Techniques
Extracorporeal Shock-Wave Lithotripsy
Fluidotherapy
Gastric Bubble
Heart Transplantation
Hydrotherapy
Hyperbaric Oxygen Therapy
Liver Transplantation
Percutaneous Lithotripsy
Percutaneous Transluminal Coronary Angioplasty
Photocoagulation Treatments
Photopheresis
Phrenic Nerve Stimulation
Short Wave Diathermy
Stents, Iliac and Coronary
Thoracic Duct Drainage
Topical Oxygen Therapy
Total Parenteral Nutrition
Transcutaneous Electrical Nerve Stimulation
Ultraviolet Light Therapy
Wound Healing
Wrist Fracture Surgical Treatments

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Research Efforts

Medical Technology

Medical Technologies and Procedures: Utilization, Costs and Payments - Subjects of this study include heart transplantation, percutaneous transluminal coronary angioplasty (PTCA), extracorporeal shock-wave lithotripsy (ESWL), magnetic resonance imaging (MRI) and treatment of decubitus ulcers. Procedures involve collecting primary data on current practice patterns and clinical applications, capital expenditures and operating costs, resource consumption patterns and utilization rates.

Workshops and Forums on Medical Technologies - Workshops and forums, directed by MTPPI, congregate clinicians, researchers, academicians, private third-party payers, patient advocacy representatives and government regulators to assess issues related to costs and quality of health care delivery, coverage and reimbursement and access and regulation.

Worldwide Technology Assessment Models - In collaboration with the Foundation for Health in Mexico, MTPPI will study domestic and international and public and private technology assessment models. The resulting efforts will provide Mexico with models for its health care system. The project is funded by one of only 12 grants awarded by the U.S.-Mexico Foundation for Science and is unique because it is the only study devoted to health.

MRI Scans - MTPPI is formulating cost profiles on MRIs for a study whose results will influence HCFA's rate-setting policy concerning technical component payments for MRI scans.

Practice Patterns

Trends in Undergraduate and Graduate Medical Education - Studies include indebtedness and career plans of students in allopathic and osteopathic medical schools, follow-up of recent graduates, residency and practice location patterns and medical school applicant patterns by state, gender and ethnicity.

Manpower Needs in the Biotechnology Industry - Surveys have been conducted to elucidate scientific personnel needs of biotechnology firms by type of specialty and degree requirements.

Health Care Reform Analyses - Using state level secondary databases, MTPPI explores the impact of managed competition on key segments of the health care system.

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Research Efforts

MTPPI spearheads breakthrough research in the health care field. The following pages contain a sample of health services, medical technology and practice patterns research.

Health Services Research

Quality of Life and Pharmaco-economic Studies - A validated quality of life instrument used to measure patient satisfaction and a customized health resource consumption model are under development to assess cost-effectiveness of selected AIDS treatment therapies.

Orphan Drug Act Research - Exploring issues surrounding access to highly-priced orphan drugs, MTPPI has examined the role of insurance status, lifetime caps and co-payments; the relationship between exclusivity, innovation and competition; the development and diffusion of "blockbuster" drugs; and the role of the Federal government in subsidizing the development, testing and diffusion of orphan drugs.

End Stage Renal Disease (ESRD) Research - Practice pattern variations and patient outcomes relating to reuse of dialyzers and analyses of various adjunctive therapies as well as access to and utilization of human recombinant erythropoietin have been studied.

Access, Utilization and Practice Patterns of Erythropoietin - A major, multi-year collaborative study utilizing Medicare and Medicaid administrative databases, including HCFA's ESRD Program Management and Medical Information System, analyzes the access to and consumption of erythropoietin.

Use of Intravenous Iron Among Dialysis Populations - Data from two dialysis chains are employed to analyze the effect of intravenous iron and human recombinant erythropoietin treatment regimens on selected clinical outcomes, including hematocrit, ferritin and serum iron levels achieved.

Direct and Indirect Medical Costs Associated With Diabetes and its Chronic Complications - Specific components of direct and indirect medical costs in diabetes have been measured to include inpatient hospital, institutional, outpatient physician and outpatient hospital care as well as premature morbidity and mortality.

Practice Patterns Studies - Under examination are factors influencing physician and non-physician provider specialty and practice location choices, including demographic factors, financial incentives and the impact of the Medicare Resource Based Relative Value System.

Intervention Program Designs - MTPPI has been devising means to improve patient compliance with anti-hypertensive regimens, TB therapy and other chronic and acute disease conditions.

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Health Services Research

Over the last seven years, MTPPI has conducted a wide range of prospective and retrospective research endeavors designed to address issues concerning the provision of health care services in a dynamic and increasingly complex environment.

Health Services

Patient Outcomes Research - MTPPI devises methods to evaluate the "real-world" clinical outcomes for patients treated with specific pharmaceuticals, biotechnology products and medical devices. These analyses permit the longitudinal tracking of patients throughout the health care system, the identification of rare adverse events and the standard medical practices of care.

Quality of Life Assessments - The staff designs methods to assess quality of life and to measure the intangible costs and benefits of emerging technologies for application during Phase III (pre-marketing) clinical trials as well as in Phase IV (post-marketing) studies.

Pharmacoepidemiologic Research - The Institute performs prospective and retrospective studies evaluating the relative risk of adverse reactions, drug-drug interactions and patient compliance associated with pharmaceutical and medical devices.

Medical Practice Pattern Variations Research - MTPPI profiles factors influencing patient access to and utilization of various medical technologies in a "real-world" setting. Patient demographics, insurance status, geographic location, physician specialty and provider institutional characteristics are analyzed.

Health Economics

Cost-Effectiveness Analyses - Members of the MTPPI team collaborate on studies measuring the cost-effectiveness of pharmaceutical, medical and surgical interventions. These studies incorporate cost-benefit methods, utility assessments, econometric studies and other quantitative techniques.

Cost-of-Illness Studies - Primary and secondary data sources are combined to study the direct and indirect medical costs of acute and chronic diseases. Life-time and annual cost-of-illness studies for a variety of diseases and medical conditions are conducted.

Methodological Techniques

Statistical Modeling - Health services research, health economic analyses and health policy studies depend upon econometric modeling, logistic regression, ANOVA, relative risk and survival analyses, nonparametric techniques and other statistical and modeling techniques actively employed by MTPPI.

Survey Design - MTPPI has completed several long-term surveys to examine access, diffusion and costs of expensive technologies in inpatient and outpatient settings.

Senior Staff

NANCY FOX RAY, M.S., Director of Health Services Research. Ms. Ray received her M.S. from the State University of New York at Stony Brook in Urban and Policy Sciences with a concentration in the Economic Evaluation of Public Programs and Policies.

Ms. Ray's technical direction of epidemiologic and health economic studies, provides a structural framework within which health services research is conducted. She is responsible for the design and development of study protocols, medical record abstract forms, computer software and biostatistical analyses.

Her previous experience in project management includes the quantification of the direct and indirect costs of diabetes mellitus and osteoporosis in the U.S. the epidemiologic assessment of the risk of mortality associated with selected drug regimens, and the evaluation of the introduction of medical innovations on health care utilization and expenditures. In addition, Ms. Ray has more than eight years of experience in utilizing primary and secondary databases in health services research and health economic analyses of medical technologies. Her past undertakings have been sponsored by pharmaceutical manufacturers, biotechnology companies, medical device manufact-urers, trade associations and government agencies.

MAE THAMER, Ph.D., Director of Medical Technology Assessment. Dr. Thamer has a background in Biomedical Engineering from the University of Virginia and specializes in Health Care Systems and Technology Assessment.

Dr. Thamer directs the medical and scientific analyses of emerging technologies, including cost-benefit and cost-effectiveness analyses as well as medical practice pattern variations and patient outcomes studies. Additionally, she collects and analyzes primary and secondary data relating to the adoption, diffusion, appropriate use and payment for various medical and health-related technologies.

Dr. Thamer's expertise extends beyond the area of technology assessment to include minority health, mental health, substance abuse and occupational health and safety in the U.S. She has also directed several large-scale international projects sponsored by the Agency for International Development. Her national health-related projects were funded by the U.S. Department of Health and Human Services, Health Resources and Services Administration, Health Care Financing Administration and the Occupational Health and Safety Administration. With the National Institutes of Health, Dr. Thamer conducted a research project in conjunction with the World Health Organization on modeling the determinants of health development.

Senior Staff

In serving the health community, the senior staff members of MTPPI offer a wide spectrum of capabilities and talents.

DENNIS J. COTTER, M.S.E., Executive Director. Mr. Cotter has eighteen years of experience in technology assessment and applied health services related to the global diffusion of medical technologies. Mr. Cotter developed his expertise through a long-standing tenure with federal government agencies and as the founder and Executive Director of MTPPI.

In 1976, Mr. Cotter began his career at the Food and Drug Administration assessing medical device technologies. As a Deputy Associate Director at the National Center for Health Care Technology (NCHCT), he directed the evaluation of medical technologies for the Medicare and State Medicaid programs. The results of these evaluations established specific recommendations for the introduction, adoption and coverage for new technologies. As the senior staff member of the Office of Health Technology Assessment, Mr. Cotter developed technology assessment guidelines which are still used by the government and the medical community. Finally, he served as a senior staff member for the Prospective Payment Assessment Commission (ProPAC).

Mr. Cotter established MTPPI to address the challenges faced by health care providers, third party payers and medical device and pharmaceutical manufacturers in providing appropriate and cost-effective health care.

SEYMOUR PERRY, M.D., FACP, Senior Scholar, is internationally recognized as a leader in technology assessment in health care. His expertise lies in the areas of evaluation of medical technologies for safety, efficacy and costs; health care delivery systems; and health policy issues in general. As an officer in the Public Health Service, Dr. Perry spent fourteen years at the National Cancer Institute. He was the first Director of the Office of Medical Applications of Research at the National Institutes of Health and was instrumental in initiating the NIH Consensus Development Program in 1975. Three years later, Dr. Perry was appointed Assistant Surgeon General and served as the first Director of the NCHCT in the Department of Health and Human Services.

In 1983, Dr. Perry joined the Georgetown University (GU) faculty and in 1987 was asked to chair the Department of Community and Family Medicine. While retaining his dual appointments as Professor of Family Medicine and of Medicine at GU, he joined MTPPI as a senior scholar in 1993 and provides a valuable liaison between MTPPI and the resources at the University. Dr. Perry was the founder and first President of the International Society of Technology Assessment in Health Care. He is a member of the Institute of Medicine of the National Academy of Sciences, a Fellow of the American College of Physicians and an advisor on technology assessment to the World Health Organization.

Data Resources

MTPPI has considerable experience in the application of secondary databases and the collection of primary data to conduct analyses of medical practice patterns, patient outcomes, health resource utilization and direct and indirect medical costs.

Secondary Data Bases

MTPPI processes, analyzes and maintains third-party payer administrative health care claims databases. The staff works with the ***Medicare and State Medicaid Programs*** in creating and using databases of administrative health care claims for health services research applications. To examine the provision and costs of patient services, longitudinal tracking of specific patient groups throughout the health care system is possible through the use of these databases. Specific information pertaining to patient demographics and medical diagnoses, including co-morbid conditions and physician specialty, is available. Provider characteristics, specific medical procedures performed and drugs prescribed are also accessible.

MTPPI staff is well-versed in using ***National Health Care Survey Data*** in the undertaking of health services research studies. Valuable information on health resource utilization and costs of inpatient care, outpatient physician visits, medical equipment, pharmaceuticals and long-term care services is gleaned from these data sources. The Agency for Health Care Policy and Research and the National Center for Health Statistics sponsor the data sources.

The following administrative and national health care databases are available at MTPPI:

- Medicare Parts A and B
- State Medicaid Databases
- End-Stage Renal Disease (ESRD) Databases
- National Health Interview Survey
- National Hospital Discharge Survey
- National Ambulatory Medical Care Survey
- National Medical Expenditure Survey
- National Health and Nutrition Examination Survey

Primary Data Collection Techniques

MTPPI endeavors to utilize a wide variety of primary data collection techniques in support of health services research studies. Medical chart and billing record reviews as well as telephone, mail and in-person surveys of patients, clinicians and hospital personnel represent some of the efforts. In addition, MTPPI has expertise in adding specific economic and quality-of-life variables to ongoing pre- and post-marketing clinical trials. The collected information is entered into a *customized* database that is designed and maintained by the team's computer experts.

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MTPPI International Activities

The Medical Technology and Practice Patterns Institute, Inc. (MTPPI) is a non-profit organization that conducts national and international research concerned with the assessment, access to and diffusion of new and emerging medical devices and pharmaceuticals. The Institute engages in health policy analyses and provides a forum for information exchange in response to the need for active participation and communication among members of the medical device and pharmaceutical industries. The Institue's primary areas of involvement include the following:

Access and Diffusion of Medical Technologies - Barriers to the access and diffusion of medical technologies faced by trading partners, industry segments and patient populations are among the topics under study by experts at MTPPI. In addition, the impact of standards as barriers are evaluated in both national and international health care system segments.

Comparative International Analyses - MTPPI collaborates with health services researchers and government officials in both developed and developing countries. These relationships are beneficial to MTPPI in the conduct of cross-national studies of health policies, technology assessment and diffusion and access to new and emerging technologies.

Workshops and Forums on Medical Technologies - Workshops and forums convened by MTPPI provide researchers, academicians, government regulators and representatives of the health industry the opportunity to discuss issues related to cost and quality of health care delivery, and access and diffusion of medical technologies on the national and international level.

Worldwide Technology Assessment Models - In collaboration with the Mexican Foundation for Health (Fundación Mexicana Para la Salud), MTPPI is studying domestic and international as well as public and private technology assessment models. The resulting efforts will provide the country of Mexico with viable technology assessment models for possible use in its health care system. The project is funded by one of twelve grants awarded by the U.S.-Mexico Foundation for Science.

Orphan Drug Act Research - Exploring issues surrounding highly-priced orphan drugs, MTPPI examines the role of insurance status, lifetime financial caps and co-payments in obtaining these drugs; and the relationship among exclusivity, innovation and competition in orphan drug production. The development and diffusion of "blockbuster" drugs and the role of the federal governments of several countries in subsidizing the development, testing and diffusion of orphan drugs are additional areas of research.

Impact of NAFTA on the Medical Device and Pharmaceutical Industries - The North American Free Trade Agreement (NAFTA) creates significant opportunities for the medical device and pharmaceutical industries. MTPPI is working to keep interested parties informed as NAFTA evolves by constructing models of technology assessment for policymakers in Canada, Mexico and the U.S.; creating an on-line informational service for the health care technology industry; and convening work-shops and seminars that address its policy, trade, regulatory and public health implications.

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Technology Assessment

Technology innovation in health care continues to generate concern about safety, clinical effectiveness and access when devices and procedures are transferred from experimental settings into clinical practice. Issues raised include costs, reimbursement, access and long-term effects. The careful evaluation of health care technologies is therefore imperative to ensure the appropriate, rational and equitable adoption and diffusion of medical technologies.

Types of Technologies

MTPPI evaluates the following types of medical and health-related technologies:

- Public Health Technologies (anti-smoking educational campaigns)
- Preventive Technologies (cancer screening, vaccinations, and home glucose monitoring)
- Diagnostic/Screening Technologies (ultrasound and CT techniques)
- Therapeutic Technologies (litho-tripsy, angioplasty and anti-psychotic drugs)
- Critical Care Technologies (neo-natal intensive care units)
- Rehabilitation Technologies (continuous passive motion devices and prosthetics for reconstructive surgeries)

Assessment Methodology

The following methodology is utilized in conducting technology assessments:

- Define the health problem addressed by the technology in question including severity and magnitude.
- Identify and compare alternative technologies in terms of safety, effectiveness, costs and quality of life.
- Analyze potential health, economic and social impacts including:

  - Access to and availability of technology;

  - Cost-effectiveness and cost-benefit analyses;

  - Legal and ethical issues pertaining to the adoption and availability of technology.
- Identify "stakeholders" including manufacturers, medical specialty groups, third party payers, providers and others.
- Identify relevant decision-making apparatus and present findings to appropriate officials.
- Develop conclusions and recommendations.

Assessment Approaches

In addressing major public health issues, MTPPI uses a "blue ribbon panel" for guidance on clinical and policy issues. Forums with participants from industry, academia, government agencies and patient and provider groups are convened to ensure that all relevant issues are addressed. Finally, findings include a summary of the real world state-of-the-art as well as recommendations for appropriate use by way of practice guidelines.

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