Consensus Development Conference
Genetic Testing for Cystic Fibrosis

April 14 - 16, 1997

Natcher Auditorium
National Institutes of Health

SPONSORED BY: The primary sponsors of this meeting are the National Human Genome Research Institute and the Office of Medical Applications of Research, National Institutes of Health. The conference is cosponsored by the Agency for Health Care Policy and Research; the Centers for Disease Control and Prevention; the National Institute of Child Health and Human Development; the National Institute of Diabetes and Digestive and Kidney Diseases; the National Heart, Lung, and Blood Institute; the National Institute of Mental Health; the National Institute of Nursing Research; the NIH Office of Rare Diseases; and the NIH Office of Research on Women's Health.

CONTINUING EDUCATION CREDIT

The objective of this National Institutes of Health Consensus Development Conference is to review the current state of knowledge regarding genetic testing for cystic fibrosis, evaluate optimal testing practices, and identify directions for future research.

The conference will (1) present in open, public sessions state-of-the-art information regarding genetic testing for cystic fibrosis, (2) prepare a statement in response to the five specific questions, and (3) inform the biomedical research and clinical practice communities and the general public of the conclusions and recommendations of the panel.

The National Institutes of Health is accredited by the Accreditation Council for Continuing Medical Education to sponsor continuing medical education for physicians.

The National Institutes of Health designates this educational activity for a maximum of 14 hours in category 1 credit toward the Physician's Recognition Award of the American Medical Association. Each physician should claim only those hours of credit that he/she actually spent in the education activity.

To obtain certification of attendance, please complete this form. You may leave it at the continuing education table at the conclusion of the conference, or you may mail the form to Conference Management Group, Technical Resources International, Inc., 3202 Tower Oaks Boulevard, Suite 200, Rockville, MD 20852.

Please indicate hours attended per day:

I have attended the following session(s) of the conference on Genetic Testing for Cystic Fibrosis:

____April 14, 1997 (total of 8 hours) ____ hours attended
____April 15, 1997 (total of 4 hours) ____ hours attended
____April 16, 1997 (total of 2 hours) ____ hours attended

How did you first learn about the conference?_____

_____

Please complete this Continuing Education Credit Questionnaire. To indicate your answers, use the rating scale that is shown by circling the number that represents your answer.

Scale: 1 = None or not at all; 2 = Very little; 3 = Average; 4 = Considerably; 5 = Completely

1.	Were the goals and objectives of the conference clearly stated?	1	2	3	4	5
2.	To what extent was the conference topic a major medical issue?	1	2	3	4	5
3.	To what extent were the consensus conference questions relevant to the major issues?	1	2	3	4	5
4.	To what extent did the speakers' presentations help answer the conference questions?	1	2	3	4	5
5.	To what extent did the discussion periods provide an adequate forum for conference participants to express opinions?	1	2	3	4	5
6.	How useful did you find the following:					
	a. The program and abstracts book?	1	2	3	4	5
	b. Material in the conference folder explaining the [Consensus Development/ Technology Assessment] Program and process?	1	2	3	4	5
	c. MEDLINE-generated bibliography?	1	2	3	4	5
	d. Invited presentations?	1	2	3	4	5
	e. Open discussion?	1	2	3	4	5
7.	To what extent did the consensus conference/ statement:					
	a. Modify your opinion in this field?	1	2	3	4	5
	b. Modify your practice in this field?	1	2	3	4	5
	c. Reinforce your opinion in this field?	1	2	3	4	5
	d. Prepare you for your practice in this field?	1	2	3	4	5
	e. Enhance your professional knowledge or abilities?	1	2	3	4	5
8.	To what extent did the consensus conference provide the necessary information to answer the conference questions?	1	2	3	4	5

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[Please answer questions 9 and 10 after reading the draft consensus statement to be issued at the conclusion of the conference. If you did not review the draft statement, please check here [ ] and skip to question 11.]

9. To what extent does the draft consensus statement answer the conference questions?	1	2	3	4	5
10. To what extent do you find the draft statement to be:					
a. Scientific?	1	2	3	4	5
b. Directive?	1	2	3	4	5
c. Discursive?	1	2	3	4	5

11. Do you have additional comments you think would enhance the process or impact of the consensus conference?

_____

_____

Thank you for your time and cooperation.

****

Certificate of attendance should be mailed to: (please print)

_____

Name Title

_____

Organization

_____

Street

_____

City State Zip Code

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NIH Consensus Development

U.S. Department of Health and Human Services

Public Health Service

National Institutes of Health

Office of Medical Applications of Research

The National Institutes of Health launched a program in 1977 designed to improve the lines of communication from the health research community to the practicing physician and the public. The key element in this effort is "consensus development," a process that brings together biomedical research scientists, practicing physicians, consumers, and others in an effort to reach general agreement on whether a given medical technology is safe and effective. That technology may be a device, drug, or medical or surgical procedure.

The Consensus Development Program is aimed at complementing—but not replacing—the usual means of reporting research results through publication in scientific journals and other medical periodicals and through the lay media.

NIH initiated the program because there was no formal process within the research community to assure that medical research discoveries were identified and evaluated to determine if they were ready to be used by doctors and other health care workers. Since NIH is the nation's principal health research agency, it was felt that it should assume the responsibility of more fully reporting biomedical research findings to the practicing community and the public.

In recent years, there has been considerable public criticism voiced concerning the use of certain surgical and medical procedures, drugs, and devices. Many have claimed that some new technologies have reached the health care delivery system without being tested adequately. On the other hand, there are those who maintain that some well-validated technologies have been too slow in making their way from the research work bench to the hospital bedside.

A main objective of the NIH Consensus Development Program is to provide the physician and the public with current, responsible information on the pros and cons of medical technologies. This information is made public through reports containing conclusions and recommendations about a given technology, written by expert and lay members of consensus development conference panels.

With the highly complex work associated with biomedical research has come rather technical language that is not always easily understood by all audiences. Consensus development panels have, therefore, worked to produce reports that, although appropriate for the practicing physician, will also be comprehensible to the general public.

The value of these reports is that they may identify safe and useful emerging medical technologies and make a wider audience aware of their availability. At other times, they may point out some potential problems that could result from the use of an existing technology. In some instances, panels may even recommend against using a given medical or surgical procedure, device, or drug, under certain conditions.

One of the prime objectives of consensus development conferences is to provide a public forum to ensure that all points of view are aired. Specific time periods are set aside at every consensus development conference to enable individuals and groups to raise questions or issue comments, and meeting summary reports are designed to include the different viewpoints voiced at the meeting.

For further information about the NIH Consensus Development Program, contact the Office of Medical Applications of Research, National Institutes of Health, Federal Building, Room 618, Bethesda, Maryland 20892, 301-496-1143.

Upcoming Conference Schedule

(Revised 4/1/97)

NIH Consensus Development Conferences

Office of Medical Applications of Research

National Institutes of Health

TOPIC	DATE	SPONSOR
Genetic Testing for Cystic Fibrosis	April 14-16, 1997	National Center for Human Genome Research
Acupuncture: An NIH Consensus Development Conference	November 3-5, 1997	Office of Alternative Medicine
Effective Medical Treatment of Heroin Addiction	November 17-19, 1997	National Institute on Drug Abuse

Each conference is sponsored by OMAR and by an Institute, Center, or Division of NIH. Each conference also may have additional cosponsors from inside or outside NIH. All conferences are held in the Natcher Conference Center, on the NIH campus in Bethesda, Maryland, unless otherwise specified.

Consensus Development Conferences

Office of Medical Applications of Research

National Institutes of Health

Past Conferences

	CONFERENCE	SPONSOR
	1977	
1	Breast Cancer Screening *September 14–16*	National Cancer Institute
	1978	
2	Educational Needs of Physicians and Public Regarding Asbestos Exposure *May 22*	National Cancer Institute
3	Dental Implants: Benefit and Risk *June 13–14*	National Institute of Dental Research
4	Mass Screening for Colorectal Cancer *June 26–28*	National Cancer Institute
5	Treatable Brain Diseases in the Elderly *July 10–11*	National Institute on Aging
6	Indications for Tonsillectomy and Adenoidectomy: Phase 1 *July 20*	National Institute of Neurological and Communicative Disorders and Stroke
7	Availability of Insect Sting Kits to Non-Physicians *September 14*	National Institute of Allergy and Infectious Diseases
8	Mass Screening for Lung Cancer *September 18–20*	National Cancer Institute
9	Supportive Therapy in Burn Care *November 10–11*	National Institute of General Medical Sciences
10	Surgical Treatment of Morbid Obesity *December 4–5*	National Institute of Arthritis, Metabolism, and Digestive Diseases
	1979	
11	Pain, Discomfort, and Humanitarian Care *February 16*	Interagency Committee on New Therapies for Pain and Discomfort
12	Antenatal Diagnosis *March 5–7*	National Institute of Child Health and Human Development
13	Transfusion Therapy in Pregnant Sickle Cell Disease Patients *April 23–24*	National Heart, Lung, and Blood Institute
14	Improving Clinical and Consumer Use of Blood Pressure Measuring Devices *April 26–27*	American College of Cardiology
15	Treatment of Primary Breast Cancer: Management of Local Disease *June 5*	National Cancer Institute
16	Steroid Receptors in Breast Cancer *June 27–29*	National Cancer Institute
17	Intraocular Lens Implantation *September 10–11*	National Eye Institute
18	Estrogen Use and Postmenopausal Women *September 13–14*	National Institute on Aging

**Indicates those conferences and workshops sponsored by OMAR that are not Consensus Development Conferences.*

CONFERENCE		SPONSOR
19	Amantadine: Does It Have a Role in the Prevention and Treatment of Influenza? *October 15–16*	National Institute of Allergy and Infectious Diseases
20	The Use of Microprocessor-Based "Intelligent" Machines in Patient Care *October 17–19*	Division of Research Services
21	Removal of Third Molars *November 28–30*	National Institute of Dental Research
	1980	
22	Thrombolytic Therapy in Thrombosis *April 10–12*	National Heart, Lung, and Blood Institute
23	Febrile Seizures *May 19–21*	National Institute of Neurological and Communicative Disorders and Stroke
24	Adjuvant Chemotherapy of Breast Cancer *July 14–16*	National Cancer Institute
25	Cervical Cancer Screening: The Pap Smear *July 23–25*	National Cancer Institute
26	Endoscopy in Upper GI Bleeding *August 20–22*	National Institute of Arthritis, Metabolism, and Digestive Diseases
27	Cesarean Childbirth *September 22–24*	National Institute of Child Health and Human Development
28	CEA as a Cancer Marker *September 29–October 1*	National Cancer Institute
29	Coronary Artery Bypass Surgery: Scientific and Clinical Aspects *December 3–5*	National Heart, Lung, and Blood Institute
	1981	
30	The Diagnosis and Treatment of Reye's Syndrome *March 2–4*	National Institute of Neurological and Communicative Disorders and Stroke
31	Computed Tomographic Scanning of the Brain *November 4–6*	National Institute of Neurological and Communicative Disorders and Stroke
	1982	
32	Defined Diets and Childhood Hyperactivity *January 13–15*	National Institute of Allergy and Infectious Diseases
33	Total Hip Joint Replacement *March 1–3*	National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases
34	Clinical Applications of Biomaterials *November 1–3*	Division of Research Services
	1983	
35	Critical Care Medicine *March 7–9*	Warren Grant Magnuson Clinical Center
36	Liver Transplantation *June 20–23*	National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases

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CONFERENCE	SPONSOR
* Evaluating the Elderly Patient: The Case for Assessment Technology *June 29–30*	National Institute on Aging
37 Treatment of Hypertriglyceridemia *September 27–29*	National Heart, Lung, and Blood Institute
38 Precursors to Malignant Melanoma *October 24–26*	National Cancer Institute
39 Drugs and Insomnia: The Use of Medications to Promote Sleep *November 15–17*	National Institute of Mental Health
40 Dental Sealants in the Prevention of Tooth Decay *December 5–7*	National Institute of Dental Research
1984	
41 Diagnostic Ultrasound Imaging in Pregnancy *February 6–8*	National Institute of Child Health and Human Development
42 Analgesic-Associated Kidney Disease *February 27–29*	National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases
43 Osteoporosis *April 2–4*	National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases
44 Mood Disorders: Pharmacologic Prevention of Recurrences *April 24–26*	National Institute of Mental Health
45 Fresh Frozen Plasma: Indications and Risks *September 24–26*	National Heart, Lung, and Blood Institute
46 Limb-sparing Treatment of Adult Soft-tissue Sarcomas and Osteosarcomas *December 3–5*	National Cancer Institute
47 Lowering Blood Cholesterol to Prevent Heart Disease *December 10–12*	National Heart, Lung, and Blood Institute
1985	
48 Travelers' Diarrhea *January 28–30*	National Institute of Allergy and Infectious Diseases
49 Health Implications of Obesity *February 11–13*	National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases
50 Anesthesia and Sedation in the Dental Office *April 22–24*	National Institute of Dental Research
* Donor Registries for Bone Marrow Transplantation *May 13–15*	National Institute of Allergy and Infectious Diseases
51 Electroconvulsive Therapy *June 10–12*	National Institute of Mental Health
52 Adjuvant Chemotherapy for Breast Cancer *September 9–11*	National Cancer Institute

**Indicates those conferences and workshops sponsored by OMAR that are not Consensus Development Conferences.*

CONFERENCE	SPONSOR
1986	
53 Health Implications of Smokeless Tobacco Use *January 13–15*	National Cancer Institute
54 Prevention of Venous Thrombosis and Pulmonary Embolism *March 24–26*	National Heart, Lung, and Blood Institute
55 Integrated Approach to the Management of Pain *May 19–21*	Warren Grant Magnuson Clinical Center
56 The Utility of Therapeutic Plasmapheresis for Neurological Disorders *June 2–4*	National Institute of Neurological and Communicative Disorders and Stroke
57 Impact of Routine HTLV-III Antibody Testing of Blood and Plasma Donors on the Health of the Public *July 7–9*	National Heart, Lung, and Blood Institute
58 Infantile Apnea and Home Monitoring *September 29–October 1*	National Institute of Child Health and Human Development
59 Platelet Transfusion Therapy *October 6–8*	National Heart, Lung, and Blood Institute
60 Diet and Exercise in Noninsulin-Dependent Diabetes Mellitus *December 8–10*	National Institute of Diabetes and Digestive and Kidney Diseases
1987	
61 Newborn Screening for Sickle Cell Disease and Other Hemoglobinopathies *April 6–8*	National Heart, Lung, and Blood Institute
62 Management of Clinically Localized Prostate Cancer *June 15–17*	National Cancer Institute
63 Differential Diagnosis of Dementing Diseases *July 6–8*	National Institute on Aging
64 Neurofibromatosis *July 13–15*	National Institute of Neurological and Communicative Disorders and Stroke
* Health Benefits of Pets *September 10–11*	Division of Research Services
65 Geriatric Assessment Methods for Clinical Decisionmaking *October 19–21*	National Institute on Aging
66 Magnetic Resonance Imaging *October 26–28*	Warren Grant Magnuson Clinical Center
1988	
67 Prevention and Treatment of Kidney Stones *March 28–30*	National Institute of Diabetes and Digestive and Kidney Diseases
68 Cochlear Implants *May 2–4*	National Institute of Neurological and Communicative Disorders and Stroke

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CONFERENCE		SPONSOR
69	Dental Implants *June 13–15*	National Institute of Dental Research
70	Perioperative Red Cell Transfusion *June 27–29*	National Heart, Lung, and Blood Institute
71	Urinary Incontinence in Adults *October 3–5*	National Institute on Aging
	1989	
72	Therapeutic Endoscopy and Bleeding Ulcers *March 6–8*	National Institute of Diabetes and Digestive and Kidney Diseases
73	Oral Complications of Cancer Therapies: Diagnosis, Prevention, and Treatment *April 17–19*	National Institute of Dental Research
*	Modeling in Biomedical Research: An Assessment of Current and Potential Approaches *May 1–3*	Division of Research Resources
74	Sunlight, Ultraviolet Radiation, and the Skin *May 8–10*	National Institute of Arthritis, Musculoskeletal and Skin Diseases
75	Treatment of Destructive Behaviors in Persons with Developmental Disabilities *September 11–13*	National Institute of Child Health and Human Development
	1990	
76	Noise and Hearing Loss *January 22-24*	National Institute on Deafness and Other Communication Disorders
77	Surgery for Epilepsy *March 19-21*	National Institute of Neurological Disorders and Stroke
78	Treatment of Sleep Disorders of Older People *March 26-28*	National Institute on Aging
79	Adjuvant Therapy for Patients With Colon and Rectum Cancer *April 16-18*	National Cancer Institute
*	Health Care Delivery Research Using Hospital Firms *April 30-May 1*	Office of Medical Applications of Research
80	Intravenous Immunoglobulin: Prevention and Treatment of Disease *May 21-23*	National Institute of Allergy and Infectious Diseases
81	Treatment of Early-Stage Breast Cancer *June 18-21*	National Cancer Institute
82	Diagnosis and Management of Asymptomatic Primary Hyperparathyroidism *October 29-31*	National Institute of Diabetes and Digestive and Kidney Diseases
83	Clinical Use of Botulinum Toxin *November 12-14*	National Institute of Neurological Disorders and Stroke
*	Bovine Somatotropin *December 5-7*	Office of Medical Applications of Research

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CONFERENCE	SPONSOR
1991	
84 Gastrointestinal Surgery for Severe Obesity *March 25-27*	National Institute of Diabetes and Digestive and Kidney Diseases
* Effects and Side Effects of Dental Restorative Materials *August 26-28*	National Institute of Dental Research
85 Treatment of Panic Disorder *September 25-27*	National Institute of Mental Health
86 Diagnosis and Treatment of Depression in Late Life *November 4-6*	National Institute of Mental Health
87 Acoustic Neuroma *December 11-13*	National Institute of Neurological Disorders and Stroke
1992	
88 Diagnosis and Treatment of Early Melanoma *January 27-29*	National Cancer Institute
89 Triglyceride, High Density Lipoprotein, and Coronary Heart Disease *February 26-28*	National Heart, Lung, and Blood Institute
* Methods for Voluntary Weight Loss and Control *March 30-April 1*	NIH Nutrition Coordinating Committee
* The Head and Heart of Chaos: Nonlinear Dynamics in Biological Systems *June 15-16*	National Heart, Lung, and Blood Institute
90 Gallstones and Laparoscopic Cholecystectomy *September 14-16*	National Institute of Diabetes and Digestive and Kidney Diseases
91 Impotence *December 7-9*	National Institute of Diabetes and Digestive and Kidney Diseases
1993	
92 Early Identification of Hearing Impairment in Infants and Young Children *March 1-3*	National Institute on Deafness and Other Communication Disorders
93 Mortality and Morbidity of Dialysis *November 1-3*	National Institute of Diabetes and Digestive and Kidney Diseases
* Ultrasound Screening: Implications of the RADIUS Study *December 3*	National Institute of Child Health and Human Development
1994	
94 *Helicobacter pylori* in Peptic Ulcer Disease *February 7-9*	National Institute of Diabetes and Digestive and Kidney Diseases
95 Effect of Corticosteroids for Fetal Maturation on Perinatal Outcomes *February 28-March 2*	National Institute of Child Health and Human Development

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CONFERENCE	SPONSOR
96 Ovarian Cancer: Screening, Treatment, and Followup *April 5-7*	National Cancer Institute
* The Persian Gulf Experience and Health *April 27-29*	Department of Defense, Department of Veterans Affairs, Department of Health and Human Services, Environmental Protection Agency
97 Optimal Calcium Intake *June 6-8*	National Institute of Arthritis and Musculoskeletal and Skin Diseases
98 Total Hip Replacement *September 12-14*	National Institute of Arthritis and Musculoskeletal and Skin Diseases
* Bioelectrical Impedance Analysis in Body Composition Measurement *December 12-14*	National Institute of Diabetes and Digestive and Kidney Diseases
1995	
99 Infectious Disease Testing for Blood Transfusions *January 9-11*	National Heart, Lung, and Blood Institute
* Gaucher Disease: Current Issues in Diagnosis and Treatment *February 27-March 1*	National Institute of Mental Health
100 Cochlear Implants in Adults and Children *May 15-17*	National Institute on Deafness and Other Communication Disorders
* The Integration of Behavioral and Relaxation Approaches Into the Treatment of Chronic Pain and Insomnia *October 16-18*	Office of Alternative Medicine
101 Physical Activity and Cardiovascular Health *December 18-20*	National Heart, Lung, and Blood Institute
1996	
102 Cervical Cancer *April 1-3*	National Cancer Institute
* Management of Temporomandibular Disorders *April 29-May 1*	National Institute of Dental Research
1997	
103 Breast Cancer Screening for Women Ages 40-49 *January 21-23*	National Cancer Institute
104 Interventions to Prevent HIV Risk Behaviors *February 11-13*	National Institute of Mental Health
105 Management of Hepatitis C *March 24-26*	National Institute of Diabetes and Digestive and Kidney Diseases

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NIH Consensus Program Information Center
On-Site Fulfillment Center

For your convenience, the NIH Consensus Program Information Center is operating an on-site fulfillment center that will provide published consensus statements from previous conferences. At the center, you can obtain past statements or place an order to have them delivered to your home or office.

The following is a sampling of available statements:

- Infectious Disease Testing for Blood Transfusions
- Helicobacter pylori in Peptic Ulcer Disease
- Morbidity and Mortality of Dialysis
- Gallstones and Laparoscopic Cholecystectomy
- Gaucher Disease

The center is located in the lobby of the Natcher Center's main floor across from the registration desk. The hours of operation are from 11:00 a.m. to 5:00 p.m. on Monday, April 14, from 7:30 a.m. to 12:30 p.m. on Tuesday, April 15 and from 8:30 a.m. to 12:30 p.m. on Wednesday, April 16.

Conference Statement Order Form
National Institutes of Health

The conference statements listed below are available through the NIH Office of Medical Applications of Research (OMAR), using one of the following methods:

- **By Mail:** P.O. Box 2577, Kensington, MD 20891
- **By Telephone:** 1-888-NIH-CONSENSUS (644-2667)
- **By Fax:** (301) 816-2494
- **By Internet:**
  World Wide Web: http://consensus.nih.gov
  ftp: ftp://public.nlm.nih.gov/hstat
  Gopher: gopher://gopher.nih.gov/Health and Clinical Information

Please print or type:

Name _____ Degree(s) _____

Position _____

Organization _____

Address _____

City _____ State _____ Zip Code _____

Telephone _____ Fax Number _____ Country _____

☐ **CHECK HERE IF YOU WISH TO BE ADDED TO THE MAILING LIST FOR ALL FUTURE OMAR CONFERENCE STATEMENTS**
☐ **CHECK HERE IF YOU WISH TO RECEIVE THE UPCOMING CONFERENCE SCHEDULE**

1997
___105 Management of Hepatitis C
___104 Interventions to Prevent HIV Risk Behaviors
___103 Breast Cancer Screening for Women Ages 40-49

1996
___TMD Management of Temporomandibular Disorders
___102 Cervical Cancer

1995
___101 Physical Activity and Cardiovascular Health
___REL The Integration of Behavioral and Relaxation Approaches Into the Treatment of Chronic Pain and Insomnia
___100 Cochlear Implants in Adults and Children
___GAU Gaucher Disease: Current Issues in Diagnosis and Treatment
___99 Infectious Disease Testing for Blood Transfusions

1994
___IMP Bioelectrical Impedance Analysis in Body Composition Measurement
___98 Total Hip Replacement
___97 Optimal Calcium Intake
___PGE The Persian Gulf Experience and Health
___96 Ovarian Cancer: Screening, Treatment, and Followup
___95 Effect of Corticosteroids for Fetal Maturation on Perinatal Outcomes
___94 *Helicobacter pylori* in Peptic Ulcer Disease

1993
___USS Ultrasound Screening: Implications of the RADIUS Study
___93 Morbidity and Mortality of Dialysis
___92 Early Identification of Hearing Impairment in Infants and Young Children

1992
___91 Impotence
___90 Gallstones and Laparoscopic Cholecystectomy
___CHA The Head and Heart of Chaos: Nonlinear Dynamics in Biological Systems
___VWL Methods For Voluntary Weight Loss and Control
___89 Triglyceride, High Density Lipoprotein, and Coronary Heart Disease
___89V Free video for Triglyceride, High Density Lipoprotein, and Coronary Heart Disease
___89A Free audiotape for Triglyceride, High Density Lipoprotein, and Coronary Heart Disease
___88 Diagnosis and Treatment of Early Melanoma

1991
___87 Acoustic Neuroma
___86 Diagnosis and Treatment of Depression in Late Life
___85 Treatment of Panic Disorder
___DRM Effects and Side Effects of Dental Restorative Materials
___84 Gastrointestinal Surgery for Severe Obesity

1990
___BST Bovine Somatotropin
___83 Clinical Use of Botulinum Toxin
___82 Diagnosis and Management of Asymptomatic Primary Hyperparathyroidism
___81 Treatment of Early-Stage Breast Cancer
___80 Intravenous Immunoglobulin: Prevention and Treatment of Disease
___HCD Health Care Delivery Research Using Hospital Firms
___79 Adjuvant Therapy for Patients with Colon and Rectum Cancer
___79V Free video for Adjuvant Therapy for Patients with Colon and Rectum Cancer
___78 Treatment of Sleep Disorders of Older People
___77 Surgery for Epilepsy
___76 Noise and Hearing Loss

1989

__75 Treatment of Destructive Behaviors in Persons with Developmental Disabilities
__74 Sunlight, Ultraviolet Radiation, and the Skin
__MBR Modeling in Biomedical Research: An Assessment of Current and Potential Approaches: Applications to Studies in Cardiovascular/Pulmonary Function and Diabetes
__73 Oral Complications of Cancer Therapies: Diagnosis, Prevention, and Treatment
__72 Therapeutic Endoscopy and Bleeding Ulcers

1988

__71 Urinary Incontinence in Adults
__71V Free video for Urinary Incontinence in Adults
__70 Perioperative Red Cell Transfusion
__69 Dental Implants
__67 Prevention and Treatment of Kidney Stones

1987

__65 Geriatric Assessment Methods for Clinical Decisionmaking
__63 Differential Diagnosis of Dementing Diseases
__61 Newborn Screening for Sickle Cell Disease and Other Hemoglobinopathies

1986

__60 Diet and Exercise in Noninsulin-Dependent Diabetes Mellitus
__59 Platelet Transfusion Therapy
__58 Infantile Apnea and Home Monitoring
__56 The Utility of Therapeutic Plasmapheresis for Neurological Disorders
__55 Integrated Approach to the Management of Pain
__54 Prevention of Venous Thrombosis and Pulmonary Embolism

1985

__51 Electroconvulsive Therapy
__50 Anesthesia and Sedation in the Dental Office
__49 Health Implications of Obesity
__48 Travelers' Diarrhea

1984

__47 Lowering Blood Cholesterol to Prevent Heart Disease
__45 Fresh Frozen Plasma: Indications and Risks
__44 Mood Disorders: Pharmacologic Prevention of Recurrences
__43 Osteoporosis
__42 Analgesic-Associated Kidney Disease
__41 Diagnostic Ultrasound Imaging in Pregnancy

1983

__40 Dental Sealants in the Prevention of Tooth Decay
__35 Critical Care Medicine

1982

__32 Defined Diets and Childhood Hyperactivity

1980

__23 Febrile Seizures

1979

__21 Removal of Third Molars
__14 Improving Clinical and Consumer Use of Blood Pressure Measuring Devices

The above items are available free of charge. Audiotapes and videotapes of selected conferences are available for a reproduction fee. Please contact us for the price.

fold here ----------

NIH Consensus Program Information Service
P.O. Box 2577
Kensington, MD 20891

Office of Medical Applications of Research

OMAR Fact Sheet

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES | Public Health Service | National Institutes of Health

The Office of Medical Applications of Research (OMAR) is the focal point for health technology assessment and transfer activities at the National Institutes of Health (NIH).

Located in the Office of the Director, OMAR works closely with the various NIH Institutes, Centers, and Divisions in an effort to improve the process of translating the results of biomedical research into knowledge that can be used effectively in the delivery of health services. Additionally, the office is involved in evaluating the safety and effectiveness of drugs, devices, and medical procedures that are already in general practice.

A major responsibility of OMAR is the coordination of the Consensus Development Program, through which medical technologies are assessed by non-Federal specialists, generalists, other health professionals, and consumers in open forum and the results disseminated widely to the health care community.

Another area of responsibility for OMAR is the coordination of NIH responses to Medicare coverage issues raised by the Public Health Service (PHS). Specifically, the PHS asks NIH experts to evaluate safety and effectiveness of drugs, devices, and procedures that are being reviewed for possible reimbursement under Medicare.

In carrying out its overall mission of technology assessment and transfer, OMAR:

- Works with NIH Institutes, Centers, and Divisions to promote effective dissemination of information gathered through consensus conferences and other assessment activities.
- Advises the NIH Director on development in medical technologies and the applications of medical research.
- Provides a link among the technology assessment activities of the Institutes, Centers, and Divisions of NIH.
- Monitors the progress and effectiveness of NIH health technology assessment and transfer efforts.

Additional information about OMAR and its activities may be obtained from the Office of Medical Applications of Research, Federal Building, Room 618, Bethesda, Maryland 20892, phone (301) 496-1143. Copies of past Consensus Statements as well as the schedule of upcoming Consensus Development Conferences also are available.

Boyer, Joy

From: owner-genetics[SMTP:owner-genetics@LISTSERV.CDC.GOV]
Sent: Monday, April 14, 1997 1:30 PM
To: GENETICS
Subject: Re: Prophylactic Mastectomy and Breast Cancer Risk

Sorry for the earlier version of this. Hopefully this is easier to read!

From: O'Leary, Leslie
To: GENETICS
Subject: Prophylactic Mastectomy and Breast Cancer Risk
Date: Monday, April 14, 1997 12:43PM

The CDC Task Force on Genetics in Disease Prevention makes available the following information as a public service only. Providing this information does not constitute endorsement by the CDC.

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>From the Philadelphia Inquirer - April 14, 1997

Study finds breast removal helps in genetic-risk cases

By Daniel Q. Haney
ASSOCIATED PRESS

SAN DIEGO -- The increasingly common practice of surgically removing both breasts while they are healthy is an effective, if radical, way of preventing breast cancer in women at high risk of the disease, a study found.

Until recently, bilateral prophylactic mastectomy, as doctors call it, was rare. But the development of tests for the inherited genes that can trigger breast cancer has increased demand for this approach.

When a woman discovers she has a high genetic susceptibility to cancer, there is little she can do besides frequent checkups or having her breasts removed. Some doctors are reluctant to offer the screening test because of uncertainty about whether a preemptive mastectomy actually works as well as common sense would suggest it should.

To help settle the issue, doctors from the Mayo Clinic followed up on 950 women who had bilateral prophylactic mastectomies, mostly because of a strong family history of breast cancer. They found it reduced their breast cancer risk by 91 percent.

But it was not totally effective. Even when the breasts are removed, surgeons often leave tiny bits of breast tissue on the chest wall. These remnants can turn cancerous. Furthermore, undetected cancer may sometimes have already spread to other parts of the body before the breasts are removed.

The study, directed by physician Lynn C. Hartmann, followed women who had

the surgery between 1960 and 1993 --before screening for breast-cancer genes became common.

Hartmann said her findings were the first to suggest that mastectomies in women with cancer genes would work as intended.

Hartmann presented her findings yesterday at a conference sponsored by the American Association for Cancer
Research.

While there are no clear figures on how many women are opting for mastectomies to prevent cancer, Henry T. Lynch of Creighton University said the numbers had clearly increased since the discovery of two powerful cancer genes in 1994 and 1995.

Mutant forms of these genes, called BRCA1 and BRCA2, together cause about 5 percent to 10 percent of all breast cancer and 5 percent of all ovarian cancers. While rare, the genes greatly increase the cancer risk for those who have them.

A woman with either BRCA1 or BRCA2 has about an 85 percent lifetime risk of breast cancer. BRCA1 also gives her a 40 percent to 60 percent risk of ovarian cancer, while BRCA2 carries a 10 percent to 20 percent risk of ovarian cancer. The genes also cause less dramatic increases in the risk of colon cancer and prostate cancer in men.

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Cost-Effectiveness of Prenatal Carrier Screening for Cystic Fibrosis

Tracy Lieu, M.D., M.P.H., Susan Watson, M.P.H., and
A. Eugene Washington, M.D., M.Sc.

Objective

This study's objective was to evaluate the economic consequences of routinely offering cystic fibrosis (CF) carrier screening to pregnant white women under 35 years of age. ~~The data below reflect outcomes from the 1994 analysis; the analysis is currently being updated to include new information.~~

Methods

Decision analysis was used to evaluate the health outcomes and medical costs of a screening program from the health care payer's perspective. Probabilities were taken from the literature; cost data were based on consultations with laboratory and hospital administrators. This analysis has been updated from the 1994 paper to include new information: a higher cost of care for CF, an improved test sensitivity, and a lower discount rate. Sensitivity analysis was performed for key assumptions.

Results

If the test acceptance rate were 78 percent and the screening test identified ~~85~~ 90 percent of carriers, a prenatal CF carrier screening program would identify slightly more than half of the high-risk pregnancies in the population. For a cohort of ~~1 million~~ 100,000 pregnant women, the program would cost ~~$83~~ $8.4 million. If the proportion of couples choosing abortion were 30 percent and the ~~lifetime~~ annual cost of medical care for CF were ~~$243,650~~ $41,693, the program would save ~~$12~~ $4.6 million in averted costs of medical care for CF, for a net cost of ~~$71~~ $3.8 million. Even after ~~accounting for~~ subtracting the savings in averted medical care for CF, the net cost per high-risk pregnancy identified would be ~~$82,000~~ $29,000; the net cost per unwanted CF birth averted would be ~~$1.4 million~~ $490,000.

Results were sensitive to the cost and the sensitivity of the screening test. They were also highly sensitive to were also highly sensitive to the proportion of CF pregnancies in which termination was chosen, between 10 and 50 percent. An alternative analysis conducted from the long-term perspective of a large health care provider suggested that CF screening might result in net savings. ~~, but relatively insensitive to the test acceptance rate and to therapeutic abortion rates between 50 percent and 100 percent among pregnancies identified with CF.~~

Conclusions

A prenatal CF carrier screening program would not ~~save the health care payer money~~ result in net savings for the general population under ~~most~~ current assumptions~~, but~~ . However, it may be justified if the benefit of the early information provided to expectant parents is judged worth the cost.

Implications for Consensus Panel

General population screening of pregnant women for CF mutations would enable some families to anticipate or avert CF births, but at a relatively high short-term cost. ~~Selective screening of groups at elevated risk would be more cost-effective.~~ In the long-term, most of this cost might be recouped, or net cost savings might result, depending on the proportion of parents who chose termination of CF pregnancies. For future research and policy on genetic testing, economic models should be initiated early and updated as key information becomes available. Studies are needed on how patients and the general population value relevant nonfinancial outcomes such as the psychological ~~costs~~ value of advance identification of a CF pregnancy.

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Project Date: May 1991 to May 1993

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Project Start Date: April 1995

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NATIONAL INSTITUTES OF HEALTH

CONSENSUS DEVELOPMENT CONFERENCE STATEMENT

GENETIC TESTING FOR CYSTIC FIBROSIS

April 14–16, 1997

NIH Consensus Statements are prepared by a nonadvocate, non-Federal panel of experts, based on (1) presentations by investigators working in areas relevant to the consensus questions during a 2-day public session; (2) questions and statements from conference attendees during open discussion periods that are part of the public session; and (3) closed deliberations by the panel during the remainder of the second day and morning of the third. This statement is an independent report of the panel and is not a policy statement of the NIH or the Federal Government.

Introduction

When the gene for cystic fibrosis (CF) was discovered in 1989, a great deal of attention was given to the implications of this discovery for widespread testing for CF mutations. At the time, scientists, health care providers, and the public urged that research be carried out to examine knowledge, attitudes, interest, and demand for CF testing; the effectiveness of educational interventions; optimal informed consent procedures; laboratory issues associated with carrying out such tests; costs and benefits of testing; and possible deleterious effects associated with this testing. They suggested that alternative delivery mechanisms be explored and called for Federal funds to carry out such research. Since that time, new research has yielded a large body of data on these and other issues.

For the reasons listed above, the National Human Genome Research Institute and the Office of Medical Applications of Research of the National Institutes of Health (NIH), along with cosponsors the Agency for Health Care Policy and Research; Centers for Disease Control and Prevention; National Institute of Child Health and Human Development; National Institute of Diabetes and Digestive and Kidney Diseases; National Heart, Lung, and Blood Institute; National Institute of Mental Health; National Institute of Nursing Research; NIH Office of Rare Diseases; and NIH Office of Research on Women's Health sponsored a Consensus Development Conference on April 14–16,

1997. Following 1½ days of testimony by experts in the relevant fields and discussion from the audience, a consensus panel representing research investigators, health care providers, epidemiologists, geneticists, ethicists, and other experts, as well as representatives of the public, considered the evidence and formulated a consensus statement to address the following five predefined questions:

1. What is the current state of knowledge regarding natural history, epidemiology, genotype-phenotype correlations, treatment, and genetic testing of cystic fibrosis in various populations?

2. What has been learned about genetic testing for cystic fibrosis regarding (public and health professional) knowledge and attitudes, interest and demand, risks and benefits, effectiveness, cost, and impact?

3. Should cystic fibrosis carrier testing be offered to (1) individuals with a family history of cystic fibrosis, (2) adults in the preconception or prenatal period, and/or (3) the general population?

4. What are the optimal practices for cystic fibrosis genetic testing (setting, timing, and the practices of education, consent, and counseling)?

5. What should be the future directions for research relevant to genetic testing for cystic fibrosis and, more broadly, for research and public policy on genetic testing?

1. What Is the Current State of Knowledge Regarding Natural History, Epidemiology, Genotype-Phenotype Correlations, Treatment, and Genetic Testing of Cystic Fibrosis in Various Populations?

2. What Has Been Learned about Genetic Testing for Cystic Fibrosis Regarding (Public and Health Professional) Knowledge and Attitudes, Interest and Demand, Risks and Benefits, Effectiveness, Cost, and Impact?

3. Should Cystic Fibrosis Carrier Testing Be Offered to (1) Individuals with a Family History of Cystic Fibrosis, (2) Adults in the Preconception or Prenatal Period, and/or (3) the General Population?

4. What Are the Optimal Practices for Cystic Fibrosis Genetic Testing (Setting, Timing, and the Practices of Education, Consent, and Counseling)?

5. What Should Be the Future Directions for Research Relevant to Genetic Testing for Cystic Fibrosis and, More Broadly, for Research and Public Policy on Genetic Testing?

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Speakers

David A. Asch, M.D., M.B.A.
"How Much Information About the Risk of Cystic Fibrosis Do Couples Want To Know?"
"Prescriptive Decision Modeling for Cystic Fibrosis Screening"
Assistant Professor of Medicine
Senior Fellow, Leonard Davis Institute of Health Economics
Department of Medicine
University of Pennsylvania
Philadelphia, Pennsylvania

Arthur L. Beaudet, M.D.
"Making the Case for Offering Cystic Fibrosis Carrier Testing on a Population Basis"
Henry and Emma Meyer Professor and Acting Chairman
Department of Molecular and Human Genetics
Baylor College of Medicine
Investigator
Howard Hughes Medical Institute
Houston, Texas

Barbara A. Bernhardt, M.S.
"Offering Cystic Fibrosis Carrier Screening to an HMO Population: Utilization, Knowledge, and Factors Influencing the Decision To Be Tested"
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Other Treatment Approaches

strategies to correct mutant protein

① Intro

② lower temp - Phenylbutyrate

oral PB 3x a day

Chloride conductance channel

Activating Mutant CFTR - Milrinone

Sodium Channel blocker Amiloride

Human Beta-Defensin-1

anti-microbial activity is salt sensitive

2 companies have developed defensins that are not salt sensitive

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4/-18/85 — 6/30/94

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Conventional T.

Assessments

Therapies
- Antibiotics
- Physiotherapy
- Enzyme replacement

Median Survival

1940 - 1
1996 - 30

most focus on lung disease

mucus plugging
infection
inflammation
↓
lung injury

Inflammation

prednisone - lower dose
Ibuprofen -

inhaled anti protease inhibitors are now being used
Enzyme Therapy - Dornase Alfa
28% reduction in infection
$8-10,000 per year per use
DNase, Gelsolin

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lung transplantation

- CF patients are good candidates
- Transplant does not develop CF
will eventually develop lung blockage

Gene Therapy

Adenovirus (cause inflammation)

Adenoassociated virus
(does not cause infection or inflammation)

liposome - least immunogenic & least effective

① Itworks, is transient

② doesn't always work & causes inflammation

Future

① develop efficient stealth vector targeting

② site specific vector targeting progenitor cells

Cafeteria Information

Natcher Conference Center

7:00 a.m.–9:30 a.m.
(Full breakfast)
9:30 a.m.–11:00 a.m.
(Continental breakfast)
11:00 p.m.–2:00 p.m.
(Lunch)

Auditorium Level

The cafeteria is located off the main lobby of the Natcher Conference Center. (To the left of the building entrance.)

Building 38A—Lister Hill

7:00 a.m.–10:15 a.m.
(Full breakfast)
10:00 a.m.–11:00 a.m.
(Continental breakfast)
11:00 a.m.–1:30 p.m.
(Lunch)
1:30 p.m.–3:30 p.m.
(Snacks)

Lower Level (B-1) Cafeteria

Directly across the road from the Natcher Building. Enter through front doors then take stairs down one level.

Building 1—Administration

7:15 a.m.–9:00 a.m.
(Breakfast)
9:00 a.m.–10:30 a.m.
(Coffee, snacks)
11:00 a.m.–1:30 p.m.
(Lunch)
2:15 p.m.–3:00 p.m.
(Coffee)

Third Floor Cafeteria

Go out the front doors of the Natcher Conference Center and follow Center Drive around to Building 1 on the left. Enter front of Building 1 and take the elevators to the 3rd floor Cafeteria.

Building 10

To get to Building 10

Go out the front door of the Natcher Conference Center and follow Center Drive to the corner of Center and Memorial Drives. Follow the sidewalk up to Building 10 (Clinical Center).

7:00 a.m.–9:30 a.m.
(Continental breakfast)
10:00 a.m.–2:00 p.m.
(Lunch)
2:00 p.m.–5:00 p.m.
(Grill and snacks)

Second Floor Cafeteria

Turn right at the front door and follow the corridor to the escalator on the right. Take the escalator to the 2nd floor and the cafeteria is on the right.

5:30 a.m.–11:00 a.m.
(Continental breakfast)
7:00 a.m.–9:30 a.m.
(Full breakfast)
11:00 p.m.–2:30 p.m.
(Lunch)

Basement Level Cafeteria

From the front of the building, go straight back to the elevators. Take the elevators down to the B1 level. As you come off the elevator, turn right and follow the corridor to the cafeteria on the left.

NIH Transportation Options

Directions by Metrorail (Preferred)

From Metro Center take Metrorail (Red Line) to the Medical Center station, which is located on the NIH campus. Exit the Metrorail station via the escalator. At the top of the escalator (street level), turn left and follow the path to the Natcher Conference Center. (You will see the building from the station.)

Directions by Bus

To Building 10

Metrobus: J2 (J1 rush hour only) on the Bethesda/Silver Spring Line

Ride-On Buses: 30 (from Bethesda Metro), 35 (from Wheaton Metro), 42 (via Rockville Pike)

To Medical Center Metro:

Metrobus: J2 (J1 rush hour only)

Ride-On Buses: 30, 35, 42, 46; during rush hour: 27, 33, 34

Call Ride-On at 217-RIDE for further details.

Directions by Car

PLEASE NOTE: Because of new construction on the NIH campus, visitor parking is virtually nonexistent. You are strongly encouraged to take public transportation. If you must drive, there are a limited number of visitor spaces for all day parking in lot 41B at the south end of the NIH campus. Please plan accordingly.

Interstate 495 Westbound

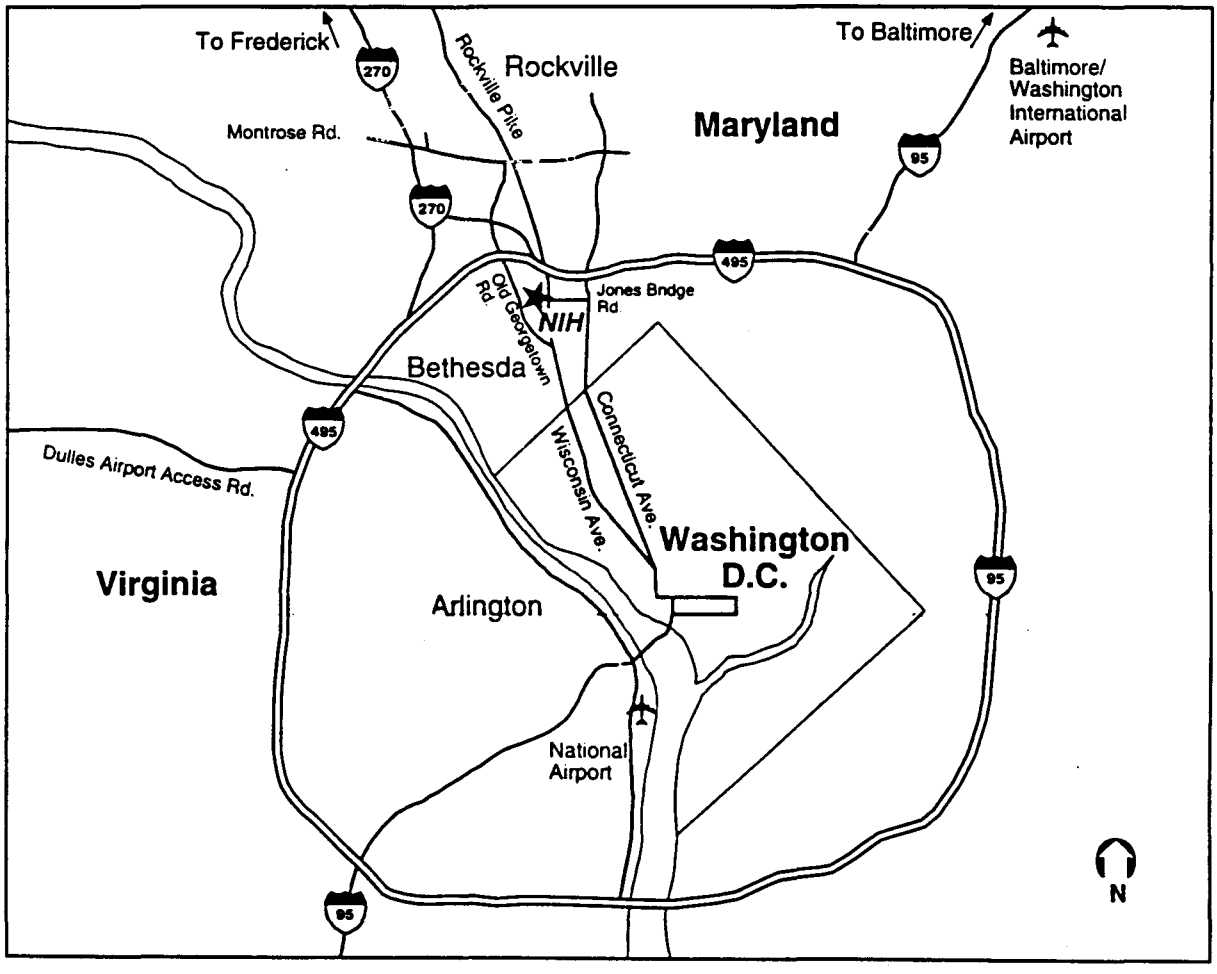
Take exit 33B ((South) [Connecticut Ave.]). At second traffic light, turn right onto Jones Bridge Road and proceed 2 more traffic lights to the intersection of Rockville Pike. Travel through the intersection onto Center Drive, make third left and follow signs to parking lot 41B.

Interstate 495 Eastbound

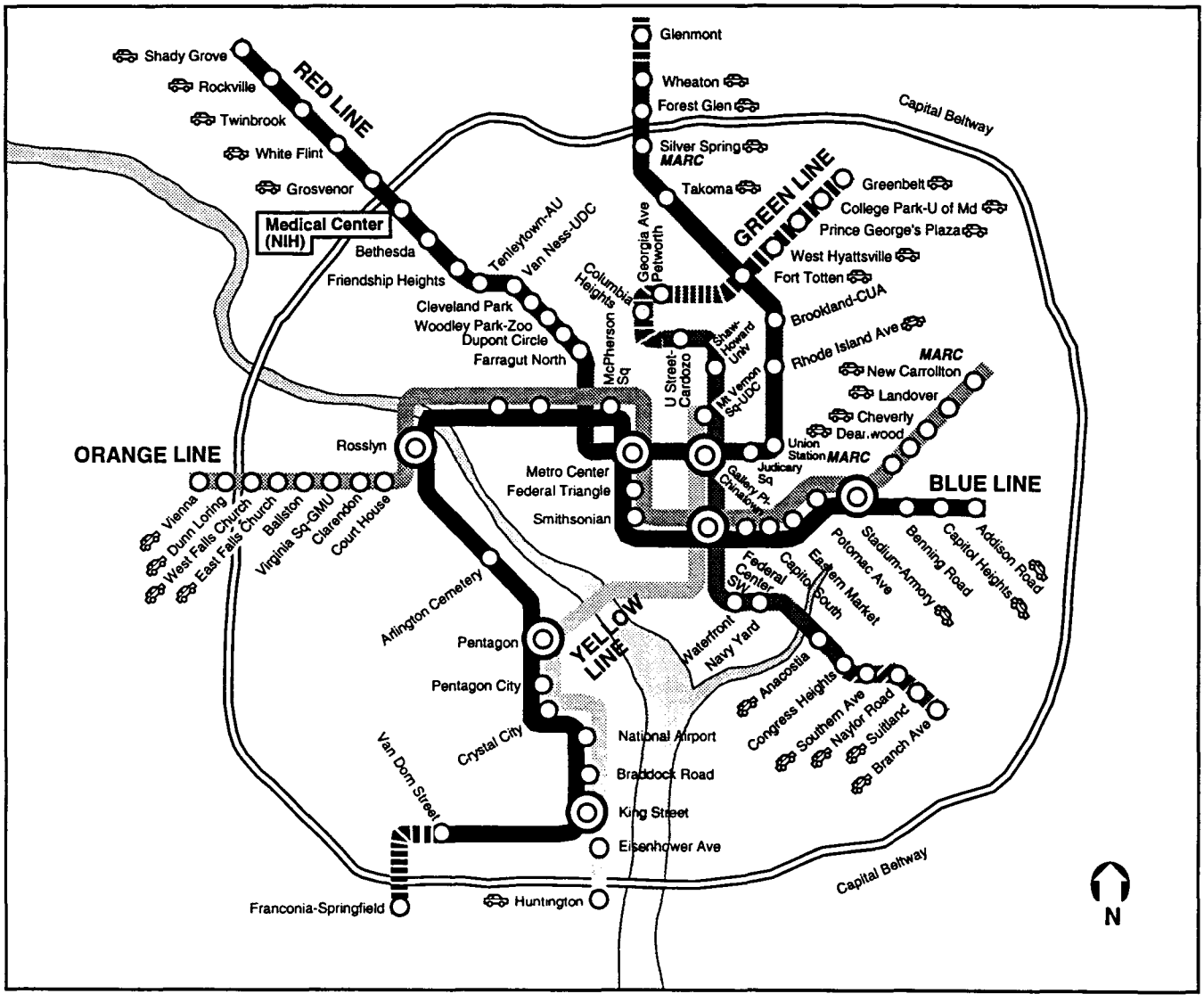
Take exit 34B ((South) [Bethesda/Wisconsin Ave.]). Proceed 2 miles south on Rockville Pike. At fifth traffic light, turn right onto Center Drive, make third left and follow signs to parking lot 41B.

Wisconsin Ave. (from the District)

Proceed north from the District to 9000 Rockville Pike [Wisconsin Ave.]. Turn left onto Center Drive (first traffic light after Ramada Inn). Make third left and follow signs to parking lot 41B.



Metro System Map



Directions by Metrorail

From Metro Center take Metrorail (Red Line) to the Medical Center Station which is located on the NIH campus.

M metro

Legend

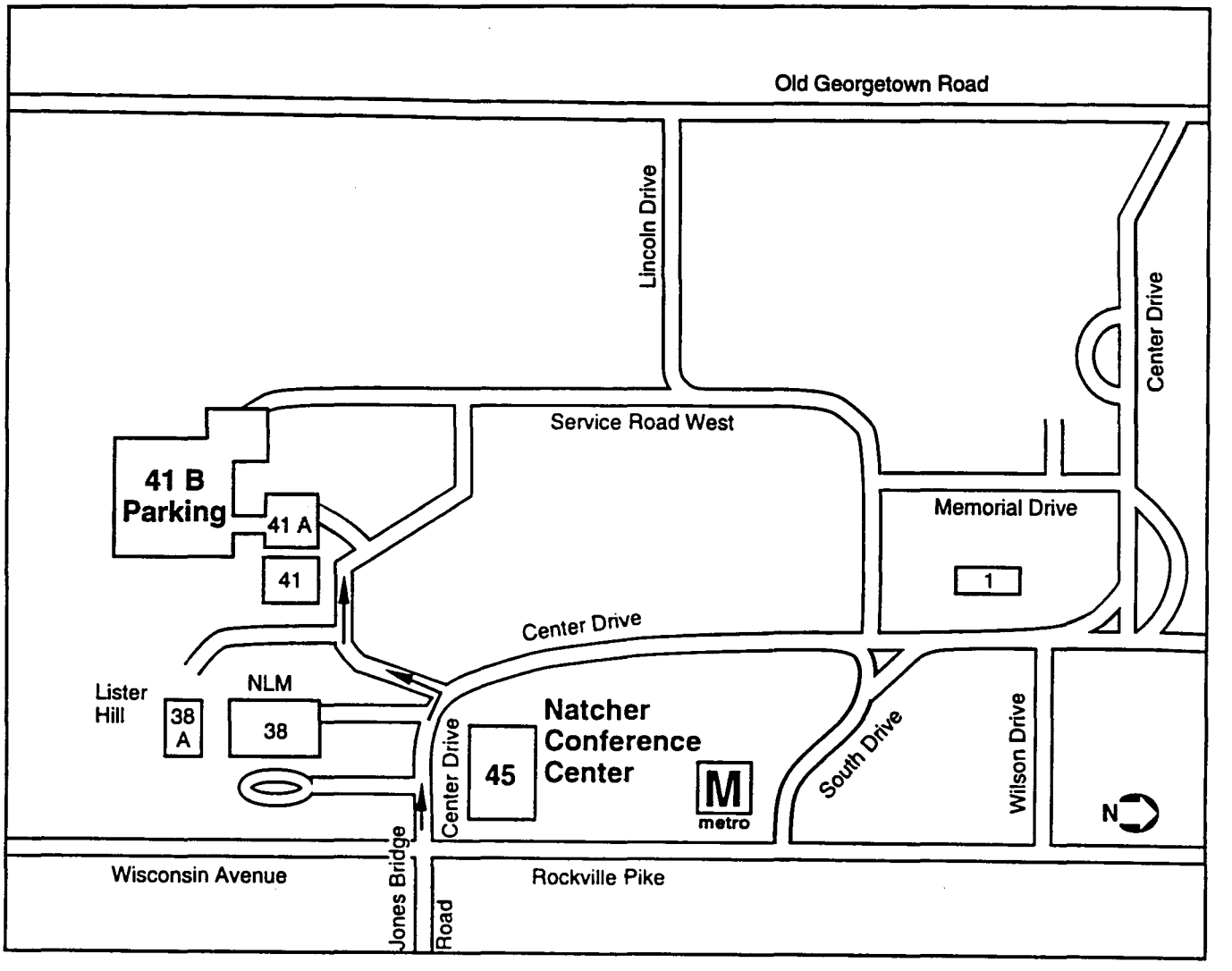
- RED LINE - Wheaton to Shady Grove
- BLUE LINE - Addison Road to Van Dorn Street
- ORANGE LINE - New Carrollton to Vienna
- YELLOW LINE - U Street-Cardozo to Huntington
- GREEN LINE - Anacostia to U Street-Cardozo
- Transfer Station
- All-day Parking
- *MARC* Commuter Rail Service
- Capital Beltway

NIH Parking Instructions

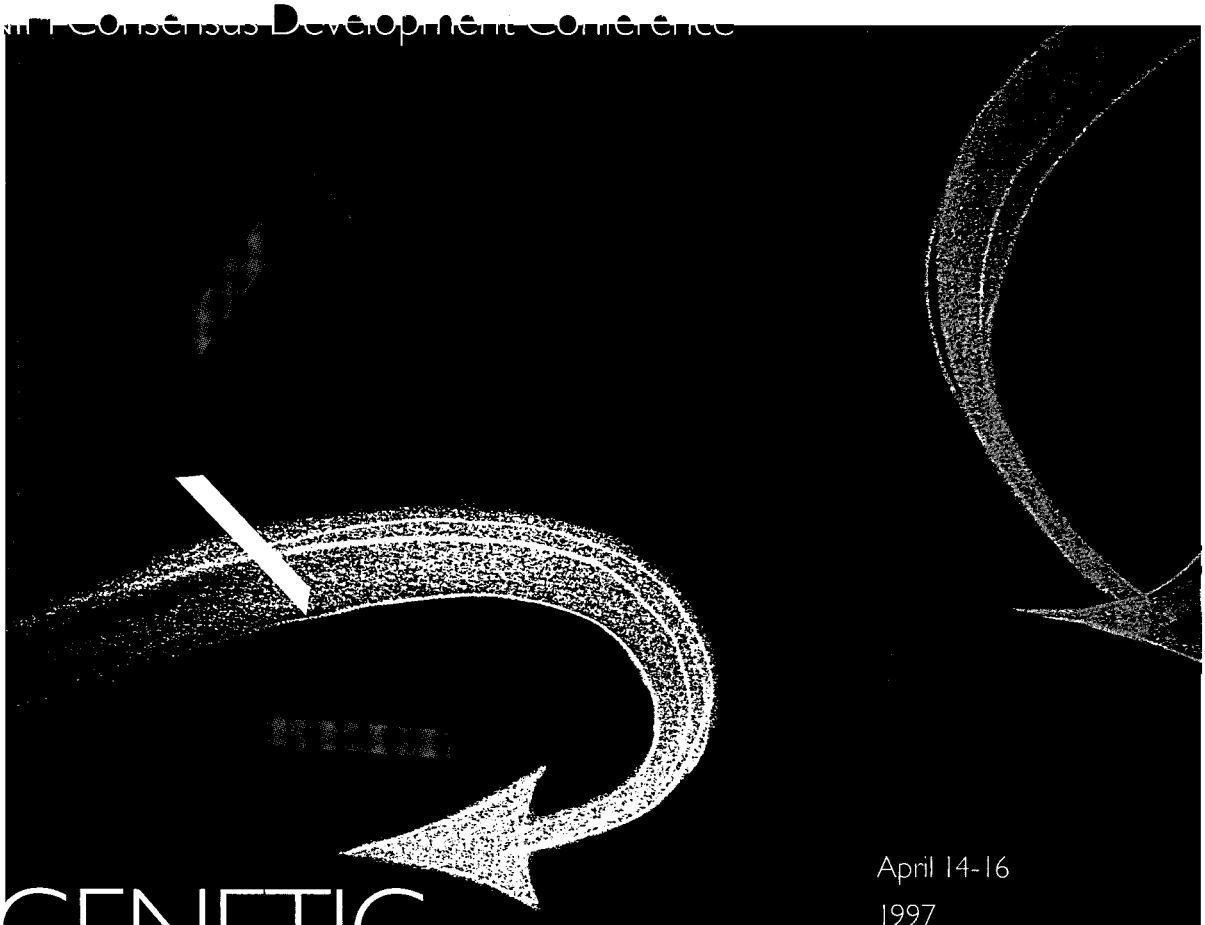
Conference Attendees

Visitor parking is virtually nonexistent; therefore, you are strongly encouraged to take public transportation. The Medical Center Metrorail Stop (on the Red Line) is within easy walking distance. If must drive, there are a limited number of visitor spaces for all day parking in lot 41B at the south end of the NIH campus. Please plan accordingly.

Directions to lot 41B: Entering the campus from Wisconsin Ave. onto Center Drive, make third left, follow signs to lot 41B.



NIH Consensus Development Conference



GENETIC TESTING FOR CYSTIC FIBROSIS

April 14-16
1997
Natcher
Conference
Center
National Institutes
of Health
Bethesda, Maryland

For information
and registration,
call 301-770-3153
send e-mail to
confdept@tech-res.com
or visit
http://consensus.nih.gov
on the World Wide Web

Sponsored by the National Human Genome Research Institute and the NIH Office of Medical Applications of Research.

Cosponsored by the National Institute of Diabetes and Digestive and Kidney Diseases; the National Heart, Lung, and Blood Institute; the National Institute of Child Health and Human Development; the NIH Office of Rare Diseases; the National Institute of Mental Health; the National Institute of Nursing Research; the NIH Office of Research on Women's