

This material may be protected by copyright law (Title 17 U.S. Code).

694
694
697
699
700
701
701
708
709
713
715
717
719
723
725
727
727
730
731
735
736
739
741
746
746
750
752
755
757
760
761
766
766
772
773
777
778
783
784
788
791
796
796
805
808
812
814
818
820
823
825

Participants

John Alman
Outpatient Clinic
Veterans Administration
17 Court Street
Boston, Massachusetts 02108

Robert A. Bagramian
Department of Community Dentistry
School of Dentistry
University of Michigan
Ann Arbor, Michigan 48109

Hazen Baron
Director, Consumer Dental
Care Research
Johnson & Johnson Products, Inc.
501 George Street
New Brunswick, New Jersey 08903

Bradley B. Beiswanger
Director of Clinical Research
Preventive Dentistry Research Institute
410 Beauty Avenue
Indianapolis, Indiana 46202

Robert M. Bell
Associate Statistician
Rand Corporation
Santa Monica, California 90406

Bernard W. Bollmer
The Procter & Gamble Company
11511 Reed Hartman Highway
Cincinnati, Ohio 45241

William H. Bowen
Chairman
Department of Dental Research
University of Rochester
School of Medicine and Dentistry
602 Elmwood Avenue
Rochester, New York 11462

William W. Briner
The Procter & Gamble Company
11511 Reed Hartman Highway
Cincinnati, Ohio 45241

Janet A. Brunelle
Chief, Biometry Section
NIDR
Westwood Building
5333 Westbard Avenue
Bethesda, Maryland 20205

James P. Carlos
Director, National Caries Program
NIDR
Bethesda, Maryland 20205

John Carr
Dental Officer
Parklawn Building HFN-160
5600 Fishers Lane
Rockville, Maryland 20857

William S. Cash
Colgate-Palmolive Company
Research and Development
909 River Road
Piscataway, New Jersey 08854

Neal W. Chilton
Senior Research Scientist in Biostatistics and Preventive Dentistry,
Columbia University
Executive Secretary, Task Force
on Design and Analysis
2975 Princeton Pike
Lawrenceville, New Jersey 08648

Ralph B. D'Agostino
Professor of Mathematics
Boston University
264 Bay State Road
Boston, Massachusetts 02215

T. Graham Davies
Dental Health Unit
Turner Dental School
University of Manchester
Bridgeford Street
Manchester M15 6FH
England

Charles Donnelly
Associate Professor of Health Services
Administration
Johns Hopkins University
School of Hygiene & Public Health
615 Wolfe Street
Baltimore, Maryland 21205

Martin C. Downer
Chief Dental Officer
Department of Health & Social Security
Elephant & Castle
London SE1 6BY, England

John W. Fertig
Professor of Biostatistics (*Emeritus*)
Columbia University
5 Ironwood Lane
Woodbury, Connecticut 07798

Stuart L. Fischman
Professor of Oral Medicine
School of Dentistry
SUNY at Buffalo
Buffalo, New York 14214

Joseph L. Fleiss
Professor & Head
Division of Biostatistics
Columbia University
School of Public Health
600 W. 168th Street
New York, New York 10032

Clarence Gilkes
Senior Dental Officer
5600 Fishers Lane
FDA Bureau of Drugs HFD 160
Parklawn Building
Rockville, Maryland 20857

Robert L. Glass
Forsyth Dental Center
140 The Fenway
Boston, Massachusetts 02115

Judith D. Goldberg
Head, Statistical Design and Analysis
Department
Lederle Laboratories
American Cyanamid Co.
Pearl River, New York 10965

Robert M. Grainger
Research Consultant
R.R. No. 1, Prescott
Ontario, Canada KOE 1T0

Richard Graves
Associate Professor of Community
Dentistry
University of Kentucky
College of Dentistry
Department of Community Dentistry
Lexington, Kentucky 40536

Bernard Greenberg
Kenan Professor of Biostatistics
School of Public Health
University of North Carolina
Chapel Hill, North Carolina 27514

John Hefferren
ADAHF - Research Institute
211 East Chicago Avenue
Chicago, Illinois 60611

Stanley Heifetz
National Caries Program, NIDR
Bethesda, Maryland 20205

Kirk Hoerman
Professor of Community Dentistry
Loyola University of Chicago
School of Dentistry
2160 S. First Avenue
Maywood, Illinois 60153

Philip J. Holloway
Professor, Department of Child Dental
Health
University Dental Hospital of Manchester
Bridgeford Street
Manchester M15 6FH
England

Herschel S. Horowitz
Chief, Community Programs Section
National Caries Program, NIDR
Bethesda, Maryland 20205

Peter B. Imrey
Associate Professor of Biometrics and
Health Education
University of Illinois College of
Medicine
190 Medical Sciences Building
506 South Mathews Avenue
Urbana, Illinois 61801

Mary Johnson
Group Leader
Division of Biometrics
Food and Drug Administration
Bureau of Drugs HFN-713
5600 Fishers Lane
Rockville, Maryland 20857

Ralph V. Katz
Associate Professor & Chairman
Department of Restorative Dentistry
University of Connecticut
School of Dental Medicine
Farmington, Connecticut 06032

Albert Kingman
Biostatistician
National Caries Program, NIDR
Bethesda, Maryland 20205

Larry Laster
Associate Professor of Biostatistics
School of Dental Medicine
University of Pennsylvania A-1
4001 Spruce Street
Philadelphia, Pennsylvania 19104

Robert W. Lehnhoff
Director, Clinical Operations and
Biometrics
The Procter & Gamble Company
6110 Centerhill Road, Room 1W00
Winton Hill Technical Center
Cincinnati, Ohio 45241

Kwo Hwa Lu
Professor and Chairman
Department of Biostatistics
Oregon Health Sciences University
611 S.W. Campus Drive
Portland, Oregon 97701

Peter Mainwaring
Guy's Hospital Dental School
London SE1 9RT, England

Irwin D. Mandel
Professor and Director, Division of
Preventive Dentistry
School of Dental and Oral Surgery
Columbia University
630 W. 168th Street
New York, New York 10032

Thomas A. Marthaler
Associate Professor
Department of Cariology,
Periodontology & Preventive
Dentistry
Dental Institute
University of Zürich
Plattenstrasse 11
P. O. Box 138
CH-8028
Zürich, Switzerland

Cynthia M. Mitropoulos
University of Manchester
Dental Health Unit
Turner Dental School
Bridgeford Street
Manchester M15 6FH, England

Richard D. Mumma, Jr.
Dean and Professor of Behavioral
Sciences and Community Health
New York University College of
Dentistry
421 First Avenue
New York, New York 10010

Malcolm N. Naylor
Professor of Preventive Dentistry
Guy's Hospital Dental School
London Bridge
London SE1 9RT, England

Robert T. O'Neill
Deputy Director
Division of Biometrics
National Center for Drugs
and Biology
HFN-710
5600 Fishers Lane
Rockville, Maryland 20857

John K. Peterson
Director, Division of Dental Health
North Dakota Department of Health
Capital Building
Bismarck, North Dakota 58505

Sven Poulsen
Professor and Head
Department of Pedodontics and
Preventive Dentistry
Royal Dental College
DK-8000 Aarhus C
Denmark

George F. Reed
Mathematical Statistician, Epidemiology
and Biometry Research Program
National Institute of Child Health and
Development
7C08 Landon Building
Bethesda, Maryland 20205

Melvin L. Ringelberg
Health Program Office
State of Florida
1317 Winewood
B-1 Room 108
Tallahassee, Florida 32301

Louis W. Ripa
Professor & Chairman
Department of Children's Dentistry
School of Dental Medicine
Health Sciences Center
SUNY at Stony Brook
Stony Brook, New York 11790

Norton Ross
Director
Dental/Oral Sciences
Warner Lambert Company
170 Tabor Road
Morris Plains, New Jersey 07950

James Rule
Professor, University of Maryland
School of Dentistry
Baltimore College of Dental Surgery
Baltimore, Maryland 21201

Arje Scheinin
Rector
University of Turku
Lemminkaisenkatu 2, SF-20520
Turku, Finland

Gordon H. Schrotenboer
Assistant Executive Director
Scientific Affairs
American Dental Association
211 East Chicago Avenue
Chicago, Illinois 60611

Malcolm K. Slakter
Professor
Department of Counseling and
Educational Psychology
SUNY at Buffalo
407 Baldy Hall
Buffalo, New York 14260

Harry Smith
Professor of Biostatistics
Mt. Sinai School of Medicine
110th Street & 5th Avenue
New York, New York

Martyn R. Smith
Assistant Professor of Mathematics
Department of Mathematical and
Computer Sciences
Michigan Technological University
Houghton, Michigan 49931

John W. Stamm
Professor and Chairman
Department of Community Dentistry
McGill University
Montreal, PQ, Canada H3A 2B2

George K. Stookey
Department of Preventive Dentistry
Indiana University
School of Dentistry
1121 W. Michigan Avenue
Indianapolis, Indiana 46202

O.P. Sturzenberger
Research Dentist
The Procter & Gamble Company
Sharon Woods Technical Center
11511 Reed Hartman Highway
Cincinnati, Ohio 45241

André A. O. Varma
Professor and Chairman
Department of Community Medicine
School of Medicine
Health Sciences Center
SUNY at Stony Brook
Stony Brook, New York 11794

Anthony R. Volpe
Associate Director for Clinical
Investigations
Colgate-Palmolive Research Center
909 River Road
Piscataway, New Jersey 08854

Alexander G. Vongris
Medical Director
Colgate-Palmolive Research Center
909 River Road
Piscataway, New Jersey 08854

Samuel L. Yankell
Research Associate Professor
Department of Periodontics
School of Dental Medicine
University of Pennsylvania
4001 Spruce Street
Philadelphia, Pennsylvania 19104

Walter A. Zacherl
College of Dentistry
Ohio State University
305 W. 12th Avenue
Columbus, Ohio 43210

Stuart O. Zimmerman
Professor & Head
Department of Biomathematics
M.D. Anderson Hospital
University of Texas
System Cancer Center
6723 Bertner
Houston, Texas 77030

Observers

Lester Apperson
Colgate-Palmolive Company

A.S. Blinkhorn
University of Edinburgh

Harry Bohannon
National Preventive Dentistry
Demonstration Program, AFDH

Charles K. Burchell
Unilever Research, UK

Keith Callahan
Beecham Products

Noel Childers
University of Alabama

Valerie Clerehugh
University of Manchester, UK

Martin E.S. Curzon
Eastman Dental Center

Judith Disney
National Preventive Dentistry
Demonstration Program, AFDH

William Driscoll
NIDR

Arthur Hefti
University of Basel, Switzerland

Alan Kirsch
Beecham Products

Michael Lennon
University of Manchester, UK

Dennis Leverett
Eastman Dental Center

Shou-Hau Li
NIDR

Jon Meiers
University of Minnesota

Bernard Misek
Beecham Products

David G. Pendrys
University of Minnesota

Kaisu Pienihakkinen
University of Turku
Finland

Horace M. Stiles
NIDR

Philip Swango
NIDR

Helen Worthington
University of Manchester, UK

John Timothy Wright
University of Alabama

PLANNING COMMITTEE

Neal W. Chilton
Executive Secretary
Task Force on Design
and Analysis

John W. Fertig
Chairman
Task Force on Design
and Analysis

John J. Hefferren
American Dental Association

Robert W. Lehnhoff
The Procter & Gamble Company

Richard D. Mumma, Jr.
Dean
New York University
College of Dentistry

John W. Stamm
McGill University

Anthony R. Volpe
Colgate-Palmolive Company

Gordon H. Schrottenboer
American Dental Association

Opening Remarks

JOHN COADY: It is my pleasure to welcome you to the Association headquarters for this Conference on Clinical Caries Trials. I am told that the last time this conference was convened here was 15 years ago in 1968, and that the first conference was held in 1955. Your deliberations at this conference, as with those in the past, will have a profound effect on the dental practice of the future. The declining caries rate is glad news to us in our constant effort to improve the oral health of the American people. At the same time, it has meant very real changes in the way we as dentists manage our professional lives. As the caries rate continues to decline, we will see even more substantial change in the way our profession functions. The eradication of dental caries, once a mere hope for the profession of dentistry, moves steadily toward becoming a reality. This is due in large part to your efforts. You have our congratulations for your past endeavors and our best wishes on your deliberations here this week. Thank you.

JAMES CARLOS: I am delighted to be here. I would like to thank the ADA for their willingness, once again, to sponsor this meeting, and thank John Coady personally, and of course to thank Gordon Schrottenboer. He is remarkable. We thank you, Gordon, for your efforts. Certainly the same thanks are due to Neal Chilton, who worked with Gordon. Neal, in fact, was the person who stimulated this meeting. If any of you have read his latest edition of his textbook*, you will know what I think of Neal. The best cross-section of people that has ever been assembled in the area of dental clinical trials — or perhaps in clinical trials in general, for that matter — is here today. We obviously have academics represented, government, to be sure, industry, and, of course, international research. That's the kind of understanding that we in the caries program have tried to encourage since we began all this about 12 years ago. It is a good example, I think, of the success in trying to get everybody involved in the problems of preventing dental caries.

It occurred to me that one of the reasons I am here at this particular meeting is because I had the good fortune quite a while ago to encounter a person who has also made tremendous contributions to the effort of improving the quality of dental caries clinical trials. I am speaking of Professor John Fertig. He is a remarkable teacher, a great friend and supporter of dental research. I would like to take this opportunity to thank him publicly.

Last night I did a survey of a small sample of those attending, and I find that there are two recurring interesting issues which I hope we will be able to get some insight into while we are here, in addition to the formal papers which appear on the program. The first issue is that no one trusts anyone else's data. I don't know why that is so, but it seems quite prevalent. I think there are some real problems there which I hope will be aired when we talk one to another about our results. The other issue is not one exact-

ly of clinical trials but closely allied, because all of us are equally interested in epidemiology. The issue is that everybody agrees that dental caries is declining, but I don't agree with that. Everyone agrees that dental caries is declining in the industrialized countries, but there is tremendous difference of opinion about the reasons. I hope that's another thing we will be able to talk about while we are here.

Once again, my warm greetings to everybody. We are delighted to have you here. We appreciate the efforts of the ADA, of Gordon Schrottenboer, and of Neal Chilton, and wish you a very profitable conference.

NEAL W. CHILTON: Working with Gordon has been a pleasure, and I want to thank him publicly for all his fine efforts in arranging this Conference in addition to all his many activities as Assistant Executive Director of the Association.

The Task Force on Design and Analysis in Dental and Oral Research is a co-sponsor of this conference. Every member of the Task Force is here with the exception of Dr. André Varma, who is now in India as an international consultant to WHO, and his paper will be read by John Fertig. I also want to pay tribute to my teacher and good friend since 1945, Professor John Fertig. Without him, most of the work I have done in this field would never have been accomplished, and without his leadership the Task Force would not be in existence. I want to thank John formally and publicly.

The Task Force started originally as one of four task forces in the second caries conference sponsored by the American Dental Association and the Division of Dental Health of the USPHS in 1968. A similar conference on clinical trials in periodontal disease, under the sponsorship of the New Jersey State Health Department and the Division of Dental Health of the USPHS, was held at the Sugar Loaf Conference Center of Temple University in Philadelphia. The Proceedings were published as Supplement 14, *Journal of Periodontal Research*, in 1974.

Since 1974, the Task Force activities have been sponsored by grants from various industrial concerns. We are currently sponsored by (alphabetically) Beecham Products, Colgate-Palmolive, Johnson & Johnson, Procter & Gamble, Warner Lambert, and the William Wrigley, Jr., Company. I would like to thank them all for their continued support.

The conference will be conducted in the following way: Following each formal presentation, there will be a formal discussion. All of these papers have been made available to you so that you could read them in advance to allow for good informal discussion from the floor. After each session of the formal presentations and discussions, discussion will be led by pre-arranged panels, listed in the program. After this, discussion will be open from the floor. We have arranged it so that there will be more than adequate time for complete discussion. All discussants are please asked to identify themselves.

I'd like, again, on behalf of the Task Force, to welcome all of the participants and observers and hope that you enjoy the meeting and have a very profitable time.

*Design and Analysis in Dental and Oral Research, 2nd ed., New York: Praeger, 1982.