NIH Consensus Development Conference on

ANTENATAL CORTICOSTEROIDS REVISITED REPEAT COURSES

August 17–18, 2000
Masur Auditorium
National Institutes of Health
Bethesda, Maryland

Sponsored by:
National Institute of Child Health and Human Development
NIH Office of Medical Applications of Research

Cosponsored by:
National Institute of Nursing Research
National Heart, Lung, and Blood Institute
INTRODUCTION

Preterm delivery is a major cause of death and illness in infants. Corticosteroid treatment of pregnant women delivering prematurely was first introduced in 1972 to enhance fetal lung maturity. Subsequent research has focused on the ability of glucocorticoids to reduce mortality and brain injury in preterm neonates.

In 1994, the National Institutes of Health sponsored a Consensus Development Conference on the Effect of Corticosteroids for Fetal Maturation on Perinatal Outcomes to assess the effectiveness of antenatal glucocorticoid therapy. The consensus panel concluded, in part, that giving corticosteroids to pregnant women at risk for preterm delivery reduces the risk of death, respiratory distress syndrome, and intraventricular hemorrhage in their preterm infants.

The 1994 panel noted that optimal benefit of antenatal corticosteroid therapy lasts 7 days. The panel also noted that the potential benefits and risks of repeated administration of antenatal corticosteroids 7 days after the initial course are unknown and called for additional research on this issue.

The NIH is organizing this 1 1/2 day conference to present research on repeat courses of antenatal corticosteroid therapy. After a day of presentations and audience discussion, an independent, non-Federal consensus development panel will weigh the scientific evidence and write a draft statement that will be presented to the audience on the second day. The panel's statement will address these questions:

- Is the evidence on benefits and risks of repeat courses of antenatal corticosteroids sufficient to permit consensus recommendations?
• If so, what are the recommendations?
• If not, what additional information should be obtained?

General Information

Conference sessions will be held in the Masur Auditorium of the Clinical Center (Building 10), National Institutes of Health, Bethesda, Maryland. Sessions will run from 8 a.m. to 3 p.m. on Thursday and from 8:30 a.m. to 12:30 p.m. on Friday. The telephone number for the message center is (301) 496-2520.

Cafeteria

The cafeteria in the Clinical Center is located one floor below the auditorium in the basement of the building. It is open from 7 a.m. to 2:30 p.m., serving breakfast and lunch.

Sponsors

The primary sponsors of this conference are the National Institute of Child Health and Human Development and the NIH Office of Medical Applications of Research. Additional sponsors are the National Institute of Nursing Research and the National Heart, Lung, and Blood Institute.

Statement of Interest

In accordance with ACCME requirements, each speaker presenting at this conference has been asked to submit documentation outlining all outside involvement pertaining to the subject area. Please refer to the chart in your participant packet for details.
AGENDA

THURSDAY, AUGUST 17, 2000

8:00 a.m. Opening Remarks and Acknowledgements
Duane Alexander, M.D., Director
National Institute of Child Health and Human Development

8:10 a.m. Charge to the Panel
Barnett Kramer, M.D., M.P.H., Director
Office of Medical Applications of Research

8:20 a.m. Conference Overview
Larry C. Gilstrap III, M.D.
Emma Sue Hightower Chairman and Professor
Department of Obstetrics, Gynecology, and Reproductive Sciences
University of Texas-Houston Medical School

I. Overview

8:25 a.m. Criteria for Evaluating the Quality of Evidence
John C. Sinclair, M.D., Professor
Department of Pediatrics
McMaster University Medical Center

8:40 a.m. Pharmacology of Corticosteroids
Robert M. Ward, M.D., FAAP, F.C.P., Professor
Department of Pediatrics
University of Utah School of Medicine
8:55 a.m. Glucocorticoids and Normal Development
James F. Padbury, M.D., Professor and Vice Chairman
Department of Pediatrics
Brown University School of Medicine
Pediatrician-in-Chief
Women and Infants Hospital of Rhode Island

9:10 a.m. History of Repeat Courses and Patterns of Current Use
in the United States, the United Kingdom, and Australia
Michael Socol, M.D., Professor
Section of Maternal-Fetal Medicine
Department of Obstetrics and Gynecology
Northwestern University Medical School

II. Preclinical Studies
9:30 a.m. Review of Effects of Repeat Courses of Antenatal
Steroids in Animal Models
Alan Jobe, M.D., Ph.D., Professor of Pediatrics
Children’s Hospital Medical Center of Cincinnati

III. Clinical Evidence
10:00 a.m. Multicenter Randomized Controlled Trial on Repeat Courses
Deborah Guinn, M.D., Assistant Professor
Department of Obstetrics and Gynecology
University of Colorado Health Sciences Center

10:15 a.m. Data on Repeat Courses of Antenatal Steroids
From the TRH Trial
Beverly Banks, M.D., Ph.D., Neonatologist
Division of Neonatology
Children’s Hospital of Philadelphia

10:30 a.m. Discussion
11:00 a.m. Long-Term Outcome After Repeat Courses:
French et al. Study
*Noel French, MBChB, FRACP*, Head of Neonatal Followup
King Edward Memorial Hospital, Australia

11:15 a.m. Long-Term Outcome After Repeat Courses:
Esplin et al. Study
*M. Sean Esplin, M.D.*, Instructor
Division of Maternal-Fetal Medicine
Department of Obstetrics and Gynecology
University of Utah Health Sciences Center

11:30 a.m. Discussion

12:00 p.m. Lunch

1:00 p.m. Short-Term Outcome After Repeat Courses
*James R. Scott, M.D.*, Professor
Department of Obstetrics and Gynecology
University of Utah Health Sciences Center

1:20 p.m. Review of Repeat Courses in Patients With Special Circumstances and Populations
*Brian Mercer, M.D.*, Director, Maternal-Fetal Medicine
Department of Obstetrics and Gynecology
MetroHealth Medical Center

1:40 p.m. Review of Design of Ongoing Trials in the United States, the United Kingdom, Australia, and Canada
*Ronald J. Wapner, M.D.*, Director
Division of Maternal-Fetal Medicine
Thomas Jefferson University Hospital

2:00 p.m. Discussion

2:30 p.m. Comments from Organizations

3:00 p.m. Adjournment (Panel Executive Session)
FRIDAY, AUGUST 18, 2000

8:30 a.m.  Presentation of Consensus Statement
           Larry C. Gilstrap III, M.D.
           Emma Sue Hightower Chairman and Professor
           Department of Obstetrics, Gynecology, and
           Reproductive Sciences
           University of Texas-Houston Medical School

8:50 a.m.  Discussion

10:00 a.m. Panel Meets in Executive Session

11:30 a.m. Press Conference

12:30 a.m. Adjournment
PANEL MEMBERS

Panel Chair: Larry C. Gilstrap III, M.D.
Emma Sue Hightower Chairman and Professor
Department of Obstetrics, Gynecology, and Reproductive Sciences
University of Texas-Houston Medical School
Houston, Texas

William H. Clewell, M.D.
Associate Director
Department of Maternal-Fetal Medicine
Good Samaritan Regional Medical Center
Phoenix, Arizona

Mary E. D’Alton, M.D.
Virgil G. Damon Professor of Obstetrics and Gynecology
Director, Division of Maternal-Fetal Medicine
Columbia University
College of Physicians and Surgeons
New York Presbyterian Hospital
New York, New York

Marilyn B. Escobedo, M.D.
Professor, Department of Pediatrics
Division of Neonatology
Medical Director, University Hospital Newborn Intensive Care Unit
University of Texas Health Science Center at San Antonio
San Antonio, Texas

Dwenda K. Gjerdingen, M.D.
Associate Professor
Department of Family Practice and Community Health
University of Minnesota Medical School
St. Paul, Minnesota
Jan Goddard-Finegold, M.D.
Associate Professor of Pediatrics and Pathology
Division of Pediatric Neurology
Baylor College of Medicine and Texas Children’s Hospital
Houston, Texas

Robert L. Goldenberg, M.D.
Charles E. Flowers Professor
Department of Obstetrics and Gynecology
University of Alabama at Birmingham
Birmingham, Alabama

Maureen Hack, M.D.
Director of High Risk Followup Program
Rainbow Babies and Children’s Hospital of
University Hospitals of Cleveland
Case Western Reserve University
Cleveland, Ohio

Thomas N. Hansen, M.D.
Chairman, Department of Pediatrics
Ohio State University
Chief Executive Officer
Children’s Hospital
Columbus, Ohio

Ralph E. Kauffman, M.D.
Marion Merrell Dow/Missouri Chair in Medical Research
Professor of Pediatrics and Pharmacology
University of Missouri–Kansas City
Children’s Mercy Hospital
Kansas City, Missouri

Emmett B. Keeler, Ph.D.
Senior Mathematician
Health Program
The RAND Graduate School
Santa Monica, California
William Oh, M.D.
Sylvia Kay Hassenfeld Professor of Pediatrics
Chairman, Department of Pediatrics
Brown University School of Medicine
Pediatrician-In-Chief
Rhode Island Hospital
Medical Director
Hasbro Children’s Hospital
Providence, Rhode Island

E. Albert Reece, M.D.
Abraham Roth Professor and Chairman
Department of Obstetrics, Gynecology, and Reproductive Sciences
Temple University School of Medicine
Philadelphia, Pennsylvania

Elizabeth J. Susman, Ph.D., R.N.
Jean Phillips Shibley Professor
Department of Biobehavioral Health
Pennsylvania State University
University Park, Pennsylvania

Marlyn G. Vogel, Ed.D.
Licensed Psychologist
Special Services
School District of Hatboro-Horsham
Ambler, Pennsylvania
SPEAKERS

*Bevery Banks, M.D., Ph.D.*
Neonatologist
Division of Neonatology
Children’s Hospital of Philadelphia
Philadelphia, Pennsylvania

*M. Sean Esplin, M.D.*
Instructor
Division of Maternal-Fetal Medicine
Department of Obstetrics and Gynecology
University of Utah Health Sciences Center
Salt Lake City, Utah

*Noel French, MBChB, FRACP*
Head of Neonatal Followup
King Edward Memorial Hospital
Subiaco, Perth, Australia

*Deborah Guinn, M.D.*
Assistant Professor
Department of Obstetrics and Gynecology
University of Colorado Health Sciences Center
Denver, Colorado

*Alan Jobe, M.D., Ph.D.*
Professor of Pediatrics
Children’s Hospital Medical Center of Cincinnati
Cincinnati, Ohio

*Brian Mercer, M.D.*
Director
Maternal-Fetal Medicine
Department of Obstetrics and Gynecology
MetroHealth Medical Center
Cleveland, Ohio
James F. Padbury, M.D.
Professor and Vice Chairman
Department of Pediatrics
Brown University School of Medicine
Pediatrician-in-Chief
Women and Infants Hospital of Rhode Island
Providence, Rhode Island

James R. Scott, M.D.
Professor
Department of Obstetrics and Gynecology
University of Utah Health Sciences Center
Salt Lake City, Utah

John C. Sinclair, M.D.
Professor
Department of Pediatrics
McMaster University Medical Center
Hamilton, Ontario, Canada

Michael Socol, M.D.
Professor, Section of Maternal-Fetal Medicine
Department of Obstetrics and Gynecology
Northwestern University Medical School
Chicago, Illinois

Ronald J. Wapner, M.D.
Director
Division of Maternal-Fetal Medicine
Thomas Jefferson University Hospital
Philadelphia, Pennsylvania

Robert M. Ward, M.D., FAAP, F.C.P.
Professor
Department of Pediatrics
University of Utah School of Medicine
Salt Lake City, Utah
PLANNING COMMITTEE MEMBERS

Planning Committee Chair: Duane Alexander, M.D.
Director
National Institute of Child Health and Human Development
National Institutes of Health
Bethesda, Maryland

John A. Bowersox
Communications Specialist
Office of Medical Applications of Research
Office of the Director
National Institutes of Health
Bethesda, Maryland

Jerry M. Elliott
Program Analysis and Management Officer
Office of Medical Applications of Research
Office of the Director
National Institutes of Health
Bethesda, Maryland

Barnett Kramer, M.D., M.P.H.
Director
Office of Medical Applications of Research
Office of the Director
National Institutes of Health
Bethesda, Maryland
Catherine Spong, M.D.
Project Director
Maternal-Fetal Medicine Units Network
Pregnancy and Perinatology Branch
Center for Research for Mothers and Children
National Institute of Child Health and Human Development
National Institutes of Health
Bethesda, Maryland

Judith M. Whalen, M.P.A.
Associate Director for Science Policy, Analysis, and Communication
National Institute of Child Health and Human Development
National Institutes of Health
Bethesda, Maryland

Linda Wright, M.D.
Special Assistant to the Director
Center for Research for Mothers and Children
National Institute of Child Health and Human Development
National Institutes of Health
Bethesda, Maryland
BIBLIOGRAPHY OF BACKGROUND MATERIALS


