SECRETARY'S ADVISORY COMMITTEE ON INFANT MORTALITY

Meeting Minutes of
July 13–14, 2004

The Hotel Washington
Washington, D.C.

GENERAL SESSION

TUESDAY, JULY 13, 2004

CALL TO ORDER

James W. Collins, Jr., M.D., M.P.H., Chairperson, Secretary's Advisory Committee on Infant Mortality; Associate Professor of Pediatrics, Northwestern University Medical School, Chicago, IL

Welcome and Introductions

Dr. James W. Collins, Jr., welcomed participants to the Secretary's Advisory Committee on Infant Mortality (SACIM) meeting. Because of the large number of new members, the participants were asked to give expanded comments during their self-introductions:

- Dr. Collins is a neonatologist at Children's Memorial Hospital in Chicago and associate director of the hospital's Pediatric Residency Training Program. His research interests are in racial disparities in preterm labor, low birth weight, very low birth weight, and postneonatal mortality. He completed his medical school training at the University of Michigan.

- Dr. Betty K. Tu is from Orange County, California, and is a trained obstetrician-gynecologist and clinical professor in obstetrics and gynecology at the University of Southern California (USC) School of Medicine. She was in private practice for 20 years. After receiving an M.B.A. in 1999, she became involved in system restructuring and reorganization for quality improvement in practice and medical management. She continues her direct patient care service as a volunteer attending physician at USC's Women and Children's Hospital. She also has started a new company that handles health care service content and products, with plans to extend its services in Asia. This is her second term on SACIM.

- A pediatric emergency physician, Dr. Robert E. Sapien is chief of the Division of Pediatric Emergency Medicine at the University of New Mexico. A Health Resources and Services Administration (HRSA) grant recipient, his research interests are asthma and school-based emergency care. His professional endeavors relate to injury prevention and pediatric emergencies.

- Ms. Christina M. Ryan, a new member of SACIM, is the chief executive officer of The Women's Hospital in southern Indiana. She was trained as a pediatric nurse and then became an obstetric nurse. She was involved in one of the first Healthy Start grants in Gary and Hammond, Indiana. She has opened a home for pregnant teenagers and is working on a program called Fit for Life to combat childhood obesity.

- Ms. Renee T. Barnes, another new member of SACIM, is an assistant professor in the School of Nursing at Hampton University. She has been involved in several community-based coalitions, local and regional, ranging from working with infants at

risk to school-age children and adolescents. Her research interest is in continuing education for nurses.

- Dr. Robert E. Hannemann became a member of SACIM in 1998 after serving as president of the American Academy of Pediatrics. He is a SACIM liaison member of the Interagency Coordinating Council on Low Birth Weight and Preterm Birth (LBWCC). He started out as a chemical engineer, was in the armed services, and became a pediatrician. He has worked in general pediatrics for more than 40 years and is a visiting professor of biomedical engineering, chemical engineering, and child psychology at Purdue University. His research interests are in low birth weight and preterm birth.

- Ms. Deborah L. Frazier, another new SACIM member, is the director of the Arkansas Health Services Permit Agency, which is the planning agency for the State of Arkansas. She has been involved as a nurse in public health for a number of years and worked with an early Fetal and Infant Mortality Review (FIMR) project and later with the American College of Obstetricians and Gynecologists (ACOG) to develop FIMR guidelines. She also has worked with a number of other projects funded by the Maternal and Child Health Bureau (MCHB), including Healthy Start. She is interested in the complexity of the factors that contribute to infant mortality and methods to reduce infant mortality nationwide.

- Ms. C. Renee Elmen Hollan is an R.N. with a bachelor of arts in nursing. She does volunteer work in South Dakota related to type 1 diabetes and school nutrition.

- Dr. Bernard Guyer is another new member of SACIM. Trained as a pediatrician, he has been active in the public health field his entire career. He worked on infant mortality in Massachusetts, where the efforts of public and private agencies met with some success in reducing infant mortality. He also chaired the Maryland Commission on Infant Mortality for 5 years.

- Dr. Robyn J. Arrington, Jr., is an obstetrician-gynecologist. He joined Total Health Care, a health maintenance organization (HMO) in Detroit, in the 1980s. He is the medical director of Total Health Care in Michigan and Florida. The Michigan HMO serves a large number of poor people in the greater Detroit area. Dr. Arrington also served in the Army for 28 years and was appointed State Surgeon General of the Michigan Army National Guard.

- Dr. Kevin J. Ryan, a new member of SACIM, is chief of the Women's and Children's Health Section of the North Carolina Department of Health and Human Services. The agency administers an array of programs, including programs in maternal health, family planning, child health, children's special health care needs, the Women, Infants, and Children (WIC) program, early intervention, and immunizations. Dr. Ryan was trained as an obstetrician-gynecologist and has worked in an academic setting, an HMO setting, and private practice. He is interested in population-based issues and has a master's degree in public health.

- Dr. Yvonne Bronner is the director of the Public Health Program at Morgan State University, the only historically black college and university (HBCU) that offers a doctorate in public health. A nutritionist by training, her primary research interest involves breastfeeding, including male role support of breastfeeding and early family health. She is interested in integrating a maternal and child health component into the HBCU public health programs.

- Reverend Dr. Ann Miller is a pediatric chaplain by training, a Baptist minister, a licensed professional counselor, and a marriage and family therapist, with a doctorate in child development. Ministry is her second career; she spent a number of years on the faculty of Southern Methodist University in Dallas as a music therapy professor. She is interested in creative arts therapies and medical ethics.

- Dr. Maxine Hayes is a pediatrician who is new to the committee. She has served in the State of Washington as the maternal and child health director and is currently the State health officer. Having grown up in Mississippi, she is familiar with the issue of infant mortality.

- A nurse-midwife, Dr. Joyce E. Roberts is the director of the Women's Health and Nurse-Midwifery Program in the College of Nursing at Ohio State University. Her career has focused on nurse-midwifery education, practice, and research. She has worked largely in the public sector in Chicago and Denver, pursuing practice issues in the care of women during labor, specifically, helping women in their bearing-down efforts, with an interest in the cardiovascular area and the urogynecologic outcomes of that practice.

- Dr. David Ray Baines, who is new to the committee, is from the Tsimshian Tribe of southeast Alaska. A family physician by training, he trains family doctors in the Alaska Family Practice Residency Program to serve in rural settings. His interests focus on cultural competency and health disparities.

- Dr. Jennifer M. Cernoch is new to the committee. She is the executive director of Family Voices, Inc., a national nonprofit organization of 40,000 families and friends speaking on behalf of children and youth with special health care needs. In operation for the past 12 years, Family Voices has as its primary mission to advocate for child health care services that are family centered and culturally competent. She worked for 16 years with the Texas legislature as a child advocate. Her doctorate is in child development and developmental psychology.

- Dr. Fredric D. Frigoletto, Jr., is an obstetrician-gynecologist, chief of the obstetrics and general gynecology service at the Massachusetts General Hospital in Boston, and professor of obstetrics and gynecology at Harvard Medical School. His research interest is in the areas of preterm birth and evidence-based medicine.

- Dr. Ann M. Koontz is the Associate Director for Perinatal Policy in the Division of Perinatal Systems and Women's Health at MCHB. She is a nurse-midwife, with

clinical experience with the public population of Baltimore with one of the early maternal and infant care projects. She helped to develop a program at Johns Hopkins University that combined preparation in nurse-midwifery with a graduate degree in public health. Since receiving a doctorate in public health, she has worked at MCHB for 23 years.

- Dr. Peter C. van Dyck is the executive secretary of SACIM, Associate Administrator for Maternal and Child Health, and a pediatrician. He was an MCH director and professor of pediatrics at the University of Utah in 1990 when he was asked to be an inaugural member of SACIM.

- Howard Zucker is the Deputy Assistant Secretary for Health at the Department of Health and Human Services (HHS). He is a pediatrician, pediatric cardiologist, pediatric critical care specialist, and pediatric anesthesiologist. He is representing Dr. Cristina Beato, Acting Assistant Secretary for Health in HHS and an ex officio member of SACIM.

- Patricia Daniels is the national director of the WIC program. She is representing Dr. Peter S. Murano, the Deputy Administrator for Special Nutrition Programs at the Food and Nutrition Service in the U.S. Department of Agriculture and an ex officio member of SACIM. As the national WIC program director, Dr. Daniels attends SACIM meetings as an observer so that SACIM's discussions can be given due consideration in the policy development of the WIC program.

A motion was made, seconded, and passed to approve the minutes from the March SACIM meeting. Dr. Collins circulated an article on racial disparities in infant outcome after preterm delivery, looking at a life course conceptual model.

Overview of the Health Resources and Services Administration and Maternal and Child Health Bureau

Peter C. van Dyck, M.D., M.P.H., Associate Administrator for Maternal and Child Health, Health Resources and Services Administration; Executive Secretary, Secretary's Advisory Committee on Infant Mortality

Dr. van Dyck presented background information about MCHB and then described a number of MCHB programs.

Background Information About MCHB

The MCHB law is often called Title V. It authorizes appropriations to States to improve the health of mothers and children; provide mothers and children with access to quality maternal and child health services; reduce infant mortality, preventable diseases, and handicapping conditions among children and increase the number of immunized children; increase the number of low-income children receiving health assessments and diagnosis and treatment services; promote health by providing prenatal, delivery, and postpartum care; promote the health of children by providing preventive and primary care services;

provide rehabilitation services for some blind and disabled individuals younger than age 16; and provide and promote family-centered, community-based, coordinated care for children with special health care needs and facilitate community-based systems of services for such children and their families.

Four national goals are set forth in MCHB's strategic plan:

1. To provide national leadership for maternal and child health by creating a shared vision and goals for maternal and child health, informing the public about maternal and child health needs and issues, modeling new approaches to strengthen maternal and child health, forging strong collaborative partnerships, and fostering a respectful environment that supports creativity, action, and accountability for maternal and child health issues.

2. To eliminate health disparities in health status outcomes through the removal of economic, social, and cultural barriers to receiving comprehensive timely and appropriate health care.

3. To ensure the highest quality of care through the development of practice guidance, data monitoring, and evaluation tools; the utilization of evidence-based research; and the availability of a well-trained, culturally diverse workforce.

4. To facilitate access to care through the development and improvement of the maternal and child health infrastructure and systems of care to enhance the provision of the necessary coordinated, quality health care.

MCHB is responsible for about $4 billion of maternal and child health service delivery and system building across the United States. Three-quarters of $1 billion is in the MCHB block grant, which includes Special Projects of Regional and National Significance (SPRANS) grants. MCHB operates a number of other programs that are not part of Title V, including Healthy Start, newborn hearing screening, emergency medical services for children, poison control centers, and abstinence education programs.

The MCHB pyramid helps to describe the panoply of programs, including, from top to bottom, direct health care services (basic health services and specialty services), enabling services (transportation, translation, outreach, case management), population-based services (immunization, newborn screening, lead screening, sudden infant death counseling, injury prevention, nutrition counseling), and infrastructure-building services (needs assessment, evaluation, planning, policy, quality assurance, standards development, monitoring). MCHB provides all four levels of services, while concentrating on the lower levels and leaving the direct health care services to the other agencies and the private sector. Community Health Centers, the Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) program, and the State Children's Health Insurance Program (SCHIP) provide services primarily at the top part of the pyramid.

MCHB Programs

Dr. van Dyck reviewed a number of programs within MCHB:

- *Early Childhood*. Research on brain development during early childhood has shown that during this period, young children attain developmental milestones that include emotional regulation and attachment, language development, and motor skills. Environmental stressors and other negative risk factors can seriously affect the appropriate development of these milestones. To be healthy, children need nurturing relationships, safe environments, developmentally appropriate experiences, quality support services, health insurance coverage, and a medical home. Critical components in early childhood development systems of care include access to medical homes, addressing the needs of children at risk for the development of mental health problems, early care and education services, parent education services, and family support services. Gaps remain in access to medical homes and in mental health and social-emotional development. Two years ago, MCHB instituted a major program to support States to plan, develop, and ultimately implement collaborations and partnerships to support families and communities in their development of children who are healthy and ready to learn at school entry. The anticipated outcomes of the program are strong State maternal and child health leadership and participation in early childhood systems development, a completed needs assessment for early childhood intervention, a completed plan for action based on the needs assessment, and development of strategic partnerships among critical State stakeholders. The grant cycle includes 2-year planning grants at $100,000, with an optional third year at $100,000. States can apply for third-year implementation grants up to $140,000 and third-year special projects grants up to $180,000. A total of 52 States and territories now have programs developing a system of care for early childhood.

- *Bullying.* Dr. van Dyck defined bullying; described its overall frequency, its prevalence in and away from school, and the forms it takes; and emphasized its seriousness by pointing out its prevalence and consequences. The target audience of MCHB's Youth Campaign on Bullying Prevention includes "tweens," teens, parents, schools, and communities.

- *Bright Futures.* The Bright Futures program developed a set of expert guidelines and takes a practical developmental approach to providing health supervision. The program's goals are to increase family knowledge, skills, and participation in health promotion and disease prevention activities and to enhance health professionals' knowledge, skills, and practice of developmentally appropriate health care in the context of family and community. Bright Futures is a partnership with many organizations and professions. Implemented in 1995, the program is incorporated into EPSDT guidelines, SCHIP, Head Start, and WIC programs. It offers materials on oral health, nutrition, mental health, and so on, all of which can be downloaded from the Web or ordered.

- *Newborn Screening.* Newborn metabolic screening is a major public, State, and family concern. A new committee on newborn screening and genetic diseases for infants and children was formed by the Secretary of HHS and is staffed by MCHB. The Bureau is responsible for newborn screening in partnership with the States, which are responsible for facilitation. MCHB's vision for newborn screening involves quality, partnership, and equity for families. The National Newborn Screening and Genetics Resource Center (http://genes-r-u.uthscsa.edu) serves as a focal point for national newborn screening and genetics activities and provides related resources to benefit consumers, health professionals, the public health community, and government officials. The newborn screening program goals are (1) to support a framework for effective partnerships between parents and professionals and among professions, agencies, and officials at the Federal, State, and community levels and between the public and private sector, (2) to strengthen existing public health infrastructure and facilitate integration with the health care delivery system, and (3) to provide ongoing leadership and support for the development of newborn screening standards, guidelines, and policies because State screening can cover anywhere from 1 to 30 or more conditions. An expert panel was convened to review the available information on newborn screening based on the accumulation and analysis of the best scientific evidence. The panel's report will (1) address model policies and procedures and minimum standards for State newborn screening programs, (2) create a model decision matrix for changing newborn screening panels, and (3) develop a uniform panel of conditions for screening.

- *National Survey of Children With Special Health Care Needs (CSHCN).* MCHB, in partnership with the National Center for Health Statistics (NCHS), created the National Survey of CSHCN 3 years ago. The survey will be repeated every 4 years to determine prevalence estimates of the number of children with special health care needs in each State. About 13 percent of all children nationwide have special health care needs. The needs vary by age and by type of special need. The survey also reports the number of reported unmet health service needs by income and the impact of a child's condition on the parent's employment. There is a significant effect on the family related to the child's condition and the poverty level of the family; poor people have much more difficulty maintaining employment, depending on the functional ability of their special needs child.

- *Children's Survey.* The National Survey of Children's Health was just finished, and data are being analyzed. The purpose of the survey was to produce reliable State and national data for *Healthy People 2010,* Title V needs assessment, and Title V program planning and assessment and to provide a new data resource for researchers, advocacy groups, and others. The survey addresses eight areas: (1) demographics, (2) physical and mental health status, (3) health insurance, (4) health care utilization and access, (5) medical home, (6) family functioning, (7) parents' health, and (8) neighborhood characteristics.

- *Obesity.* The increase in children's obesity began in the period from 1976 to 1980. The data show a significant increase in obesity in black and Hispanic children

between 1999 and 2000 compared with the period from 1988 to 1994. Almost 30 percent of children are obese.

Dr. van Dyck ended his presentation by listing the following Web sites:

- mchdata.net
- www.stopbullyingnow.hrsa.gov
- cshcndata.org
- brightfutures.aap.org
- www.cdc.gov/nchs/slaits.htm
- mchb.hrsa.gov

Dr. Zucker reported that Secretary Thompson will announce grants of $4.25 million for decreasing infant mortality in Illinois, South Carolina, Michigan, and Mississippi, as well as two tribal areas in the United States, addressing in particular the issues of increased infant mortality among the African American population, Native Americans, and Alaska Natives.

Discussion

Dr. van Dyck's presentation prompted the following questions and concerns related to obesity, medical home, and bioterrorism.

- Dr. Hayes asked Dr. van Dyck to comment on MCHB's relationships with other agencies within HHS. Dr. van Dyck referred to the operational divisions within HHS and mentioned MCHB's relationships with professional organizations, States, and counties.

Obesity

- Dr. Frigoletto referred to the interesting association between obesity and fetal neonatal mortality. He asked about speculation regarding the confounding variables. Dr. van Dyck suggested inviting speakers to elucidate the information about obesity and infant mortality. Dr. Collins characterized the information as population-based observations and stated the need to control for confounders. More indepth work is needed on the topic.

- Dr. Hayes reported on an international meeting at the New York Society of Medicine on the pandemic of obesity. Women are leading the pandemic; therefore, there are implications for children and for infant mortality. Interventions should be increased, and the focus should be on the health of women.

- Dr. Hannemann stressed the importance of transmitting information about obesity to the general public and to food suppliers. SACIM should work to accelerate the transmission of this type of alarming information. Dr. van Dyck pointed out that

Secretary Thompson supports the issue of obesity prevention and improving the quality of food nationwide.

Medical Home

- Dr. Roberts asked about the critical components in the early childhood systems development, namely, the access to medical home. She pointed out that parents or consumers do not understand the meaning of "medical home" and that providers do not view themselves as the coordinators of a range of services. What does the term mean, how important is it, and how should it be implemented? Dr. van Dyck stated that the concept of medical home has been developing over a period of about 20 years. Medical home is a place where a primary care provider facilitates the provision of care for a family. MCHB has given grants to States and communities to develop systems of care that include medical homes.

- Dr. Hayes stated that chapters of the American Academy of Pediatrics have worked with the maternal and child health programs in the States on the concept of medical home. Dr. Roberts asked for clarification about where and how the work has proceeded. Dr. Cernoch stated that for families with children with special health care needs, the concept of medical home is very important and has been very successful in certain communities. She will share information about medical home with SACIM.

- Dr. Hannemann reported that a major problem concerns adequate funding for the comprehensive care that medical home entails. Private insurance and the Medicaid program do not always provide the needed funding for this important service.

Bioterrorism

- Dr. Guyer asked if emergency medical services for children (EMSC) programs at the State level are integrated with the Centers for Disease Control and Prevention (CDC) in terms of planning for bioterrorism events. Also, in all-hazard situations, are there services specifically targeted to pregnant women? Dr. van Dyck referred to funding granted to States and hospitals for developing plans for bioterrorism. A requirement is built into the guidance that States should consider pregnant women, children in daycare, and children with special health care needs. It has been a struggle to get States to recognize these populations. At the Federal level, there is an attempt to integrate the work of EMSC and other trauma programs into the bioterrorism program. The link to CDC is at the State level. The overall State plans are reviewed jointly by both CDC and HRSA at the same time.

- Dr. Hayes commented that States have integrated EMS much better than special populations. The language in the guidance is important because "what gets measured gets done." Dr. Cernoch asked about the bioterrorism dollars in the MCHB budget. Dr. van Dyck explained that those dollars were once housed in MCHB but have been transferred to special programs.

- **ETHICS RULES FOR SPECIAL GOVERNMENT EMPLOYEES ON ADVISORY COMMITTEES**

Jennifer L. Jordan, Ethics and Personnel Security Specialist, Health Resources and Services Administration

Ms. Jennifer L. Jordan referred to a packet of information titled "Ethics Rules for Advisory Committee Members and Other Individuals Appointed as Special Government Employees (**SGEs)." Ms. Jordan defined "SGE"; described the financial disclosure** reporting requirements, including work and holdings, liabilities, outside activities, assets and income to be received, and gifts; and explained the criminal conflict-of-interest statutes, including standards of ethical conduct, employment by or gifts from foreign governments, lobbying activities, and political activities. Ms. Jordan announced that waivers are being prepared for those SACIM members who have prohibited interests that conflict with the advisory committee. Members can contact Ms. Jordan with questions at jjordan@hrsa.gov. A 20-minute video on the topic was shown.

OVERVIEW OF SACIM

James W. Collins, Jr., M.D., M.P.H., Chair, Secretary's Advisory Committee on Infant Mortality; Associate Professor of Pediatrics, Northwestern University Medical School, Chicago, IL

Peter C. van Dyck, M.D., M.P.H., Associate Administrator for Maternal and Child *Health, Health Resources and Services Administration; Executive Secretary, Secretary's Advisory Committee on Infant Mortality*

Dr. Collins presented an overview of infant mortality and how it relates to SACIM's mission. SACIM's primary goal is to provide advice to the HHS Secretary on infant mortality. The committee was formed in 1991. At that time, two-thirds of infant deaths occurred in the first month of life. Although neonatal mortality rates have declined dramatically, the incidence of preterm birth, low birth weight, and very low birth weight has not improved since 1991. Furthermore, racial disparities continue to persist. African Americans have about a twofold greater rate of low birth weight, a twofold greater rate of intrauterine growth restriction (IUGR), a twofold greater rate of low birth weight, and a threefold greater risk of very low birth weight. Prematurity, low birth weight, and IUGR are the leading causes of neonatal mortality. About one-third of infant deaths occur in the postneonatal period. A small percentage of these deaths are delayed neonatal deaths. However, the vast majority are from preventable causes such as sudden infant death syndrome (SIDS), injuries, and infections. Although the genetics and the biology of sleep position are unknown, it is clear from population-based studies that putting babies to sleep on their backs has a tremendous benefit in reducing the risk of SIDS. Despite this information, African Americans and Native Americans have a two- to threefold greater risk of SIDS than their white counterparts.

In addition to providing information to the Secretary regarding racial and ethnic group disparities in infant mortality, SACIM is charged with providing advice about coordinating Federal, State, and local agencies and private foundations that are interested

in reducing infant mortality rates in the United States. SACIM is managed by HRSA and meets three times a year.

Dr. van Dyck continued the orientation of new members by explaining the organization of the 12 operational divisions within HHS. SACIM is part of HRSA, which comprises five operational bureaus, one of which is MCHB. MCHB encompasses five operational divisions.

Dr. van Dyck highlighted some aspects of SACIM's charter, including its purpose, function, structure, meetings, and reports. SACIM communicates directly with the Secretary, and the Secretary writes a formal response to SACIM's communications. The executive secretary of SACIM oversees the official business of the committee. Dr. Koontz provides staff to the committee, arranges staff work for the committee, facilitates the agenda, and supplies special information to the committee. Ms. Michelle Loh is a staff assistant.

SACIM has produced three reports: (1) recommendations on the future of the Healthy Start initiative, (2) a low birth weight report and recommendations, and (3) an early discharge report.

Dr. van Dyck described the special roles of some SACIM members. Dr. Frigoletto is one of the liaisons to the LBWCC. As a past president of ACOG, Dr. Frigoletto also carries many of SACIM's issues back to that group. Dr. Hannemann served as co-chair of the low birth weight subcommittee and is a liaison to the LBWCC. Dr. Hannemann pointed out that a number of programs across 12 different agencies are involved in the issue of low birth weight, preterm birth, and SIDS. The problem has been in coordinating these particular efforts and in prioritizing the research agenda. He stated his belief that these issues might be looked at from a fresh perspective. Dr. Collins is the liaison with the new committee on heritable disorders and genetic diseases in infants and children, which had its inaugural meeting in June. Dr. Mary Lou de Leon Siantz is the liaison to the Healthy Start evaluation activity. Various ex officio members attend SACIM meetings.

Dr. van Dyck stated that the meetings usually include a legislative update, program updates, approval of the minutes, and substantial presentations related to issues determined by the interests of the committee. After reviewing the agenda, he urged the participants to think about future topics for discussion related to infant mortality and low birth weight.

Discussion

The presentation by Drs. Collins and van Dyck prompted the following questions and comments:

- Dr. Hayes asked when the committee will have an opportunity to review its assumptions about infant mortality, especially regarding evidence-based medicine and the understanding of causality. If the segments of the infant mortality questions

are broken down, it can be seen that the context of the components often goes beyond science. Geographical variations exist in infant mortality, which could necessitate a change in the assumptions underlying the approaches taken. In addition, she asked how the committee can ensure that its recommendations are implemented. The question is whether assumptions and interventions should be changed. Dr. Collins mentioned that the next day's discussions might include regional differences, different intervention strategies, recommendations that are not followed up on, and so on.

- Dr. Guyer asked about the LBWCC, namely, what its agenda is, especially regarding field implementation activities. How is the LBWCC working with the implementers to accomplish a common agenda? Do any other agencies have advisory committees related to infant mortality? If so, how are the implementation efforts coordinated? Dr. van Dyck remarked that the LBWCC questions will be answered during the next day's presentations. He stated that he knows of no other committee on infant mortality advising another agency, although some advisory committees might overlap in some ways.

- Dr. Miller emphasized that the creation of the LBWCC was an immediate response of the Secretary to SACIM's suggestion to form a committee to study low birth weight and preterm birth. Dr. Hannemann clarified that the original subcommittee on low birth weight compiled a list of items related to low birth weight. The major recommendation to the Secretary was to appoint an interagency coordinating council to inventory the work being done in the itemized areas. The next task will be to review the LBWCC report and prioritize the research that remains to be done. Dr. Hannemann explained that the SIDS issue was added later as was a special request for an emphasis on disparities.

- Dr. Hayes raised a question related to Medicaid. Some of the most at-risk individuals are recipients of Medicaid. The infant mortality rate rose in the 1980s. The States became the laboratories for improving the way infant mortality and prenatal care were viewed. The nonmedical components made the difference. Now the work in the States is slipping because of budget problems. Perhaps the evidence of that slippage can be seen in the rising infant mortality rate. Therefore, SACIM must pay attention to the policies that get translated at the State level. Dr. van Dyck responded that SACIM may make recommendations that affect Medicaid and the Secretary will determine how the recommendations are implemented. Dr. Hannemann pointed out that SACIM discussed the potential impact of block-granting Medicaid. Dr. van Dyck stated that SACIM usually has two presentations a year about States' budgets. Any issue can come before the committee.

U.S. TRENDS IN BIRTHS AND INFANT DEATHS

Joyce A. Martin, M.P.H., Lead Statistician, Reproductive Statistics Branch, National Center for Health Statistics, Centers for Disease Control and Prevention
Kenneth D. Kochanek, M.A., Statistician, Mortality Statistics Branch, National Center for Health Statistics, Centers for Disease Control and Prevention

Ms. Joyce A. Martin stated that the information necessary to definitively explain the unexpected rise in the infant mortality rate in 2002 will be available soon. This presentation from NCHS reviewed the 2002 increase within the broader context of recent trends in U.S. birth outcomes. The presentation covered outcome measures (preterm birth and low birth weight) and perinatal mortality.

Ms. Martin explained that the presented data are based on vital statistics, that is, they are derived from certificates of live birth, death certificates, and reports of fetal death. The registration of vital events is the responsibility of the States and independent reporting areas. NCHS is mandated by law to disseminate national vital statistics data. The center contracts with the States for the data and cooperates with them to set standards. The recently revised U.S. standard birth and death certificates are a result of this collaboration.

NCHS also works with the States to develop definitions for vital events. The definitions of live birth, fetal death, and infant death are based on those promulgated by the World Health Organization (WHO) and are generally adopted by all reporting areas. The definitions are as follows:

- A live birth is defined as a product of conception that is expelled or extracted from the mother and shows any evidence of life that is not transient or fleeting. Registration of live births in the United States is considered to be essentially 100 percent complete.

- A fetal death is defined as death that occurs *in utero* and is not an induced termination of pregnancy, in which the fetus does not show any evidence of life. The Model Vital Statistics Act recommends reporting fetal deaths at 350 grams or 20 or more weeks of gestation. Although all States officially report deaths of at least 20 weeks or more, fetal deaths, especially those occurring between 20 and 27 weeks, are believed to be somewhat underreported.

- Infant death is defined as the death of a live-born infant within the first year of life.

Review of U.S. Births and Trends in Preterm Birth and Low Birth Weight

About 4 million babies are born in the United States each year, more than half to non-Hispanic white mothers, 22 percent to Hispanic mothers, 14 percent to non-Hispanic black mothers, 5 percent to Asian or Pacific Islander mothers, and about 1 percent to American Indian mothers. These levels are based on the self-reported race of the mother.

A large shift in the U.S. distribution over the past decade has been the increase in Hispanic births. In 1990, only 15 percent of all babies were born to Hispanic mothers.

Eighty-four percent of women who gave birth in 2002 began prenatal care in their first trimester of pregnancy. Levels of prenatal care utilization changed little during the 1980s but have improved fairly steadily in more recent years, especially among groups that historically have lower levels of adequate care. Although large disparities persist among racial and ethnic groups, timely care has risen by more than 20 percent among non-Hispanic black, Hispanic, and American Indian women since 1990. Substantial declines in late and no prenatal care also have been reported. This improvement has been linked to the expansion of Medicaid for pregnant women, which began in the late 1980s.

Unfortunately, two key predictors of infant health have not improved along with prenatal care. Preterm birth and low birth weight rates have been climbing slowly for more than a decade. Preterm birth is defined as fewer than 37 weeks of gestation, and low birth weight as less than 2,500 grams. Between 1990 and 2002, the preterm birth rate increased 14 percent and the low birth weight rate increased 11 percent, to the highest levels reported in more than two decades.

Data for preterm birth rates by race show that preterm birth rates for infants born to black mothers historically are substantially higher than those for other groups. For 2002, the preterm birth rate for black infants was nearly 50 percent higher than that for infants of all races. More troubling, the rate of very preterm birth was twice as high. Since about 1990, preterm birth rates have been essentially flat among black births, up slightly for Hispanics, and have risen more than 25 percent among white births.

Similar large differences in the risk of low and very low birth weight also are seen by race. Infants born with very low birth weight (less than 1,500 grams) are about 100 times more likely to die in the first year of life than heavier infants. Trends in low birth weight by race over the past decade are similar to those for preterm births.

The increase in preterm birth and low birth weight rates is partially fueled by the rise in multiple births, which now comprise more than 3 percent of all births each year. The birth rate for twins has climbed 65 percent since 1980. A 3-percent jump was reported for 2002. The rise in the triplet and higher order multiple birth rates is even more remarkable. This rate has soared 400 percent since 1980. The birth rate for triplets appears to have leveled off over the past few years, likely the result of changes in assisted reproductive therapy (ART).

The dramatic growth in the multiple birth rate has had an important impact on overall preterm birth and low birth weight rates because multiples are so much more likely to be born too early and too small. More than half of all twins and nearly all triplets are born preterm and/or low birth weight. Of even greater concern, more than 10 percent of twins and 35 percent of triplets are born with very low birth weight or very preterm.

Infertility therapies are strongly associated with a rise in multiple births. Fertility drugs and ART, such as *in vitro* fertilization, are estimated to account for about one-third of all twins and more than 80 percent of all triplets born in 2001. However, these therapies also may affect outcome measures for singletons. Although the risk of multiples is greatly elevated with ART, most ART births are singletons, and growing evidence indicates that ART-conceived singletons are at elevated risk of poor perinatal outcome compared with infants conceived spontaneously. ART births, excluding fertility drugs for which reliable data are not available, accounted for about 1 percent of all births in 2001 and 0.6 percent of all singletons.

Although much of the rise in preterm birth and low birth weight rates can be attributed to the influence of plural births, rates also have been creeping up among singletons. The low birth weight rate for singletons rose 4 percent between 1990 and 2002, and the preterm birth rate for singletons rose 8 percent over that period. However, all of the increase is among moderately preterm births. The rate of very preterm births among singletons actually declined very slightly between 1990 and 2002.

Another recent phenomenon that may be driving preterm birth and low birth weight rates is changes in the management of labor and delivery. Induction of labor among preterm births nearly doubled between 1990 and 2000. However, levels appear to have stabilized over the past couple of years. The rate of preterm cesarean delivery also has been on the rise and shows no sign of abating; preterm cesarean delivery went up more than 30 percent between 1990 and 2002.

Data regarding early (20 to 27 weeks of gestation) and late (28 or more weeks of gestation) fetal mortality rates for 1990 to 2002 show that the early fetal mortality rate has increased slightly since 1990. This lack of improvement might in part be attributed to improved reporting of fetal deaths at these early gestational ages. In contrast, the late fetal mortality rate has declined steadily over the past decade. More aggressive management of labor and delivery may play a role in this improvement, as well as other factors, such as more effective prevention of perinatal infections and treatment of maternal medical conditions.

Recent Trends in Perinatal Mortality

Mr. Kenneth D. Kochanek stated that the infant mortality rate in the United States, as tracked in vital statistics, has shown a steady, often rapid, decline. Between 1940 and 2001, the U.S. infant mortality rate dropped 86 percent, from 47 deaths for every 1,000 live births to fewer than 7 deaths. A previous interruption in the long downward trend occurred more than 40 years ago, when small but significant increases were reported for the years 1957 and 1958.

Infant mortality rates vary by race and Hispanic origin. The rate for non-Hispanic whites in 2001 was 5.7 infant deaths per 1,000 live births. The lowest rate was for Asian or Pacific Islanders at 4.7 per 1,000 live births, and the highest rate was for non-Hispanic blacks at 13.5 per 1,000 live births. For all groups except American Indians, most infant

deaths occur within the first month of life, the neonatal period. The postneonatal period includes deaths to infants from 1 month to a year.

The five leading causes of infant death accounted for 53 percent of all infant deaths in the United States in 2001:

- Congenital malformations, deformations, and chromosomal abnormalities comprised 20 percent of all infant deaths.

- Disorders related to short gestation and low birth weight accounted for 16 percent of all infant deaths.

- SIDS accounted for 8 percent of all infant deaths.

- Maternal complications of pregnancy accounted for 5 percent of all infant deaths.

- Respiratory distress of the newborn accounted for 4 percent of all infant deaths.

Forty-seven percent of infant deaths were attributable to other causes.

The leading cause of infant death for whites is congenital anomalies, accounting for 24 percent of all white infant deaths, whereas the leading cause of infant death for blacks is preterm birth or low birth weight, accounting for 22 percent of all black infant deaths. The distribution of the other leading causes of infant death between whites and blacks is similar. Despite the rise in the proportion of higher risk infants, overall infant mortality has continued to decline as the result of improvements in survival for very small infants.

The decline in infant mortality slowed somewhat but continued through the recent decade until preliminary data for 2002 indicated a 3-percent statistically significant increase in the infant mortality rate, from 6.8 to 7.0 infant deaths per 1,000 live births. According to the 2002 preliminary data, the infant mortality rate for both black and white infants increased. The increase was statistically significant for white infants but not for black infants.

Infant deaths that occur soon after birth tend to be from pregnancy-related causes, but deaths occurring later are more likely to be from external causes, such as accidents, or from SIDS. The increase in the infant mortality rate in 2002 appears to be among neonatal deaths during the first month of life, which were up 4 percent from 2001 to 2002, and particularly among early neonatal deaths, within the first week of life. The postneonatal rate was unchanged between the 2 years.

The leading causes of infant death appear to account for most of the increase in the infant mortality rate in 2002. Congenital anomalies, preterm birth, low birth weight, and maternal complications all increased for 2002. All of these causes are considered pregnancy related, that is, resulting from problems occurring before birth.

Final, unedited 2002 fetal death data indicate that the late fetal mortality rate declined 3 percent between 2001 and 2002, which was slightly greater than the average decline for recent years. The decline in fetal deaths did not completely offset the increase in neonatal deaths. However, the fairly substantial decline in late fetal mortality, combined with the increase in early neonatal deaths, resulted in a stable perinatal mortality rate for 2002. Therefore, the overall risk of death during the perinatal period did not worsen for 2002.

In February, NCHS released the preliminary report for deaths for 2002 and the *Supplemental Analyses of Recent Trends in Infant Mortality*. The supplemental analyses document summarized the complex issues concerning the rise in infant mortality for 2000. The next challenge for NCHS will be to definitively explain the rise in the infant mortality rate in 2002 using the 2002 linked birth and infant death data set. An examination of the data will enable investigators to determine whether the increase is related to factors that develop before birth (the rise in plural births) or changes in risk of death after birth (changes in obstetric and neonatal care). The data set also can provide crucial explanatory information on maternal risk factors and infant characteristics.

NCHS is working with its State partners to reengineer the vital statistics systems. The primary objective is to improve the timeliness, quality, and sustainability of the decentralized vital statistics system by adopting technologically sophisticated yet cost-effective model information technology systems based on nationally developed standards and models. The new electronic systems are designed to vastly improve data timeliness and quality. As a result, vital information will be provided more quickly and effectively to decisionmakers. For example, the new systems will enable a more immediate and much more thorough analysis of any changes in perinatal mortality because linked birth and infant death data will be available simultaneously. In addition, data items will be improved to facilitate direct estimates of the impact of infertility therapies. Other risk factors associated with prematurity and low birth weight, such as cigarette smoking, the use of fertility therapies, maternal infections, and congenital anomalies, will be reported and measured with greater precision.

Links to birth data, mortality data, or the linked birth and infant death file data can be accessed at www.cdc.gov/nchs/nvss.htm.

Discussion

The NCHS presentation prompted the following comments and questions:

- Dr. Hayes remarked on the usefulness of the presentation, especially in providing specificity about causality. The presentation raised questions about policies and issues concerning pregnancy; congenital malformations, deformations, and chromosomal abnormalities as the leading cause of infant mortality; and the environmental health side of the issue. Ms. Martin responded that vital statistics are not a good source for that type of information; however, vital statistics cover the

entire population, make geographic details possible, and facilitate the isolation of certain areas.

- As a point of clarity, Dr. Collins added that linking geographic data to vital statistics is needed. He also pointed out that because the percentage of deaths due to congenital anomalies is higher does not mean that the death rate for congenital anomalies is higher. As the percentage of deaths due to other causes declines, the percentage of deaths due to congenital anomalies rises. The issue of causality is questionable. Mr. Kochanek added that congenital anomalies have been the leading cause of death overall in infant mortality for quite a long time; there is no real pattern of any sustained increase or decrease over the past 10 to 15 years.

- Dr. Tu asked about the cutoff points for very low birth weight and moderately low birth weight. She also asked whether the low birth weights were appropriate for gestational age. Ms. Martin replied that very low birth weight is defined as less than 1,500 grams and moderately low birth weight is defined as between 1,500 and 2,499 grams. These measures are based on birth weight alone, not gestational age.

- Dr. Frigoletto asked whether NCHS will be able to determine whether the "flip" between the decrease in fetal death rate and the increase in neonatal death rate is due to a more aggressive approach to dealing with infants who otherwise would not have survived *in utero.* Does early extraction based on prenatal diagnosis lead to early and aggressive interventions that may not change the outcomes but merely redistribute them in terms of where the death occurred? Ms. Martin responded that NCHS will not be able to make any definitive statements about the point raised; however, an analysis might suggest a relationship.

- Dr. Cernoch asked whether any Federal or State laws require the reporting of data on early fetal mortality rates compared with late fetal mortality rates. Ms. Martin explained that the system is purely cooperative. All States report fetal deaths to NCHS at 20 weeks or older. Some States report all periods. The quality of reporting varies, but it is thought that the reporting between 20 and 27 weeks is reasonably complete and that it has improved somewhat over the past decade. Ms. Martin noted that she does not attribute the lack of change in the rate to the fact that the reporting has improved.

- Dr. Guyer pointed out that for the past 20 years, complacency led to the expectation that infant mortality would decline every year. It is intolerable that increases or decreases in infant mortality are not known for 2 years after the fact. SACIM should seize the opportunity to use new methods for geographic analysis, rapid handling of data, interpretation of data on very small samples, and decisionmaking about quality assurance. The vital statistics model is useful for national records but not for policymaking. Statistical techniques can turn data into policy-relevant information that can be used for intervention. Dr. Guyer asked whether SACIM can influence the reengineering project to develop a system that would create relevant information to interpret changes in infant mortality rates. Dr. Hayes pointed out that the issue is at

the policy level in the States. Automating the State systems will result in earlier information that might enable policies to be redirected in a timely manner.

- Dr. Hayes asked about the status of fetal mortality reviews in States. Ms. Martin responded that NCHS has been working on reengineering the vital statistics electronic systems and currently has a model prototype system that will be fielded in Georgia in 2005. Other States can then copy this prototype to reengineer and revise their systems. The reengineered systems will result in a surveillance system in which events are reported within 48 hours. Births and infant deaths are automatically linked in the prototype. Because data are edited at the source, their quality is improved dramatically. The problem is that funds are lacking to implement the system nationally. Concerning the capturing of data on fetal deaths that occur before 20 weeks of gestation, Ms. Martin reiterated that NCHS cannot mandate reporting of vital statistics. She would prefer to see improvement in the quality of data at 20 weeks and above instead of in the quantity of reported data.

- Dr. Miller stated that from her perspective the lag in information means "500 additional funerals, 500 additional grieving families, and the loss of the gift of 500 additional lives that could have benefited our community and our society." Waiting longer than is necessary to get the information is unthinkable. She compared the budgetary costs of fetal death reporting with the reporting for organ procurement, which is federally mandated and tied to Medicaid and Medicare funding and which relies on the use of telephones instead of extremely sophisticated computer equipment. Perhaps SACIM could recommend that some rudimentary data on infant mortality be available to MCHB.

- Dr. Bronner pointed out the different implications of preterm birth and low birth weight. She asked whether an analysis can be done combining these two outcomes. Ms. Martin stated that the increase in infant mortality occurred among IUGR infants defined as preterm and low birth weight. She remarked that she could provide SACIM with statistics on small for gestational age (SGA) infants.

- Dr. Guyer explained two approaches to the problem of obtaining new resources and better compliance: one is to state what could be done if the resources were available and the other is to release the information and point out how valuable it is. He suggested releasing the information from the prototype system in Georgia to show, for example, what happened to infant mortality in the first 3 months of 2004. The approach would demonstrate the benefits that are derived from upgrading the systems, from strengthening the knowledge that comes from the systems, and from turning the knowledge into action that Federal and State officials can work with. He added that reengineering the vital statistics system is different from the incremental improvements that have taken place over many years.

- Dr. Hayes stated that a precedent for what Dr. Guyer described is the sharing of what can be done with Pregnancy Risk Assessment Monitoring System (PRAMS) data; for

example, the reframing of the issue of unintended pregnancy based on PRAMS data can result in a State legislature allocating more money for family planning services.

- Dr. Bronner asked whether reports link infant data directly to maternal data, such as weight gain. Ms. Martin replied that the infant death record is linked with the birth certificate, which includes a wealth of information about the mother.

- Ms. Frazier pointed out the importance of making a recommendation that all the States be required to report all the information in the same way. Data can be pulled together from bordering States, but it is only provisional data until all the States cooperate. Ms. Martin stated that NCHS works with the States on how to report vital statistics but more training is needed.

- When Dr. Frigoletto asked whether the observation of increased infant mortality is a definite finding or whether it might be overturned after further analysis, Ms. Martin responded that the increase in infant mortality is a hard fact.

- Dr. Roberts referred to the presentation information that identified induction of labor and cesarean section as associated with higher rates of infant mortality and preterm birth. She asked whether a method exists to determine whether those inductions and cesarean sections were indicated or elective. Ms. Martin responded that with the limited data on the certificate, that determination can be made up to a point; however, some reasons for induction of labor and cesareans are not in the certificate data, which can lead to problems. Dr. Roberts asked whether the reporting requirements could be made more stringent so that indicators could be identified and those mothers considering elective procedures could be informed of gestational age. She described her impression that elective procedures are becoming rather casually undertaken without evidence of gestational age. If that is happening and contributing to the higher rates, then health policy should discourage elective procedures when dating techniques are less than optimal. Ms. Martin stated that the new systems are designed for easy modification to pick up new information, although it will be a few years before this capability is realized. Dr. Roberts reiterated that the available data should be used to determine whether the policy about elective induction merits some additional information about the appropriateness of elective versus indicated procedures.

- Dr. Frigoletto stated that the increase in infant mortality occurred in the middle group where inductions are not elective. Ms. Martin stated that low birth weight and infant mortality cannot be connected without linked birth certificate and infant death data. The causes of death that increased were among the smaller low birth weight infants. In a couple of months, making those connections will be possible. What is known is that for 2002, low birth weight levels increased, preterm levels increased, and multiple births increased. These facts may or may not explain the rise in infant mortality.

- Dr. Tu stated that all cesarean sections should be indicated. She pointed out that the increase in low birth weight rates may be the result of confidence in the abilities of neonatologists to salvage extremely low birth weight infants. Low birth weight is not to be equated with low gestational age. Dr. Roberts referred to spokespeople who advocate elective inductions and cesarean sections. To what extent are those procedures contributing to outcomes that might be preventable? Dr. Tu referred to discussions about elective cesarean section by maternal request and stated that obstetricians have ethical standards to uphold when such requests are made.

- Dr. Hannemann mentioned the speculation that an elective cesarean section rate of 50 percent might occur in the near future. Dr. Frigoletto referred to a growing acceptance in the marketplace and on the part of patients and providers that a woman has the right to elect a cesarean section after she has been appropriately informed about the risks and benefits of such a procedure compared with a vaginal delivery. A growing body of "soft evidence" points to the incidence of reduced birth trauma with cesarean section and to its effects on long-term pelvic floor support. Dr. Frigoletto reinforced the observation that cesarean section rates have been rising. The national rate now is 28 percent.

- Dr. Hannemann referred to the need for applying engineering and computer principles to health care data. The issue concerning the need for an electronic basis for obstetric data was brought up numerous times in the report to the Secretary. One of the LBWCC recommendations was to develop effective mechanisms involving a pilot study at the Federal, State, community, and census-track level for the tracking and systematic collection of standard electronic data from patients' obstetric care records.

- Dr. Hayes raised the question of whether SACIM might play a role in the release of the NCHS report in late summer 2004 to inform the public about the need to carry out the recommendation to which Dr. Hannemann referred. Dr. Collins pointed out that SACIM's primary goal is to advise the Secretary, not the public. Dr. Hayes stated that SACIM could advise the Secretary to use the media opportunity to promote the recommendation.

- Dr. Guyer asked about the procedure for making recommendations. Dr. Hannemann responded that the recommendation has already been made; however, the recommendation deserves more emphasis and reinforcement.

INTERNATIONAL PERINATAL DATA AND COMPARISONS

K.S. Joseph, M.D., Ph.D., Associate Professor, Departments of Obstetrics & Gynecology and Pediatrics, Dalhousie University and the IWK Health Centre, Halifax, Nova Scotia, Canada; Member, Steering Committee, Canadian Perinatal Surveillance System

F. Sam Notzon, Ph.D., Director, International Statistics Program, National Center for Health Statistics, Centers for Disease Control and Prevention

Canadian Perinatal Data

Dr. K.S. Joseph offered some preliminary information to orient the participants to his presentation. With a population of about 31.5 million, Canada's birth rate is about 10 per 1,000, its death rate is about 7 per 1,000, its infant mortality rate is 5.2 per 1,000, and its preterm birth rate is 7 percent.

Recent History

An upturn occurred in Canadian infant mortality from 6.1 infant deaths per 1,000 live births in 1992 to 6.3 infant deaths per 1,000 live births in 1993. The increase represented some 8,200 excess infant deaths. The national news media focused on the possibility of toxicity in the environment as an explanation for the increase in the infant mortality rate. An alternative explanation rested on the hypothesis that the registration of live births less than 500 grams, which is variable, could in fact be increasing. The infant mortality rate among such live births may be as high as 90 to 95 percent, setting up the potential for the confounding of temporal trends in infant mortality by changes in registration policies, especially changes at the borderline of viability.

Dr. Joseph discussed trends in low birth weight in Canada in various low birth weight categories. Live births of less than 500 grams increased from .47 per 1,000 in 1987 to about .85 per 1,000 in 1993, an 80-percent increase that was statistically significant. A 14-percent increase in live births at 500 to 749 grams was nominally significant. No real change occurred in the low birth weight live births of less than 2,500 grams. A 4-percent increase was not statistically significant. When the infant mortality rate trends were recalculated to show the crude infant mortality rate and infant mortality among live births 500 grams and over, an upswing was apparent in the crude rate, but no such increase appeared in the live births over 500 grams. In the next year, the infant mortality rate did not show any increase and continued to decrease monotonically thereafter.

In 1994, Canada experienced a low birth weight epidemic in one of its provinces. Ontario registered an increase in its low birth weight rate from 5.5 percent to 6.5 percent between 1992 and 1994. There was no associated increase in infant mortality, but the increase was an issue of great concern. The national press reported on the epidemic and attributed it to maternal stress, poverty, and poor nutrition.

When the low birth weight frequency distribution for the province of Ontario in 1992 was plotted, the birth weight distribution was approximately normal. However, when the birth weight distribution for 1994 was plotted, the resulting distribution showed spikes and

troughs at odd points. When the data were transformed into pounds and ounces, the 1992 data showed a bell-shaped distribution, and the 1994 data showed spikes at regular intervals at 1 ounce past the pound. It was determined that someone had dropped the second digit from the ounces so that 5 pounds 10 ounces to 5 pounds 15 ounces had been converted to 5 pounds 1 ounce. Since 5 pounds 8 ounces is the low birth weight cutoff, many babies from above the cutoff were moved to below the cutoff.

Data Quality Issues

The error in the birth weight and gestational age distribution in Ontario occurred because those two fields in the birth certificate were declared noncritical due to funding cutbacks. The errors have since been corrected. Dr. Joseph pointed out that this situation reinforces the importance of the collectors of the data (vital statistics) working closely with the users of the data (departments of health).

Information on birth weight and gestational age has been of good quality in Canada, excluding Ontario, where the situation continues to be monitored. The Canadian Perinatal Surveillance System (CPSS) reports now provide the data for Ontario separately from the data for the rest of Canada.

Substantive Focus of CPSS

CPSS has two distinctive features:

1. CPSS focuses not on infant mortality but on fetal and infant health. Its study group is called the Fetal and Infant Health Study Group.

2. CPSS focuses not on low birth weight but on preterm birth and fetal growth. It does not publish low birth weight statistics; it provides preterm birth weights and SGA rates separately.

Trends in Perinatal Health in Canada

Dr. Joseph provided information about various trends in perinatal health in Canada. There has been a sharp increase in twin and triplet births, and SGA rates are dropping sharply. Preterm birth rates have increased due to increases in obstetric intervention, which is viewed in a positive light. Obstetric intervention prevents death but results in preterm birth. Trends in mortality among singletons weighing more than or equal to 500 grams show steady declines in stillbirth rates, neonatal mortality rates, extended perinatal mortality rates, and infant and fetal death rates.

The data on causes of death among singletons of 500 grams or more show no change in fetal deaths due to congenital anomalies. There has been a sharp decrease in late fetal deaths due to congenital anomalies and substantial declines in complications of the placental cord and membranes. Trends also show a decrease in fetal deaths due to hypoxia and asphyxia and fetal deaths of unspecified cause.

There is a tremendous decrease in infant mortality due to congenital anomalies among singletons of 500 grams or more. The data also show a sharp decline in infant deaths due to SIDS and respiratory distress syndrome. Trends in twin mortality also show substantial declines. In addition, substantial declines have occurred in triplet mortality, except in the most recent year, which shows a stagnation. In general, the mortality trends are reassuring.

Current Areas of Interest

Some concern exists about international comparisons because Canada's global infant mortality ranking has slipped substantially in recent years. The medical literature documents the lack of standardization regarding the registration of births at the borderline of viability across different countries, and several papers have shown a 54-percent variation in the registration of live births less than 500 grams across countries and across regions within countries. WHO advocates that infant mortality comparisons across countries be made among live births of 1,000 grams and over, but such estimates are generally unavailable. CPSS reports have started providing such estimates to enable international comparisons and interprovincial comparisons.

The Matthew effect in health development was described in the 1960s as a psychosocial phenomenon in science and subsequently extended into health development. It proposes that those countries with a good baseline state in infant mortality will make significant gains over time. For example, Japan decreased its infant mortality rate from 18 to 6 percent between 1965 and 1985, for a 66.7-percent decrease overall, while Mexico went from 82 to 50 percent in the same time period, for a total decrease of 39 percent. Dr. Joseph pointed out that when the Matthew effect was applied to regions in Canada after the passage of the Medical Care Act in 1968, which provides universal health insurance coverage, Ontario's infant mortality rate declined by 73 percent, but Yukon and the Northwest Territories, which had much higher infant mortality rates, had larger declines over the same period. Therefore, the insurance coverage acted as an anti-Matthew effect force.

Dr. Joseph noted the infant mortality differentials among vulnerable subpopulations in Canada. A 2- to 2.5-fold difference in infant mortality rates persists between the First Nations peoples and the general population. An examination of the birth weight and gestational age data from the First Nation Metís and Inuit populations suggests the existence of small gaps at the borderline of viability, and the differential may be slightly higher than what is recorded.

Data from Nova Scotia, where birth information was linked with income tax records for about 76,000 women, showed no differential in preterm birth rates by economic status. However, families that made a registered retirement savings investment in the year of the child's birth had a 10-percent lower preterm birth rate compared with families that did not. On the other hand, an examination of SGA differentials by family income quintile reveals a very sharp gradient; women having babies in the poorest families tend to have a

much higher rate of SGA, 56 percent in the lowest income quintile. Similarly, a 20-percent protection exists if the family made an investment in the year of the child's birth.

Dr. Joseph commented on recent influences acting to lower infant mortality, including prenatal diagnosis and termination of pregnancies affected by major congenital malformations and increases in medically indicated early delivery. CPSS has found that increases in prenatal diagnosis and termination have resulted in declines in infant mortality due to congenital malformations. Dr. Joseph referred to the issue of the upturn in infant mortality in Canada. The speculation is that the "bump" occurred when prenatal diagnosis resulted in termination and the shifting of some of the late fetal deaths to live births at very early gestation (20 to 23 weeks), which were reported as infant deaths.

Dr. Joseph stated that medically indicated early delivery is an extremely important new phenomenon, the cornerstone of modern obstetrics. Rates of labor induction and cesarean delivery have increased dramatically over the past 20 years. This phenomenon is linked to newer technologies, such as antenatal corticosteroid use, surfactant use, and better methods of ventilation.

In a traditional epidemiologic model of gestational age-specific perinatal mortality, mortality decreases dramatically as gestational age increases. Therefore, the traditional epidemiologic model argues against early delivery. NCHS data from 1995–1996 and 1999–2000 show that the entire gestational age distribution shifted toward earlier delivery. Dr. Joseph referred to this phenomenon as "the paradox of modern obstetrics" and noted that it is also occurring in Canada. The labor induction and/or cesarean delivery rate increased from 339 per 1,000 to 384 per 1,000 between 1995–1996 and 1999–2000. According to the traditional epidemiologic model, this increase should result in an increase in perinatal death, but, in fact, perinatal mortality declined from 3.95 to 3.64.

CPSS proposed a slightly different model than the traditional epidemiologic model. The obstetric model is a survival analysis model. The traditional method of calculating gestational age-specific perinatal mortality counts the number of deaths in any risk period and divides them by the number of births during that period. Under the newer approach, the denominator would include all those fetuses that passed through a risk period and could have been perinatal deaths in that period. The denominator increases significantly using this strategy. When gestational age-specific perinatal mortality is calculated under the new model, perinatal mortality rises as gestational age advances, thereby giving theoretical support to the obstetric practice of medically indicated early delivery.

Newer influences that are acting to increase perinatal mortality include the increase in maternal age, in obesity and extreme obesity, and in the fecundity of women with chronic diseases. Also, the decrease in perinatal death rates is not matched by a corresponding decrease in perinatal mortality and/or serious morbidity. Therefore, modern obstetrics and improved neonatal care can prevent perinatal death, but the impact on morbidity and mortality is not yet evident.

The Canadian Perinatal Surveillance System

CPSS is an initiative of Health Canada, the federal department of health. Its contact address is cpss@hc-sc.gc.ca. Its membership includes federal and provincial stakeholders, health professional organizations, advocacy groups, and university-based researchers. The focus of CPSS is on fetal and infant health, maternal health, and maternity experiences. CPSS publishes routine surveillance reports.

The International Collaborative Effort on Perinatal and Infant Mortality, 1984–1994

Dr. F. Sam Notzon presented information on the history of the International Collaborative Effort (ICE), the major findings from ICE, and the prospects for international collaboration in the future.

History of ICE

The following factors led to the decision to start the collaborative:

- The U.S. infant mortality ranking compared with other countries in the world declined steadily after 1945. This fact, along with the percentage of money spent on health care in the United States, led to concerns about the United States lagging behind other countries.

- Because of the growing complexity of the questions involved in the problem, it was thought that an international collaboration could generate useful information and analyses not obtainable by research in a single country.

ICE membership included leading researchers in the field from HHS and senior researchers from the other member countries, including England, Wales, Scotland, Norway, Sweden, Denmark, West Germany, Israel, and Japan.

The organizing meeting took place at a symposium at the National Institutes of Health (NIH) in 1984. ICE presented some of its results at the American Public Health Association sessions in 1985 and 1989. A second symposium was held in 1990 and a workshop in 1994. The focus was on conducting collaborative research based on a common multinational data set constructed by ICE.

The data set evolved into three different forms:

1. The first database comprised frequency files by country, year of birth, type of event, plurality, race/ethnic group, and birth weight.

2. The second database comprised frequency files with a larger number of variables and more detail about each.

3. The third database comprised unit record, or microdata, files, that is, data files that would include information on each event.

Confidentiality concerns arose with the use of the third database because a number of the member countries had laws or longstanding traditions forbidding the release of such detailed information.

Major Findings From ICE

Findings of ICE on perinatal and infant mortality included the following:

- Differences in definitions can have an impact on the infant mortality rates reported, but adjustments can be made for some of these differences.

- Cause-of-death categories can be developed and are useful for comparisons of cause-specific infant mortality across countries and even across International Classification of Diseases (ICD) revisions.

- Simple data sets can produce useful information.

- Birth weight distributions can differ substantially by country, and those differences can affect the impact of birth weight on infant mortality.

- The socioeconomic gradient in infant mortality existed in all ICE countries, regardless of the health care system in effect.

Problems of International Comparison

ICE documented differences in registration practices for births, infant deaths, and fetal deaths. Major differences across countries in definitions of live- and stillbirth, as well as differences in terms of legal issues and social benefits, affect the interpretation of those registration practices or definitions. Resuscitation practices also differ. In addition, major differences in the measurement of gestational age made it extremely difficult to attempt gestational age-specific comparisons across countries. To adjust for the differences in reporting, ICE combined information on live births, infant deaths, and late fetal deaths to produce a "feto-infant mortality rate." In addition, because of major differences in reporting practices across countries, ICE decided to exclude the analysis of births and deaths of less than 500 grams or under 28 weeks and to exclude deaths in the first week of life.

Cause-of-Death Categories

ICE created eight cause-of-death categories mapped to both ICD-8 and ICD-9 to conduct cause-specific comparisons across countries. The cause-of-death categories are congenital conditions, asphyxia-related conditions, immaturity-related conditions,

infections, other specific conditions, SIDS, external causes, and remaining causes. The focus in these cause categories is on drawing attention to the prevention of infant deaths.

Simple Data Sets

ICE used the birth weight distribution information from the first database to produce some interesting findings. The birth weight distributions for singleton and multiple births are quite similar and stable across countries and across years. However, the birth weight distributions for singleton total births in three populations from ICE countries (Norwegians; citizens of Osaka, Japan; and U.S. blacks) show some very fundamental differences. The Norwegian distribution was much heavier than that of the other populations. The Osakan and U.S. black distributions had quite similar median birth weights but very different distributions below 2,500 grams. Although Osakans and U.S. blacks had similar median birth weights, Osakans had the lowest infant mortality rate of all the ICE groups and U.S. blacks had the highest.

Birth Weight Distributions and Infant Mortality

A conclusion drawn from the ICE's work was that reducing low birth weight would reduce infant mortality. Birth weight distributions and their differences can affect the impact of birth weight on infant mortality. Despite the fact that the U.S. black population has so many low birth weight births and extremely low birth weight births, the infant mortality rate at first analysis seemed lower in proportion to the other ICE populations. The analysts became convinced that these low birth weight infants were surviving better because they were more mature, that is, they had higher gestational age. Another conclusion was that reducing the low birth weight rate in the U.S. black population would not reduce infant mortality; instead, the birth weight-specific infant morality at each birth weight for this population had to be addressed. To do so, the birth weights were adjusted to eliminate the influence of the mean or average birth weight in order to create a firmer basis on which to compare the birth weight-specific infant mortality rates. When that procedure was carried out, it was seen that black infant mortality rates were higher than any other population, with the exception of Israeli non-Jews. About 30 percent of the black infant mortality differential was due to the proportion of low birth weight, but about 70 percent was due to the differential in infant mortality at specific birth weight intervals.

Socioeconomic Differences

ICE found socioeconomic differences in infant mortality in the ICE countries. Regardless of the existing health care system, of whether prenatal care was universal, or of ease of access to care for infants, the lowest socioeconomic groups experienced higher rates of infant mortality. The conclusion was that, in attempting to reduce infant mortality, other issues besides access to care, such as behavioral issues, must be addressed.

Prospects for Future International Comparisons

ICE was a very cost-effective approach to encouraging international collaboration. Expenditures were limited to payment for travel for members to attend annual meetings and symposia, and volunteer labor was used to conduct the analyses. A future ICE would necessitate finding new participants to replace retirees. Data confidentiality also will make it difficult to create detailed multicountry data sets at the unit record level. In addition, university faculty would need research grants to carry out this work. Research grants would be a major facilitator of future collaboration.

Discussion

The presentations by Drs. Joseph and Notzon elicited the following comments and questions:

- Dr. Tu remarked about Dr. Joseph's slide displaying the obstetric model of fetuses at risk of perinatal mortality or serious morbidity. She pointed out that beginning in the 1990s, obstetricians used cesarean section deliveries linked to new technologies to exchange infant death for neonatal morbidity. She added that the factors affecting obstetrical practice include the same factors affecting perinatal mortality (increases in maternal age, obesity, and fecundity of women with chronic diseases), with the additional element of the decrease in family size. Another consideration in the late 1990s was that obstetricians often were under pressure to induce labor or to use cesarean section at 40 to 42 weeks instead of risking fetal death while waiting for spontaneous labor. Dr. Tu thanked Dr. Joseph for mentioning these facts in his presentation.

- Dr. Guyer asked Dr. Joseph about the timing and frequency of the data from Canada's vital statistics system and about the relationship between CPSS and the Canadian vital statistics system. He also asked whether field investigations were conducted or whether the statistical information is based on an analysis of the variables in the data set from vital statistics. Dr. Joseph explained that the data used are collected by two different systems. One is the vital statistics system, which is very cumbersome and slow. The other is hospital discharge information related to pregnancy and delivery, which is computerized. Dr. Joseph declared that the Canadian system is not superior to that of the United States; he explained that the upturn in infant mortality occurred in 1993, the analysis was done in 1995, and the paper was published in 1996. CPSS is trying to improve the timeliness of its work through the use of electronic records, but it is lagging behind. A common electronic perinatal record at the obstetric practice level would result in the necessary information, but it is difficult to sell that concept to the different provinces. Dr. Joseph pointed out that health care is a provincial responsibility in Canada. Dr. Notzon stated that the real challenge for both Canada and the United States revolves around the province-based or State-based vital statistics systems. In the United States, each State must be convinced to undertake new approaches that involve expensive changes without substantial support from the Federal Government. In addition, some States are very slow in reporting their data.

- Dr. Hayes remarked that these presentations set the stage for the conversation that SACIM should have about its assumptions. She commented on the difference in perspective among the Canadians, who look at fetal and infant health as opposed to infant mortality and who emphasize preterm and fetal growth instead of low birth weight. She also mentioned the periods-of-risk model and its relationship to the development of interventions or policies. In addition, Dr. Hayes referred to the impact of maternal chronic disease on infant outcome. She asked Dr. Joseph to comment on the periods of risk. Dr. Joseph responded that two issues are involved in the consideration of periods of risk: (1) obstetric intervention sometimes can prevent fetal death and result in a normal healthy infant, but obstetric intervention that is not early enough or is too early in gestation can result in neonatal death or morbidity and (2) a fraction of postneonatal mortality and morbidity, previously associated with infection, might be due to pregnancy complications.

- Dr. Collins reemphasized that from an intervention perspective, it may be easier to address infant mortality in terms of reducing the disparity among term infants. He asked Dr. Joseph about the percentage of the Canadian population that is of African descent and the preterm rate differential between those of African descent and those of non-African descent. He asked why, if that information is not available, race is not a major variable to be examined on a national level in Canada. Dr. Joseph replied that about 4 million of the 30 million people who live in Canada are visible minorities: about 1 million Chinese, 1 million South Asians, 1.3 million First Nations people, and 650,000 blacks. The preterm birth rate among the Canadian African population is not known.

- Dr. Frigoletto commented on the goal of having data available sooner. Referring to the "very anemic" response from SACIM to the presentation on the electronic medical record in the past, he suggested that SACIM might be ready to give the issue a higher priority.

ISSUES IN PREMATURITY: PREVENTION, MANAGEMENT, AND RESEARCH NEEDS

Catherine Spong, M.D., Chief, Pregnancy and Perinatology Branch, Center for Developmental Biology and Perinatal Medicine, National Institute of Child Health and Human Development, National Institutes of Health

Dr. Catherine Spong presented information on issues in prematurity, including its consequences, etiologies, risk factors, markers, prevention strategies, and research needs and focus.

Preterm delivery and low birth weight are public health priorities. One in eight infants is born preterm. Preterm delivery is a leading cause of hospitalization among pregnant women and a leading cause of death among African American infants and is associated with long-term developmental disabilities for those who survive.

Over the past 20 years, the rates of preterm birth and low birth weight have increased significantly, with preterm birth increasing almost 30 percent since 1981 and low birth weight increasing almost 15 percent since 1981. This increase can be accounted for in some part by multiple gestations; twin births increased by 74 percent since 1981. In addition, there were 22 percent more twin births with preterm delivery in 1996–1997 than in 1981–1982. A significant disparity exists in preterm birth, both by race and ethnicity, with much higher rates in the black, non-Hispanic population.

Consequences of Preterm Birth

Both preterm birth and low birth weight have been identified as the leading causes of neonatal mortality in 2001. Preterm birth and low birth weight account for one in five children with mental retardation, one in three children with vision impairment, and almost half of the children with cerebral palsy. Almost 70 percent of those infants born at 26 weeks will survive, but at significant cost, with serious morbidity occurring in more than half of those deliveries.

Substantial long-term outcome problems for preterm infants include increased risk of cardiovascular disease, including myocardial infarction, stroke, and hypertension as an adult. Other long-term outcomes for the baby are an increased risk for diabetes as an adult and a possible increase in cancer risk. In addition, mothers who experience a preterm delivery are at increased risk for subsequent preterm delivery.

Predictors of Preterm Birth

One way to address the problem of preterm birth is to identify its predictors. Identifying specific markers can lead to the initiation of risk-specific treatment, to a definition of an at-risk population and evaluation of an intervention or therapy, and to new information about the mechanisms of preterm delivery.

A number of research studies have focused on the identification of specific risk factors for preterm birth and preterm delivery, such as multiple gestation, previous preterm birth, uterine or cervical abnormalities, medical risk factors, and lifestyle risk factors. Of all the risk factors for preterm birth, prior spontaneous preterm birth is the best predictor of a subsequent preterm birth. A number of scoring systems were identified to predict women who were at highest risk for preterm delivery. Most of the scoring systems were found to have low sensitivity and high false-positive rates. The majority of women who have preterm delivery are from a low-risk group. Furthermore, the identification of high-risk status has not led to improvement in outcome. Effective intervention for a specific risk factor or marker is important.

Preterm births are categorized in three general groups:

1. More than half of preterm births are considered spontaneous.
2. Nearly one-fifth are due to preterm premature rupture of the fetal membranes.
3. Another 22 percent of preterm deliveries are indicated for fetal or maternal reasons.

Preterm birth is a very heterogeneous condition; it is extremely difficult to consider all of the different risk factors and identify a single cause or some type of intervention that will be effective for all. For example, the mechanisms of spontaneous preterm delivery include problems with the cervix, uterine contractions, infection or inflammation, and the release of cytokines and chemokines.

Studies on Infection as a Cause of Spontaneous Preterm Birth

Substantial evidence documents that infection is a cause of preterm delivery, both with clinical chorioamnionitis and subclinical chorioamnionitis. A number of studies have looked at women who are completely asymptomatic and whose amniotic fluid at 15 or 18 weeks showed evidence of infection and evidence of cytokine production, suggesting inflammation. Those women who had these abnormalities were found to subsequently deliver preterm. Therefore, a subclinical chorioamnionitis has definitely been associated with spontaneous preterm birth, with a number of bacteria associated with prematurity.

A dozen trials have looked at the role of infection and treatment with different antibiotic regimens to improve outcome and prevent preterm delivery. Although many of the antibiotics resulted in a delay in delivery, only one resulted in improved infant outcome, suggesting that antibiotics are not necessarily the answer for infection-mediated preterm birth.

Two randomized trials looked at treatment of high-risk women with bacterial vaginosis, a condition associated with preterm birth and preterm delivery. Both studies found a substantial reduction in preterm birth. Another study aimed to establish whether metronidazole therapy would reduce the risk of preterm delivery in women with asymptomatic bacterial vaginosis or *Trichomonas vaginalis.* The trial found that for women with asymptomatic bacterial vaginosis, treatment with metronidazole did not decrease preterm delivery at less than 37 weeks, 35 weeks, or 32 weeks. In the women who had asymptomatic *T. vaginalis,* treatment substantially increased the risk of preterm delivery at less than 37 weeks, less than 35 weeks, and less than 32 weeks. The Data and Safety Monitoring Board (DSMB) stopped the trial after an interim analysis found an increased risk of preterm delivery in the metronidazole group. In both groups, the treatment eradicated the organism. The conclusions from these two trials were that in asymptomatic women, treatment with antibiotics did not reduce preterm delivery or reverse perinatal outcome, and, in fact, treatment for trichomonas increased the risk of preterm delivery. Results from these trials changed the practice of indiscriminate use of antibiotics in pregnancy.

Research on Fetal Fibronectin

Fetal fibronectin (FFN) is a membrane protein localized to the area between the fetus and the mother. It has a role in implantation and placentation. When detected in cervical or vaginal secretions of asymptomatic women, FFN is associated with a greater than fiftyfold increased risk of preterm delivery at less than 28 weeks. An intrauterine

infection may disrupt the interface between the mother and the fetus and result in release of FFN.

A randomized trial was conducted for women with a positive FFN. They were treated with antibiotics to determine whether the antibiotic therapy would reduce the risk of preterm delivery. The study found no improvement in the rates of spontaneous preterm delivery or in neonatal outcome. Therefore, antibiotics were not beneficial in treating the infectious-mediated release of FFN resulting in preterm delivery.

Research on Home Uterine Contraction Monitoring

A study published in the *New England Journal of Medicine* in 1998 reported on home uterine contraction monitoring (HUCM) to prevent preterm delivery. Almost 2,500 at-risk women were involved in this study. The intervention was a weekly phone call, a daily phone call, or use of the HUCM system. The women who used the HUCM system and the women who received daily calls had the highest treatment rates, and there were no changes in preterm delivery, birth weight, or cervical dilation at admission.

An HUCM prediction study used blinded monitoring of women at risk for preterm delivery. Although contraction frequency was related to risk of preterm delivery, the contractions did not effectively predict preterm delivery. Contractions are very common in pregnancy, and although their frequency might increase in women who will have spontaneous preterm delivery, the clinical usefulness of the information is negligible. Contractions occur late in the process, and the intervention and markers must occur much earlier; therefore, HUCM as a method to identify women at risk for preterm delivery has failed.

Research on the Cervix

A body of research has focused on the cervix—its length, how it effaces, and how it changes. One study explained how the cervix goes through a dynamic changing process as it dilates and effaces. Another study looked at cervical length and its ability to predict preterm delivery. The relative risk of delivering early is substantially higher the shorter the cervix; therefore, cervical length plays a major role in identifying women who may deliver early.

Cervical length follows a bell-shaped curve. The risk of preterm delivery increases as the cervical length decreases across the entire range of the length. Cervical changes are the same at all gestational ages. Given these facts, many people advocate the use of cerclage, but a limited number of studies are available to determine the effectiveness of cerclage to prevent preterm delivery in women who are at risk or who have a shortened cervix. The studies that have been done offer no evidence to support the use of cerclage, yet it is a common technique that is used in obstetrics when a shortened cervix is apparent.

A randomized controlled trial of women with a cervical length of less than 15 millimeters and a very high relative risk of delivering early randomized the women to either a

cerclage or no cerclage. The study found no difference in the rates of preterm delivery at less than 33 weeks (22 percent versus 26 percent), adding further credence to the idea that cerclage itself may not be effective.

An ongoing trial funded by the National Institute of Child Health and Human Development (NICHD) is looking at cervical length and cerclage placement to further substantiate whether a cerclage is beneficial in women with a shortened cervix with or without prior risk factors.

Research on Progesterone

Progesterone is a steroid hormone that diffuses freely through the plasma membrane of cells and acts through binding to a progesterone receptor element, a specific sequence of DNA in the promoters of certain genes that is needed to turn those genes on and off. The complex of progesterone with its receptor forms a transcription factor. Progesterone works on the uterus and myometrium to decrease the conduction of contractions, increase the threshold for stimulation, decrease spontaneous activity, decrease the number of oxytocin receptors, and, most important, prevent the formation of gap junctions.

Trials of progesterone in the 1970s and 1980s were controversial. One study of 43 patients who were at high risk because of either recurrent abortion or prior preterm delivery found that 41 percent of the placebo group delivered preterm and all of the treated group delivered at term, suggesting that the progesterone was effective. A second study in a population of 168 pregnant women in the military found no change in low birth weight between the two groups. A meta-analysis of 17-hydroxy progesterone suggested a reduction in the rate of preterm birth and low birth weight with treatment. Two different studies followed, one in Brazil and one in the Maternal-Fetal Medicine Unit (MFMU).

The Brazilian Trial

The Brazilian trial, published in 2003, was a randomized placebo-controlled double-blind study of the prophylactic administration of progesterone by vaginal suppository to reduce the incidence of spontaneous preterm birth in women at increased risk. The study found a substantial decrease in preterm birth in the women who received the progesterone compared with those who received placebo. The rate of preterm labor also decreased. In addition, the study monitored its patients from 28 to 34 weeks and found a substantial decrease in the number of contractions in women who received the progesterone compared with women who received the placebo. The study concluded that progesterone prevented preterm delivery in women with a prior preterm birth, especially less than 34 weeks, and it reduced the frequency of uterine contractions.

The MFMU Trial

MFMU also conducted a progesterone trial at several sites across the country to establish whether weekly progesterone injections in women with a prior spontaneous preterm birth would reduce the risk of a subsequent preterm delivery. Nineteen centers enrolled women

with a documented history of spontaneous preterm birth at between 20 and 36 weeks of gestation in a previous pregnancy. The gestational age at entry was between 15 and 20 weeks, confirmed by ultrasound. All were singleton gestations, with no major fetal anomalies. The women received a trial injection of the placebo inert oil and were asked to return in 1 week. When they returned, they were randomly assigned to either placebo or progesterone and then returned for weekly injections until 37 weeks or delivery.

An interim analysis by the DSMB was performed after 351 of the patients had delivered. The analysis revealed a significant positive effect for the primary outcome. Therefore, enrollment of new subjects was halted when 463 of the 500 subjects had been randomized. Almost 3,000 women were screened for this trial, 2,000 of whom were found to be ineligible. Of the 1,000 eligible, about 500 refused consent or declined after the first injection. A total of 463 women were randomized in a two-to-one randomization scheme. The characteristics were very similar between the two groups in this study. The qualifying prior delivery was at 30 or 31 weeks, which was very early compared with other trials. The trial also found that treatment with progesterone substantially reduced the rates of a subsequent preterm delivery and that progesterone worked equally well in African American women and in non-African American women.

The study found that, in terms of the effectiveness of progesterone, five to six women with a prior spontaneous preterm birth would need to be treated to prevent one birth at less than 37 weeks. In addition, 12 women with a previous spontaneous preterm birth would need to be treated to prevent one birth at less than 32 weeks. Furthermore, this study found that progesterone also prevented neonatal complications, with a substantial reduction in intraventricular hemorrhage and necrotizing colitis and reductions, although not significant, in bronchopulmonary dysplasia, respiratory distress syndrome, and neonatal death. Compliance with the weekly injections in this trial was excellent. More than 90 percent of the women received their injections at the scheduled time. The side effects were minor and were similar in the progesterone and placebo groups.

The conclusions from the trial were that weekly injections of progesterone prevented recurrent preterm birth and improved the neonatal outcome for pregnancies at high risk of a subsequent preterm delivery. Progesterone was effective in preventing very early as well as later preterm birth. In addition, the trial concluded that progesterone was effective in both African American and non-African American women.

ACOG Committee Opinion

The Brazilian study and the MFMU study, along with the previous work that had been done on progesterone, were reviewed by ACOG. In October 2003, ACOG issued its committee opinion on the use of progesterone to reduce preterm birth. The committee found that progesterone supplementation reduces preterm birth in a select group of women, that is, those women with a prior spontaneous preterm delivery at less than 37 weeks, but that further studies are needed to evaluate the use of progesterone in patients with other high-risk conditions, such as multiple gestations, shortened cervix, or

positive FFN. The committee recommended restricting progesterone use to prevent preterm delivery for women with a prior spontaneous preterm delivery.

Effectiveness of Progesterone

The question of whether all women at risk for preterm delivery should be started on progesterone needs careful consideration. Because the etiologies of preterm delivery are heterogeneous, no one intervention will be effective in all women who are at risk of preterm delivery. The inability to predict preterm delivery is another factor. In addition, women can be at risk based on demographic characteristics, behavioral factors, and obstetric history. Not all at-risk women will benefit from progesterone.

Before the Brazilian and MFMU trials, no evidence-based research supported any preventive therapy for women who had had a prior preterm delivery. Now progesterone is available for that very select group. Overall, limited data are available for at-risk conditions, but evidence does exist to support progesterone treatment for women with a prior spontaneous preterm delivery.

Research Needs for Prematurity and Low Birth Weight

Progesterone is not completely efficacious; a substantial portion of at-risk women still delivered preterm. Major initiatives are needed into understanding the causes of preterm birth, the methods of prevention and treatment in pregnant women, and the optimal management and treatment of neonates. Much progress has been made over the past several decades in the identification of markers of preterm delivery (FFN, cervical length), in the management of preterm delivery risks (antenatal corticosteroids, antibiotics, treatment of preterm premature rupture of membranes), in the prevention of preterm delivery (progesterone), and in the management of preterm neonates (inhaled nitric oxide, optimal nutrition). However, many research needs remain to understand the mechanisms, pathophysiology, genetics, and racial and ethnic differences in preterm birth.

NICHD funds researcher-initiated grants, targeted requests, NIH multicenter networks, and specific education. Dr. Spong described the NICHD networks focused on the area of preterm birth and low birth weight, on both the obstetric and the neonatal side:

- The Neonatal Intensive Care Unit Network sites include more than 60,000 babies per year in intensive care units.

- The Maternal Lifestyle Study Network sites follow a cohort of infants who were exposed to drugs of abuse during pregnancy. These individuals are now between 8 and 11 years of age.

- The MFMU Network includes 14 sites across the country and comprises more than 120,000 deliveries per year.

- The Management of Meningomyelocele Network includes sites where fetal surgery is performed for prenatal therapy versus postnatal therapy of spina bifida.

These networks focus on high-risk pregnancies, including preterm birth and low birth weight prevention and management, management of the preterm and low birth weight neonate, and the long-term outcomes of prematurity and low birth weight.

The research needs include more investigator-initiated grants and trials in the NICHD clinical networks to identify markers, treatments, preventive therapies, and optimal management. In addition, long-term followup is critical because these infants often have long-term, acute morbidities. The National Children's Study (NCS), a long-term study of the environmental influences on children's health and development, was authorized by the Children's Health Act in 2000. It will follow 100,000 children during prenatal development, birth, and childhood and into adulthood. NCS will allow for a major scientific initiative to gain understanding in the management and treatment of preterm birth.

Dr. Spong concluded her presentation by reiterating that prematurity prevention is a public health priority. About 476,000 preterm births occur each year. Prematurity is a leading cause of neonatal death and a major cause of long-term morbidity, affecting adult health. There is a critical need for answers to major research questions, for clinical trials and longitudinal data, and for long-term followup.

Discussion

Dr. Spong's presentation elicited the following questions and comments:

- Dr. Roberts asked about the apparent inconsistency in the fact that so many women withdrew from the progesterone trial after the first injection, yet the women who remained in the trial showed 90-percent compliance with the progesterone injections. Dr. Spong explained that some of the women refused entry before they received the trial injection. The women refused to continue in the trial for a number of reasons. One can speculate that women whose prior preterm delivery at 35 or 36 weeks resulted in healthy babies might not be willing to undergo weekly injections between 24 and 36 weeks, but women whose prior deliveries occurred at 24 or 25 weeks and whose babies had substantial handicaps would be very motivated to undergo the injections. Therefore, the women in this trial were a very select high-risk group; their qualifying preterm delivery averaged around 30 weeks.

- Dr. Hayes asked about whether practitioners have integrated knowledge about treatments into their practices. Dr. Spong explained that progesterone is not currently available on the market. Local pharmacies can compound progesterone, but its quality is not known and it may not be exactly what was used in the study. Practitioners are concerned about prescribing progesterone because of the lack of a commercially available product approved by the Food and Drug Administration. As for other treatments, the MFMU Network has tried to address the translation or research into

practice, and NIH works with groups such as ACOG to convert research into clinical practice guidelines. Dr. Hayes pointed out that perinatal systems of care, which might play a role in integrating guidelines into practice, were dismantled some time ago in many States.

- Dr. Hannemann asked about basic science research at the cellular or molecular level. Dr. Spong replied that NIH supports a number of basic science research applications and grants on specific mechanisms involving the initiation and occurrence of labor. Regarding nanotechnology, proteomics, and genomics, which have not been well explored in obstetrics, NIH has issued a request for applications for sites to participate in a proteomic/genomic network focusing specifically on preterm delivery. The network will incorporate three to five clinical sites, a core site for widespread screens and high-throughput analysis, and an independent data center.

- Dr. Hannemann also asked about research using techniques of modeling and computational biology to address the multifactorial problem. Dr. Spong remarked that funding for this particular idea is difficult, but it is an area that deserves exploration.

- Dr. Frigoletto gave another example of implementation of research findings. In the early 1980s, almost incontrovertible evidence pointed to the efficacy of antenatal steroids. In 1994, because of low utilization of that intervention, NIH convened a consensus conference to stimulate use of antenatal steroids. Dr. Spong explained that antenatal steroids went from being underused to being overused to the point that it required a second consensus conference in 2000 to examine multiple courses of steroids and state that multiple courses might not be beneficial. Dr. Frigoletto asked why translational research meets hurdles in implementation, while electronic fetal heart rate monitoring and tocolysis, which are known to be ineffective, are used every day.

- Dr. Ryan commented on preconceptional prevention of preterm birth by preventing unintended pregnancies and considering life cycle issues. Dr. Spong remarked that preterm birth and low birth weight occur most commonly in women with no risk factors.

- Dr. Hayes asked whether NIH is looking at geographical disparities in preterm birth and low birth weight. Dr. Spong replied that NIH has had specific initiatives targeting disparities as a whole, but applications looking at geographic disparities have not been funded. Dr. Hayes also mentioned the Institute of Medicine (IOM) report on unequal treatment and the impact of race and racism even in the delivery of care.

- Dr. Tu asked about the possibility of a certain percentage of natural premature deliveries. Obstetricians accept double-digit spontaneous miscarriage as natural. Dr. Spong responded that preterm delivery or delivery at less that 37 weeks may be normal for some people. Perhaps for twins or triplets, it may be normal to be born at 35 or 36 weeks compared with a singleton, but it is not possible to say what percentage of that group is actually normal.

- When Dr. van Dyck asked about the percentage of miscarriages that have genetic abnormalities, Dr. Spong replied that more than 50 percent of miscarriages have genetic abnormalities, but not all miscarriages are identified. Dr. van Dyck asked about the rate of miscarriage, and Dr. Frigoletto replied that in recognizable clinical pregnancies, the rate is between 15 and 20 percent. Dr. van Dyck pointed out that the rate of genetic abnormalities in preterm infants must be much lower than 50 percent. Dr. Spong added that a number of infants with genetic abnormalities do not deliver preterm.

- Dr. Tu reiterated her interest in determining whether a certain percentage of preterm births should be accepted as normal or natural.

WEDNESDAY, JULY 14, 2004

HEALTHY START PROGRAM AND EVALUATION

Maribeth Badura, M.S.N., R.N., Director, Division of Perinatal Systems and Women's Health, Maternal and Child Health Bureau, Health Resources and Services Administration

Susanna Ginsburg, M.S.W., Managing Vice President, Abt Associates, Cambridge, MA

Ms. Maribeth Badura's presentation concentrated on the history of the Healthy Start program and administrative considerations.

History of Healthy Start

Healthy Start was established as a Presidential initiative in 1991 to improve health care access and outcomes for women and infants, promote healthy behaviors, and combat the causes of infant mortality. A total of 15 sites received funding, and 7 sites were approved but not funded. A lack of appropriations resulted in the March of Dimes supporting the seven sites that were approved and not funded. A 9-month comprehensive needs assessment was followed by 5 years of implementation of the program in the communities. The original 15 sites were mainly in urban areas, but there were 2 rural sites.

In 1998, Congress indicated that the Healthy Start program should replicate the best models/lessons learned from the demonstration phase. Four additional sites were funded, with existing sites serving as resource centers. A very elaborate system of peer mentoring was created. MCHB also established a research center on Healthy Start at the National Center for Maternal and Child Health Education at Georgetown University.

The first national evaluation of Healthy Start was published in 2000. This comparison community-level study paired each of the original sites with two communities that had the same socioeconomic demographics. The evaluation found that the Pittsburgh site was successful, and the New Orleans site reduced its infant mortality rate by 38 percent in 5 years. A total of 8 or 9 of the sites had statistically significant outcomes in reducing some of the contributing factors to infant mortality, such as adequacy of prenatal care and low birth weight. The analysis was done at the community level, not the participant level.

An internal assessment by national consultants resulted in some recommendations on the program. SACIM also worked with Healthy Start on an evaluation. SACIM recognized that there still was an urgent need to improve the condition of infants and children in all communities across the Nation. The committee recommended applying the knowledge from the Healthy Start demonstration projects of the past decade to the current projects as the program was continued.

Some overarching conclusions and lessons learned about the elements necessary for Healthy Start's success included the following:

- Strong neighborhood-based outreach and case management model
- Focus on service integration and close links to the clinical care system
- Implementation of evidence-based practices
- Consistency in program implementation over time and across program sites

Administrative Considerations

In 2000, Healthy Start was finally authorized through 2005. The initiative was expanded to include both reducing the rate of infant mortality and improving perinatal outcomes. The legislation made clear that Healthy Start should issue grants for project areas with high annual rates of infant mortality. Almost 300 counties across the United States are eligible for Healthy Start funds. The legislation also requires partnerships with statewide systems and with other community services funded under the MCHB block grant. In addition, the legislation calls for community consortiums of individuals and organizations. Women served by the project are involved in the decisionmaking of the consortium.

A total of 94 percent of the funding goes to the community sites. Up to 5 percent of the funding is used for technical assistance, dissemination, coordination, and data, and up to 1 percent is used for evaluations of projects. A provision stipulates that if the dollars become greater than the 1999 dollars, then the program may make grants to States for technical assistance, replication, and policy formation to reduce infant and maternal mortality and morbidity.

The appropriations reached a high in 1999. The President's budget requested flat-level funding so that Healthy Start's dollar base has decreased over the years. Healthy Start is now in 37 States, the District of Columbia, Puerto Rico, and the Virgin Islands. The basic grant focuses on eliminating disparities in perinatal health. Because of the funding level, five projects, rather than nine, will be funded next year. In 2005, it is expected that 71 grantees will be recompeting in an open competition of an estimated 150 applicants.

Four Healthy Start communities focus on border and Alaskan and Native Hawaiian communities. Two projects were funded in 2000 and another two in 2001. Demonstration grants focusing on the highest risk populations include funding for improving screening and treatment for perinatal depression, high-risk interconceptional care, and family violence.

The funded Healthy Start services are intended to fill gaps. The core services are outreach, case management, health education, screening and referral for depression, and interconceptional continuity of care. The projects must follow the mother and baby from pregnancy, through delivery, until 2 years after delivery. Both mothers and infants must have a medical home. There is an equal focus on core systems building, which includes consumer and consortium involvement in policy formation and implementation, local health system action plans, collaboration with Title V, and sustainability. Projects are asked to tackle an issue in the local health systems, for example, women not being screened appropriately for alcohol or substance abuse. Two measures involved in reports

to Congress are low birth weight and first-trimester entry. The initial baseline year for the current projects was 1998, when the low birth weight rate was 12.7. In 2002, the low birth weight rate was 10.5 for the participants in the project. Therefore, while low birth weight has increased nationwide, the Healthy Start communities have had a reduction in the low birth weight rate. Prenatal care entry averaged 48 percent in 1998 for the program participants and was up to 72 percent in 2002. Ms. Badura described the Healthy Start program in Ward 8 of the District of Columbia, where the infant mortality rate is 10.1 percent. The three programs in the District have adapted models and developed an excellent case management program.

The Healthy Start evaluation uses a performance measure system approved by the Office of Management and Budget (OMB). The evaluation also involves the Technical Expert Panel on the Evaluation of Healthy Start (TEPEHS), which oversees the national evaluation. The narrative component of annual progress reports complements the survey conducted by the national evaluation. Data also are collected using performance measures applicable to the Healthy Start program. Additional data elements are collected, such as characteristics of participants, risk reduction and prevention services, and major services, including core services and system building.

The Healthy Start National Evaluation

Ms. Susanna Ginsburg presented background information and an update on the evaluation activities, described the overall evaluation approach, reviewed the evaluation design of phase 1, and described the next steps. She announced that OMB clearance has been obtained and the survey is in the field, with the anticipated first deadline in the first week in August.

Evaluation Overview, Background, and Update

The evaluation is a 4-year effort. Phase 1 is focused on the full universe of grantees, and phase 2 is a more indepth evaluation of a subset of grantees. Three important principles evolved from the initial design activity:

1. The evaluation is of the national program, not of individual grantee performance.

2. The initial phase 1 evaluation focuses on implementation of the program linked to results.

3. Key stakeholder inputs are critical to the evaluation effort.

A 2-year contract was awarded in September 2002 to Abt Associates, Inc., and its subcontractor Mathematica Policy Research, Inc. The evaluation is designed to conduct an implementation evaluation. The focus is on all 96 grantees.

The continuing applications and all of the material prepared by the grantees for this new grant year have been received by the program and are being forwarded to the evaluators,

who are abstracting the grantee information. OMB clearance was received, and the survey is now in the field. Planning for phase 2 is under way.

Overall Evaluation Approach

A participatory approach to the evaluation was used to obtain input to the design and the data collection instruments. The primary stakeholders are the Healthy Start program itself, the grantees, TEPEHS, and SACIM. Input from the grantees was sought through national meetings, a listserv, and pilot testing. The inputs helped clarify the emphasis of the phase 1 evaluation, refine the key evaluation questions, develop and expand the conceptual model or framework for understanding the Healthy Start program, develop content for and refine the data collection tools, and enhance the willingness to participate in the survey efforts.

The evaluation will answer three main questions during phase 1:

1. What are the features of the Healthy Start programs?

2. What results have the Healthy Start programs achieved?

3. What is the link between program features and program results?

Phase 2 will address a fourth question: What types of Healthy Start programs (or program features) are associated with improved perinatal outcomes?

Review of Phase 1 Evaluation Design

The evaluation team developed a logic model to help it understand how the program is expected to affect results and outcomes. Two additional diagrams support more detailed examination of implementation and results. Together, these models provide a conceptual framework to help identify key features of the program and the types of results to be achieved and to develop appropriate data collection tools.

The logic model broke down the outcomes defined by the national program into intermediate and long-term outcomes. The national program identified three long-term outcomes: (1) reduced disparities in access to and utilization of health care services, (2) improved consumer voice, and (3) improved local health care system. The disparities outcome was divided into disparities involving access and disparities involving health status. Intermediate outcomes exist on the service side (changes in utilization, referrals, service intensity, behavior changes, and medical home) and the health systems side (coordination and collaboration, increased capacity, new services, cultural competence, consumer or community involvement, and impact on community values). The evaluation also is looking at the core services, program infrastructure, systems building, target population, and community characteristics.

The hypothesized link between Healthy Start services and results looks at the areas of reduction of disparities in pregnancy outcomes, infant outcomes, and women's outcomes. Research has shown that a set of evidence-based practices have an impact on reducing disparities, and the question involves how the Healthy Start program enables entry, access, and participation in those services. Services might be provided directly, contracted for, done by referral, etc.

On the systems side, the evaluation will look at two kinds of outcomes or changes that happen as a result of systems activities: changes with direct impact on participants and larger system changes. The survey will explore the systems activities in which the Healthy Start grantees actually are engaged.

Ms. Ginsberg described the data collection strategy that is part of the evaluation design. A reliance on primary data collection will ensure consistent, high-quality data. Phase 1 emphasizes primary data collected by the survey and supplemented by grantee reports and grantee calendar year 2003 performance measurement data. The use of data contained in the grantee program reporting requirements will be limited by its consistency and quality.

The survey underwent an intensive development process that entailed both pilot and cognitive testing. It was found that grantees generally have the necessary information to respond to the questions in the survey. The survey is long but doable. The electronic format will increase the ease of responding. The mailing included a disk as well as a paper copy to use for reference. The information will be supplied electronically. Refinements were made to the survey to better coordinate with new grant guidance requests. There were a minimum number of OMB questions.

The scope of the survey includes four aspects:

1. *Staffing and organizational structure.* Survey questions ask about types of staff and staffing issues, such as training, cultural competence, turnover, and service sites.

2. *Healthy Start services components.* The components covered by the survey include outreach and recruitment, intake, enrollment, retention, risk assessment, service planning, case management, enabling services, health education, home visiting, smoking cessation and reduction, perinatal depression, interconceptional care, services to infants and toddlers, and male involvement services. Another series of questions covers organizational strategies, staffing, and barriers.

3. *Systems components.* The survey contains fairly extensive questions about the various entities in the communities that Healthy Start relates to and the relationship of Healthy Start to those organizations and the nature of those relationships. Other questions include how grantees address the need for systems changes, community voice, results achieved, and barriers.

4. *Reflections on program and results.* Respondents are asked to reflect on their program, the results they have achieved, and how they think they are doing.

The structure and content of the grantee reports were revised to improve consistency across grantees. Some data elements are being abstracted from the grantee reports to reduce the reporting burden on the grantees. Data from the grantee applications may provide more detailed descriptions of Healthy Start activities.

Another data source is the performance measurement data. The data collection strategy is designed to complement (not duplicate) the information being collected through the performance measures. MCHB is currently reviewing the submitted performance data from the grantees. The evaluation has identified specific performance measures to consider for the phase 1 evaluation depending on the data quality. Potential performance measures included (1) number of people served, (2) the percentage of pregnant clients who had a prenatal visit during the first trimester, (3) adequacy of prenatal care, (4) the percentage of women and children with a medical home, (5) low birth weight births, (6) assessment of system of care for women's health services, (7) incorporation of cultural competence elements, (8) facilitation of provider screening for risk factors, and (9) number of clients screened, counseled, or referred for further assessment or treatment by risk factor.

The evaluation analysis plan has three components:

1. *Descriptive analysis of program features.* The evaluation will produce a national profile of Healthy Start program features. It will describe the Healthy Start program features, including the range and variation across programs and the "national program." A component-level analysis will show the range and variation of the approaches.

2. *Descriptive analysis of the results achieved by Healthy Start programs.* The evaluation will describe the results of Healthy Start programs during the current grant cycle, based on data collected through the survey and performance measures. The primary reliance will be on data from the survey to provide consistent quantitative data by which to describe the results achieved by the national program. The performance measures will be used selectively to support evidence on the results.

3. *Linking program features with program results.* The evaluation will seek to discover whether certain features or approaches are associated with particular results. Descriptive and multivariate analysis will be used to determine how the results vary in relation to the way programs are structured. The analysis will control for certain basic characteristics. The specific analytic approach will be developed based on findings from the first and second components.

Next Steps and Anticipated Timeline

A large number of the surveys should be in by August 6. The evaluators are continuing to abstract grantee information and are waiting to receive the program measurement data from the Healthy Start group. Data analysis will take place between September and November. A draft final report will be submitted in January or February, and the final report will be submitted in March. The plan for phase 2 is to focus on the outcomes by using a subset of grantees. Case studies and field work will enable an examination of the systems aspects of the program and an assessment of the overall program in those sites.

Ms. Ginsburg asked for input on the selection of sites in States that have linked data files to analyze Healthy Start participants versus non-Healthy Start participants. The evaluators also are considering the use of a client survey to ascertain information about interconceptional services. Performance data and other data within the program will be used to help build the database. A subset of grantees will have good data on their individual programs. That data could be synthesized into a data set to enrich the national evaluation.

Discussion

The presentations by Ms. Badura and Ms. Ginsburg elicited the following questions and comments:

- Dr. Miller thanked the presenters for their work on Healthy Start and the Healthy Start evaluation and referred to SACIM's ongoing interest in the program.

- Dr. Hayes expressed some confusion about the earlier evaluation and the current national evaluation. Ms. Badura explained that the initial 15 sites had the opportunity to determine the services they would offer. The initial evaluation revealed that the most significant impact came from case management, the use of the community health workers, and the health education activities. MCHB then set some uniform standards for the sites. Dr. van Dyck explained that a 5-year evaluation of the initial sites found that two sites had reductions in infant mortality, one at 50 percent and the other at 38 percent. About half the sites had significant reductions in low birth weight or better entrance into prenatal care. The Healthy Start program then changed, based on the lessons learned from that evaluation and those first demonstration sites. The current evaluation is a new evaluation of the reconstituted program.

- In response to a question from Dr. Hayes, Dr. van Dyck stated that Dr. de Leon Siantz is SACIM's liaison to TEPEHS.

- Dr. Hayes asked how the performance measures used in the national evaluation line up against the performance measures in the Title V block grant. She pointed out that most of the sites are clustered around the east coast, and some of the worst outcomes are anticipated in the South. Dr. Hayes asked about the evaluation outcomes being used in policy development at the Federal, State, and local levels in terms of systems

changes. Ms. Ginsburg acknowledged that the evaluation recognizes the importance of looking at the grantees in relationship to Title V. Several survey questions address this issue and should result in preliminary information that will be helpful in exploring that relationship. Ms. Badura added that the evaluation outcome measures are applied only to Healthy Start program participants, not community-level participants. Many of the survey questions parallel the block grant questions, but they focus on program participants rather than on the population as a whole.

- Dr. Bronner stated that the Healthy Start program is an excellent example of a large-scale community-based participatory research model, which presents challenges for analysis. Some of the power of the community-based participatory methodology will be masked in the overall analysis if the sites are not taken into consideration because an underlying theoretical construct of the participatory model is that each of the designs has been specified according to the problems and the contextual issues. How can the theoretical construct be maximized in the analysis? Ms. Ginsburg explained that the evaluation will not identify individual grantees or projects. Individual projects will be discussed without being identified. Analyses will be based on individual projects, with their contextual variables, and then aggregated.

- Dr. Guyer asked whether the new committee members could receive a bibliography of previous reports about Healthy Start. He also commented on the methodology of the evaluation and pointed out the absence of an initial evaluation design, randomization, control groups, and control sites, all of which, combined with a very complicated set of evaluation questions, results in several threats to validity. How is TEPEHS advising the evaluators about what can be gotten out of the evaluation? Dr. Guyer pointed out that "some of the very simple messages end up being the most powerful ones." Very complicated evaluation designs sometimes obscure the powerful messages, both positive and negative. He warned, in particular, about problems with trying to determine a dose effect of complicated programs. Ms. Ginsburg acknowledged that the evaluators and TEPEHS are very aware of the danger cited by Dr. Guyer, but they are confident that some questions can be answered. Regarding the dose effect, Ms. Ginsburg explained that the evaluators are looking for a threshold level of participation to define "participants," not a dose, and that dialogues with grantees have elucidated different ways of defining participation in Healthy Start programs. This definition is important in order to distinguish, for example, an individual who may attend a community education session from an individual who is receiving case management services. Dr. Guyer described an alternative approach in which the subjective assessment of good programs and poor programs done on a scale ended up being just as good a predictor of program outcomes as what was collected with millions of dollars worth of data collection. Sometimes methodologically sophisticated, complicated evaluations do not give a good message.

- In response to some clarifying questions from Dr. Cernoch, Ms. Ginsburg explained that a client survey of a subset of grantees is under consideration. Although there is some interest in using results of local evaluations, these evaluations vary

considerably. It might be possible to synthesize a selected number of local evaluations, which will be completed during phase 2 of the evaluation in order to enhance the understanding by the national program of what is happening at the local level. Ms. Badura stated that many programs are conducting client satisfaction surveys. MCHB also conducts a survey of its grantees and the participants in the grant program. Dr. van Dyck explained that the survey is done across all Government agencies of their clients to compare end users across a wide variety of Government agencies in a consistent way.

- Dr. Bronner asked whether the survey contains questions that are structured around some specific and already agreed-upon policy outcomes. Ms. Badura responded that the questions about core systems results and the component of interconceptional care and a medical home for women are very promising in terms of policy interventions. The focus is on women's health rather than merely the pregnancy component as the intervention to decrease infant mortality and improve outcomes. Dr. Bronner suggested that the report be structured with that consideration as a component. Ms. Ginsburg agreed that that component will be in the report. She stated that the evaluation cannot address the broader question of comparing the Healthy Start intervention with the outcomes of other interventions. However, having more specific information about Healthy Start outcomes can help to inform that discussion.

DEVELOPMENT AND FOLLOWUP OF PREMATURE AND LOW BIRTH WEIGHT INFANTS

Marilee C. Allen, M.D., Professor of Pediatrics, Johns Hopkins University School of Medicine

Dr. Marilee C. Allen outlined the objectives of her presentation:

- To describe the range of health and neurodevelopmental outcomes for extremely preterm and low birth weight infants

- To describe rates of health problems and neurodevelopmental disabilities by birth weight and gestational age groups

- To discuss important risk factors for major neurodevelopmental disabilities in preterm and low birth weight infants

- To discuss the implications of these findings for our health care systems

Neonatologists think of premature babies as those born at the lower borderline of viability, who take tremendous amounts of resources, require resuscitation at delivery and mechanical ventilation, and are often in the neonatal intensive care unit for months at a time. However, the population of preterm infants is a very heterogeneous one, with a wide range of etiologies, complications, and outcomes. The same is true for low birth weight babies. Etiologies and complications both have a significant impact on health and neurodevelopmental outcomes. Dr. Allen sprinkled her presentation with photos of

children she has treated, and she described their cases to illustrate the points she made about various outcomes related to prematurity and low birth weight.

Range of Outcomes

The criteria for determining preterm outcomes are birth weight, gestational age, and maturity. Prematurity was originally defined as birth weight less than 2,500 grams, but children in that category are now termed "low birth weight." By the 1960s, the difference between birth weight and gestational age was recognized. Some low birth weight children are full-term children who are small for their gestational age or have IUGR. Therefore, prematurity is now defined as gestational age below 37 weeks. Most outcome studies still report outcomes in terms of birth weight because birth weight is so reliably measured and gestational age is much more difficult to ascertain. Dr. Allen pointed out that birth weight and gestational age are really proxies for maturity. The degree of maturity determines, for the most part, whether babies live or die and whether they have complications; preterm infants have complications because their organs are not sufficiently developed to allow them to survive outside the womb without additional medical resources. There are no good measures of maturity.

The four birth weight categories are (1) low birth weight (less than 2,500 grams), (2) very low birth weight (less than 1,500 grams), (3) extremely low birth weight (less than 1,000 grams), and (4) incredibly low birth weight (less than 750 grams). Babies with birth weight below 600 grams and below 500 grams are called "micropreemies."

Over the past several decades, mortality has decreased for babies of each birth weight and gestational age group. Babies at the lower borderline of viability take a tremendous amount of resources. Most people would agree that 23 weeks of gestation is probably the reasonable lower limit of viability, although a few infants survive at 21 and 22 weeks of gestation. Racial differences in survival at the borderline of viability are quite pronounced. In fact, preterm African American infants have a survival advantage. In the 1970s, the gestational age at which 50 percent of white babies survived was 26.8 weeks of gestation and a little over 1,000 grams; in the 1990s, it declined to 24.5 weeks of gestation and slightly under 700 grams. In the 1970s, the gestational age at which 50 percent of African American babies survived was 25.2 weeks of gestation and a little under 1,000 grams; in the 1990s, it declined to 23.9 weeks and 670 grams. The gap between the survival rates of white and African American infants has decreased in the past two decades. In fact, the traditional survival advantage of the African American preterm infant has diminished so that from about 28 weeks of gestation and longer, the races are almost even. Mortality goes up as they approach term for the African American infants.

Health and Developmental Outcomes

The most significant chronic health problem of preterm infants is chronic lung disease (CLD). The best way to define CLD is by its effect on the infant and the infant's need for support, that is, the requirement of oxygen for more than 28 days. The criterion used to

define oxygen use was 36 weeks postmenstrual age, that is, gestational age at birth plus chronologic age. A baby who is 8 weeks old and was born at 28 weeks, would be 36 weeks postmenstrual age.

CLD is associated with multiple infections, central nervous system injuries, retinopathy of prematurity, poor nutrition, and inadequate growth. Infants with CLD often have prolonged length of hospital stay. Their rate of rehospitalization and surgery is much higher than the rate for preterm infants who do not develop CLD. CLD also is associated with language delay, minor neuromotor dysfunction, cerebral palsy, low IQ scores, and difficulty in school.

The other very significant chronic health problem of preterm infants involves nutrition and growth. It is very difficult to feed premature infants and full-term IUGR infants. Controversy exists about the optimal feeding regimen for these children. Many studies have shown that poor nutrition affects growth, development, and immunity. Recent studies suggest the fetal origins of adult disease; a significant relationship exists between low birth weight and adult hypertension, diabetes, heart disease, and kidney disease. The fetal origins of adult disease seem to be related to IUGR, not prematurity, and to the velocity of childhood growth, with the highest risk in children who quickly develop overweight and obesity problems.

Neurodevelopmental Disabilities

Research over the past four decades has studied the major disabilities, which are cerebral palsy and mental retardation. Sensory impairment, both hearing and visual, appears in the most immature infants and the sickest infants. School and behavior problems include learning disabilities, attention deficit hyperactivity disorder (ADHD), minor neuromotor dysfunction, and sensorimotor inefficiencies.

Cerebral Palsy

A number of studies have examined the prevalence of cerebral palsy in children by birth weight. In normal birth weight children, the prevalence of cerebral palsy varies from 0.4 to 1.3 per 1,000, depending on the study. Micropreemies have an increased risk of cerebral palsy over normal birth weight children, about 9 to 12 per 1,000. For very low birth weight babies (birth weight below 1,500), the prevalence is between 40 and 130 per 1,000. About half of the survivors with birth weight below 500 grams have cerebral palsy.

The most common type of cerebral palsy in preterm infants is spastic diplegia, and it tends to be mild. Many clinicians and outcomes researchers now make a distinction between mild cerebral palsy and disabling cerebral palsy.

In the continuum of motor impairment, the term “minor neuromotor dysfunction” refers to children who have mild abnormalities on their neurodevelopmental exam but no, or only mild, motor impairment. They are frequently known as clumsy children or “toe

walkers," and they frequently have sensorimotor inefficiencies. They also may have oromotor dysfunction and, therefore, present as feeding problems. The children who are very asymmetric often demonstrate either early or late hand preference; normal hand preference develops between ages 1 and 2 years. Fine motor dysfunction is frequent. One report found that as many as 70 percent of the extremely low birth weight children had some fine motor dysfunction at school age. Fine motor dysfunction also is frequent in children with CLD, who often have tremors that may be related to the medications they take.

Cognition in Preterm Children

Preterm children have a normal range of intelligence. Several meta-analyses have found that the mean IQ for the low birth weight children is about 5 to 10 points lower than for normal birth weight children. More preterm children have mental retardation and borderline intelligence and will need special education in school. IQ scores are inversely related to birth weight across the entire population; therefore, the incidence of mental retardation goes up with the smaller child or the more immature infant. Socioeconomic status affects the cognitive abilities of low birth weight children. The older the child, the more accurate the assessment of cognitive ability.

Preterm infants may have initial expressive language delay, but receptive language is usually normal. Their vocabulary may be normal when they are school aged, but they may experience difficulty with syntax, abstract verbal skills, and verb production. They have a very high risk of developing learning disabilities later. Another group of preterm children have visual-perceptual and visual-motor integrative problems, which can lead to difficulties with reading. Because IQ scores are an average and intelligence is really many different abilities, reliance on IQ scores as an outcome can mask more subtle deficits. Many preterm children may have normal intelligence, but the variation between their areas of cognitive strengths and cognitive weaknesses can disrupt the learning of academic skills.

Learning Disability in Preterm Children

In comparison with full-term controls, very low birth weight children with normal IQs have a higher incidence of language delay, have more visual-perceptual problems, have more difficulty with reading, and require more special education. Many of these children have difficulty with attention, executive function, memory, spatial skills, and fine motor function. Their rates of learning disability are independent of their IQ scores, which are average. Many preterm children have better verbal cognitive skills than nonverbal abilities. Environment has a moderating effect on learning disability.

Visual-perceptual and fine motor difficulties can make writing a major problem for preterm children. The problem of learning disability is higher in males—as much as 2.5 to 5 times greater than in females. The efficiency of the children's work becomes a problem by middle school, and the likelihood of learning disability increases with age.

For extremely low birth weight children, 74 to 86 percent at age 8 years need some kind of assistance. The required interventions change as the children get older.

Behavior Problems in Preterm Children

Behavioral and social problems are difficult to measure. Symptoms of ADHD are 2.6 to 6 times more frequent in very low birth weight and extremely low birth weight children than in normal birth weight children. Conduct disorders, shyness, unassertiveness, and withdrawn behavior also are common in preterm children. Cognitive, motor, and social skill deficits can affect self-esteem and peer relationships.

Intrauterine Growth Restriction

Developmental outcome for children with IUGR is related to etiology, timing, and perinatal complications of IUGR. Growth-restricted babies are very vulnerable to the stresses of labor and delivery. They also may have perinatal asphyxia. Prospective studies of full-term small-for-gestational-age infants fail to show an increased incidence of either cerebral palsy or mental retardation, probably because their numbers are so small. However, large retrospective studies of children with cerebral palsy or mental retardation show that a disproportionate number of these children were IUGR. The prospective studies of full-term IUGR babies show that these children have a very high incidence of the more subtle problems of central nervous system function, learning disabilities, ADHD, minor neuromotor dysfunction, and behavior problems, especially in males.

Premature IUGR infants appear to have the same high risk of major disability as appropriate-for-gestational-age premature infants who have the same birth weight. Therefore, longer length of gestation did not confer an advantage on those children. Their outcome tends to be similar to the appropriate-for-gestational-age children for their birth weight. Obstetricians must balance the risks of IUGR, which include fetal death, with the risks of preterm delivery. Dr. Allen speculated that the changes of increased incidence of prematurity and decreased fetal death may be due to the increased willingness of obstetricians to brave the risk of prematurity and balance that risk against IUGR.

Diagnosis of Neonates/Risk Factors

It is virtually impossible to diagnose any of the neurodevelopmental disabilities in the neonatal period. However, it is possible to select a group of neonates who are at high risk for neurodevelopmental disabilities. These infants require comprehensive neurodevelopmental followup and, as needed, early intervention.

“Risk” means an increased likelihood of disability. Not everyone who is at risk develops disability, and many who develop a disability had no risk factors. Statistical associations between risk factors and neurodevelopmental outcome do not imply causation. Risk factors vary in the strength of their association with disability: some carry a higher risk than others. Multiple risk factors have at least an additive effect.

Perinatal or neonatal risk factors include background characteristics such as socioeconomic status, which has an influence on cognitive outcomes. Dr. Allen stated that, in her opinion, factors such as socioeconomic status, social class, and parental education are all proxies for an enriched child-oriented environment, that is, for parents who have time to devote themselves to stimulating, nurturing, and caring for their newborns.

Obstetric and prenatal risk factors include catastrophic events, such as abruptio placenta and cord prolapse, which do not happen very often and are not good predictors. Better predictors are maternal illness, maternal drug ingestion, congenital infections, and chorioamnionitis. Multiple gestations often result in IUGR and prematurity. Condition at birth predicts outcome, although the abnormalities of central nervous system structure and function are better predictors. Low Apgar scores are worrisome, but a child who is very hypotonic, does not eat, and has neonatal seizures is much more likely to have disability later. Neonatal complications, such as CLD, neonatal seizures, and infections (sepsis and meningitis) are concerns. Dr. Allen mentioned her suspicion that it is the treatment of the complication, rather than the complication itself, that increases the likelihood of disability. She pointed out that most drugs used in neonatal intensive care units have not been studied in newborns, premature infants, or low birth weight infants. Dr. Allen referred to studies that found a higher incidence of cerebral palsy in children treated with high doses of steroids for CLD compared with infants who were not treated with steroids. The best predictors of disabilities are abnormalities of the central nervous system structure, which can be detected with neuroimaging. Other predictors are related to evaluating central nervous system function, particularly through examining the babies or looking at their movements.

Implications of Disability and Quality of Life

The effort to predict outcome is meant to help the family adapt to what the child's functional limitations will be, to help the family set realistic goals and have appropriate expectations for the child, and to help the family monitor the therapeutic and educational interventions and prepare for a lifetime of advocacy for the child.

A series of Canadian studies has looked at extremely low birth weight children over two decades. More recent studies of adolescents born with extremely low birth weight have shown that the adolescents rate their own functional level far more favorably than their health care providers and parents rate their functional level. This fact raises the question of whose point of view should be used to rate their quality of life.

Summary

The most common health sequela of premature and low birth weight children is lung disease, including asthma or reactive airway disease, frequent colds or pneumonia, and rehospitalizations. Nutrition and growth are often a concern, in terms of both poor growth and overweight or obesity. The impact of the improved survival of premature and low

birth weight children on rates of adult hypertension, diabetes and heart disease, and kidney and lung disease is unknown.

The majority of preterm and low birth weight children do not have major disability. However, the more immature the infant, the higher the risk of major disability and sensory impairment. The cause, severity, and timing of IUGR influence the risk of disability. The best predictors of neurodevelopmental outcome are signs of central nervous system injury. Many children have multiple risk factors. Risk does not mean cause; the condition, associated factors, and treatment can all play a role in causality.

Preterm and low birth weight infants have a higher incidence of learning disabilities, ADHD, minor neuromotor dysfunction, and sensorimotor inefficiencies than term children. Furthermore, these milder manifestations of central nervous system dysfunction can have a profound influence on the child's school performance, behavior, peer relationships, and self-esteem.

In an environment of limited resources, risk factors can help focus neurodevelopmental followup and early intervention efforts. High-risk infants require careful, focused neurodevelopmental followup, with appropriate referral for early intervention services. However, many insurers will not authorize neurodevelopmental followup visits for infants with risk factors who do not yet have a diagnosis of disability. Another problem is that many child health care providers do not have the training or resources to follow development in high-risk infants or to counsel parents.

The limitations of early intervention include a lack of efficacy and safety data. In most systems, individuals who provide the services often also do the evaluations, which results in a lack of objective measures. Dr. Allen asserted that early intervention services should be individualized to the child and family and should be very focused. Early intervention providers are generally not prepared to make or discuss diagnoses or to counsel parents about what to expect in the future. Infants with mild delays often receive only short-term interventions. Mild motor disability may signal a later learning disability, which necessitates continuity with preschool services. Interventions can improve cognitive and functional abilities, but they must be ongoing or their effects will be lost.

In terms of family support, evidence strongly suggests the positive influence of an enriched environment on cognitive development. However, maternal depression is common; it occurs in as many as one-third of mothers of premature infants and is more frequent with multiples. Maternal mental health affects child development, but many mothers are unable to get insurance coverage for mental health services. Although many obstetricians treat maternal depression, there is no provision for long-term support.

More resources are expended on saving sicker and more immature infants, with fewer resources available for neurodevelopmental followup, early intervention, and parent support services. There are frequent problems with cooperation among and communication between health, education, and social service agencies. Another obstacle is limited mental health services for parents or children. Early intervention services do

not seamlessly transition to services at preschool and school age. Dr. Allen expressed concern about the current educational approach, which focuses on the least restrictive educational environment. She stated that this approach sets these children up for failure. Another system problem is the lack of provisions for long-term followup through childhood to adulthood.

Some exciting research prospects involve neonatal intensive care unit studies on neuroprotection strategies, better treatments of lung disease, and relationships between nutrition, growth, and development. Another research need involves the evaluation of current and new treatments for their impact on neurodevelopmental outcome. In addition, research is needed on the improved prediction of neurodevelopmental outcome, including greater accuracy and prediction of the type and severity of disability, the cost of determining risk factors and establishing early intervention strategies, and the study of neonatal drugs and early intervention strategies. In addition, support is needed for long-term followup studies through childhood and into adulthood.

Discussion

Dr. Allen's presentation led to the following comments and questions:

- Dr. Ryan reiterated that many insurers will not authorize neurodevelopmental followup visits for infants with risk factors. He commented that States have the option in the early intervention program to cover children with risk factors. Practitioners should be aware of the possibility of using this provision as an avenue to a variety of services, including, in some States, a comprehensive followup evaluation. Dr. Ryan also posed a question about causality. In the past, complications of prematurity were thought to be caused by prematurity, but now it is thought that some of the complications are preexisting fetal conditions that might have a role in precipitating preterm delivery. If the earlier understanding is more correct, then obstetrical interventions to prevent prematurity can prevent the sequelae. If the more recent understanding is correct, then the situation is more complex. Dr. Allen stated that whatever triggers preterm delivery is very complex and that the abnormal baby is often born either early or late and also may have abnormal growth.

- Dr. Hayes noted that Dr. Allen's presentation raised many ethical issues and long-term policy issues related to education, one of which involves the least restrictive educational environment policy. She noted that a representative from the education field should be on the LBWCC to address the issue. Dr. Allen responded that a less rigid application of the least restrictive environment principle would be appropriate so that children at risk for problems in school will get the extra help they need earlier and more intensively to avoid failure and the emotional baggage that goes with this problem. Dr. Allen added that information about how children learn is not being incorporated into school environments or teacher training. Dr. Collins commented that the focus of neonatology has shifted over the past 20 years from survival to long-term followup. The public school system is ill-equipped to handle the learning disabilities of premature infants. These children require more resources than the

normal population and may learn in different ways. It is necessary to go beyond the medical model to include the social model and the educational component for these children.

- Dr. Cernoch commented on the systems problem or obstacles presented by Dr. Allen. She noted the difficulty in access to health care providers and specialists for children with special health care needs. Another component of the problem for parents is coordination of care, not merely on a daily basis, but across systems, for example, the education system, specialists, primary physicians, early interventionists, and so on. A third problem is access to information for families. Another concern involves the reimbursement system and labels for children. Dr. Allen explained that the use of labels depends on the context, for example, reporting back to health care professionals for study purposes versus deciding with parents what label should be used. She agreed that access to information is a significant problem, and she expressed concern about medical misinformation on the Internet and misinformation involving available services. Dr. Cernoch remarked that Family Voices is attempting to start family-to-family health information centers in every State.

- Dr. Tu asserted the importance of a multidisciplinary approach to evaluate problems and make diagnoses involving quality of life and quality of health for preterm and low birth weight infants.

- Dr. Bronner asked about studies on the long-term sequelae related to family formation and subsequent problems. Dr. Allen responded that one of her favorite studies was published in 1950. Pediatrician Julian Hess and nurse Evelyn Lundeen started the first hospital-based neonatal intensive care unit in Chicago at the Michael Reese Hospital. Dr. Hess published one of the first outcome articles about his survivors to convince people about the validity of trying to save these children. Dr. Allen also pointed out that a few studies have looked at young adults in terms of their employability, arrest rates, and school difficulties. Other studies of the impact of preterm birth on families, in particular, mothers of very low birth weight infants, have found a high degree of resiliency in terms of health-related quality-of-life issues.

HHS INTERAGENCY COORDINATING COUNCIL ON LOW BIRTH WEIGHT AND PRETERM BIRTH OVERVIEW

Duane Alexander, M.D., Co-Chair, Interagency Coordinating Council on Low Birth Weight and Preterm Birth; Director, National Institute of Child Health and Human Development, National Institutes of Health

Peter C. van Dyck, M.D., M.P.H., Co-Chair, LBWCC; Associate Administrator for Maternal and Child Health, Health Resources and Services Administration; Executive Secretary, Secretary's Advisory Committee on Infant Mortality

Dr. van Dyck introduced the participants to the task of reviewing the LBWCC recommendations along with the SACIM recommendations and suggesting a final list of recommendations for priority HHS research. He reviewed the purpose and charge of the LBWCC regarding the development of an HHS-wide research agenda on low birth

weight, preterm birth, and SIDS. In explaining the process that resulted in the penultimate document under review, Dr. van Dyck referred the participants to a draft inventory of the research conducted in all the agencies, a list of evidence-based interventions that might be useful for the grantees funded under the Closing the Gap Initiative on Infant Mortality, and SACIM's initial research agenda suggesting the important research topics and emphases in the prevention of preterm birth, low birth weight, and SIDS. Dr. van Dyck asked the participants to review the summation of the work of the LBWCC, SACIM, and the low birth weight committee for submission to the LBWCC and integration into its final report to the Secretary. He praised the work of Dr. Koontz, who led and facilitated the effort to distill and condense the diverse information into a cogent draft document.

Dr. Hannemann characterized the inventory of research as presented in the grid as comprehensive and accurate and called for prioritizing the research effort, perhaps with the help of a panel of experts in the field, and for emphasizing new approaches or ideas.

LBWCC RESEARCH PRIORITIES: DISCUSSION AND SACIM RECOMMENDATIONS

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Duane Alexander, M.D., Co-Chair, Interagency Coordinating Council on Low Birth Weight and Preterm Birth; Director, National Institute of Child Health and Human Development, National Institutes of Health
Peter C. van Dyck, M.D., M.P.H., Co-Chair, LBWCC; Associate Administrator for Maternal and Child Health, Health Resources and Services Administration; Executive Secretary, Secretary's Advisory Committee on Infant Mortality

Dr. Alexander oriented participants to the material under discussion and asked for their reaction to the LBWCC's recommendations for research priorities.

Preterm Birth

- *Study mechanisms of initiation of labor, with emphasis on better biomedical, social, and behavioral indicators of risk for preterm delivery. Include a focus on subgroups of at-risk populations.*

The participants offered the following questions, comments, and suggestions regarding this recommendation:

— Dr. Guyer asked whether this research would include studies of the socioeconomic gradient in low birth weight or the links between social stress and poverty and biological mechanisms. Dr. Alexander responded that the social and behavioral influence and indicators are incorporated into this research topic as well as into others.

— A participant asked whether this research would include drug use, drug abuse, and over-the-counter medication use. Dr. Alexander replied that these areas of interest appear later in the recommendations and are contemplated overall.

— Dr. Collins asked Dr. Alexander to comment on his mention of the initiation of preterm labor in terms of preterm birth. Dr. Alexander explained that the LBWCC discussed initiation of labor in general, both term and preterm, and the need to understand what triggers each.

— Dr. Roberts mentioned that the list includes research implications and implementation implications. Dr. Alexander agreed that the list is a mix of research and action steps that are applications of a research advance. He called for the committee to decide how to handle this situation. Dr. Hayes added that knowledge and practice often diverge from each other and what is needed is a sense of how to measure what is known. Dr. Ryan mentioned the issue of understanding best practices in converting research to practice. What are effective ways of disseminating evidence-based practices in the real world? Dr. Hayes pointed out that the group could generate new research without ever determining the efficacy of current knowledge applied to practice. Dr. Alexander remarked that a huge variation exists in practice from one year to another and from one place to another, as evidenced by the use of antenatal steroids in preterm labor. Following a consensus conference on the use of antenatal steroids, the information became public, and, in just a few years, the use of antenatal steroids changed from 10 to 15 percent of pregnancies to 85 percent of pregnancies. The use of antibiotics to treat bacterial vaginosis is another example of the variation in practice. Dr. Hayes pointed out that having professional organizations arrive at a consensus is an intervention in itself.

— Dr. Alexander suggested the separation of research recommendations from applications of knowledge for the purposes of the LBWCC report. Dr. Collins concurred with that suggestion. Ms. Ryan commented on the difficulty of determining evidence-based practices for public reporting.

— Dr. Collins suggested that a specific statement be added to the recommendation regarding African Americans as among the at-risk populations.

- *Study the role of infection (including bacterial vaginosis and periodontal disease), inflammation, immune regulation, and gene-environment interactions on risk of preterm delivery.* There was no discussion on this topic.

- *Work with FDA and industry to hasten the process of getting 17-άH-progesterone to market and using it in practice for women with a prior preterm delivery.*

- *Speed the initiation of studies of 17-άH-progesterone for possible reduction in risk of preterm labor for women with twin or triplet pregnancy or cervical shortening.* Dr. Alexander noted that the protocol has been completed in the Maternal-Fetal Medicine Network for the twin and triplet pregnancy study and is either beginning or about to begin. Another protocol is in development for cervical shortening.

Input from the participants on these two recommendations was as follows:

— Dr. Ryan stated that 17-άH-progesterone should be brought to market but that its uptake and use will probably be protracted. A worthwhile addition to the research agenda might be studies of the best methods of disseminating research into practice. After Dr. Alexander pointed out that the recommendation captures both getting progesterone to market and using it in practice, Dr. Ryan clarified that his comment was meant in a general sense about the translation and dissemination of research into practice. Dr. Hayes stated that she would like to see a global directive on translation and dissemination in the research recommendations.

— Dr. Sapien stated, as an example, that practitioners are not using the asthma guidelines drawn up by an expert panel at the National Heart, Lung, and Blood Institute, and he stated that work might be needed on the pieces of the process to be effective. Ms. Ryan pointed out that a mechanism is needed for publicly reporting on the use of such guidelines, especially regarding maternal and child health, and that such a mechanism for reporting is linked to reimbursements related to the Centers for Medicare & Medicaid Services (CMS).

— Dr. Roberts reported that a body of literature addresses the diffusion of innovation and the utilization of research. Tapping into that literature might yield effective strategies for translating research into practice. Dr. Hayes supported this idea, stating that it relates to systems changes. Dr. Roberts added that some literature from HMOs also might present helpful ways to encourage clinicians to follow best practices (including use of incentives).

— Dr. Alexander suggested a new recommendation: *Develop innovative ways to introduce research advances, such as 17-άH-progesterone or treatment of infection, into practice and study their effectiveness.* Dr. Frigoletto mentioned that the use of antenatal steroids could serve as a model for this suggestion, although the pharmaceutical industry might be reluctant to make a product that entails relatively small volume and significant liability.

- *Revive the ICE in epidemiologic comparisons of preterm labor, low birth weight, SIDS, and infant mortality rates and perinatal practices among developed countries to assess and attempt to account for differences in outcomes.* Later in the discussion, after Dr. Guyer raised the issue of interpreting and classifying birth weights under 500 grams, the group decided to add this issue under this recommendation.

- *Assess and improve measures/surveillance methods for monitoring trends in preterm delivery risk.*

Input from the participants was as follows:

— Dr. Tu asked if the recommendation referred to fetal surveillance to ensure fetal well-being. Well-documented, well-supported measures of surveillance can guide practicing obstetricians or perinatologists to ensure fetal well-being. Dr. Alexander suggested

adding this idea under the topic of low birth weight, specifically, the recommendation for improving and disseminating standards for ultrasound dating of pregnancy.

— Dr. Frigoletto called for more accurate methods of collecting clinical data, namely, use of an electronic standardized medical obstetrical record. Dr. Hayes agreed with this reading of the recommendation and referred to the NCHS presentation on the timeliness of surveillance information. Dr. Alexander affirmed that the electronic record would be a measure and surveillance method for monitoring trends. The full report will capture the point about electronic records and other means of surveillance.

- *Consider holding an international state-of-the-science conference on preterm birth.* There was no discussion on this recommendation.

- *Support the initiative from the IOM for a new report on preterm birth that includes an examination of health and economic consequences of preterm birth.* Dr. Ryan suggested adding "health, *educational,* and economic consequences of preterm birth."

- *Promote the use of new techniques, such as modeling methods and sophisticated mathematical methods, to examine the complex systems and problems associated with preterm birth and low birth weight.*

Input on this topic included the following comments:

— Dr. Bronner mentioned the importance of identifying new information to be obtained from the data and reported on so that the data yield more information.

— Dr. Ryan referred to the widespread sense that unintended pregnancies result in poorer birth outcomes. He suggested an investigation, either through modeling or through a study, of the impact of effective prevention of unintended pregnancies on both preterm births and low birth weight. Dr. Hayes stated that this idea might be included in the first recommendation along with other social determinants that have implications for the health of both mothers and infants. Dr. Alexander stated that this idea could be incorporated into the discussion of the first recommendation.

— Ms. Ryan mentioned the absence of the subject of the impact and outcome of obesity on preterm birth or low birth weight. Dr. Alexander acknowledged the association between obesity and preterm birth and low birth weight and suggested incorporating obesity into the first recommendation as well.

— Dr. Sapien referred to the association between trauma and preterm birth. Dr. Alexander stated that this association also can be included in the first recommendation.

— Dr. Roberts suggested that discouraging ineffective practices, such as home uterine activity monitoring, might be put in the context of best methods to translate or disseminate research into practice.

Low Birth Weight

- *Develop and test more effective behavior change strategies to end smoking during pregnancy.* Dr. Baines suggested adding "prescription narcotics and other addictive substances" to this recommendation.

- *Improve and disseminate standards for ultrasound dating of pregnancy to reduce unintentional preterm/LBW induction of delivery.* Dr. Alexander mentioned that this recommendation will be expanded to include other means of monitoring pregnancy and fetal well-being status.

Input from participants on this recommendation included the following comments:

— Dr. Frigoletto mentioned that this recommendation could be misconstrued as suggesting routine ultrasound for dating purposes. The recommendation should be reworded to clarify its intent—to study the efficacy of ultrasound for accurately dating pregnancy. Dr. Alexander will work with Dr. Frigoletto on the wording of this recommendation.

— Dr. Tu noted that the accuracy of dating is established but that the technology is abused.

- *Address the increasing prevalence of requests by women for nonindicated elective cesarean delivery by holding a state-of-the-science conference on the topic.* Dr. Alexander explained that this conference will be held within 18 months.

Comments on this recommendation included the following:

— Dr. Tu asked if the wording should be changed to "nonmedically indicated elective cesarean section." Dr. Alexander noted that the wording was discussed by the LBWCC and that the council finally settled on this terminology.

— Dr. Miller mentioned that a state-of-the-science conference alone will not decrease nonindicated elective cesarean delivery; the popular media must broach the subject with women because some of the decision is driven by consumer demand, not science.

- *Investigate ways to discourage assisted reproductive technology practices that lead to multiple pregnancy.* Dr. Alexander mentioned the need for universally applied good practice standards involving ovulation-induction drugs and monitoring of the number of eggs released during a given cycle for fertilization.

- *Investigate possible associations of pharmaceuticals in pregnancy with LBW.*

The following comments were made about this recommendation:

— Dr. Frigoletto asked whether over-the-counter products, so-called naturally occurring products, or alternative medicines are included in this recommendation. Dr. Alexander asked for the committee's advice on this question. Dr. Roberts noted the importance of raising people's consciousness about the impact of supposedly natural substances. Dr. Alexander noted that the right word will be found to describe these substances.

Dr. Miller suggested adding a recommendation about helping to disseminate information to aid physicians and families in making critical decisions about very low birth weight babies and extreme interventions. Dr. Hayes noted that such a recommendation might advance understanding of ethical decisions and policy development. Dr. Tu raised the question of whether this issue involves research versus an ethics committee opinion. Dr. Collins upheld the notion of the importance of the research component of medical ethics and the idea of quantifiability as a part of the decisionmaking process. Dr. Miller pointed out that ethical decisions can be made only in the context of good information. Dr. Alexander stated that a new recommendation will be formulated regarding this issue and will be offered for SACIM's review.

SIDS

- *Expand studies of the impact of prenatal alcohol use by Native Americans on SIDS rates and possible effective interventions.* In response to a question from Dr. Bronner about whether the recommendation is limited to Native Americans, Dr. Alexander explained that the recommendation focuses on the Native American population because prenatal alcohol use is a very prevalent problem in that group.

- *Test the efficacy of postnatal public health nurse home visits for reducing SIDS rates in American Indian populations.* Dr. Baines suggested changing the terminology to include "community health representatives" and "community health aides."

- *Develop and test culturally appropriate educational materials and programs to reduce SIDS risk factors in American Indian populations and African American communities.* Dr. Alexander noted that this activity is being carried out in a research context and can be expanded.

Participants made the following comments about this recommendation:

— Dr. Cernoch suggested looking at channels of distribution and ensuring that the educational materials are family friendly as well as culturally appropriate. Dr. Roberts asked Dr. Cernoch to elaborate on what she described as family-friendly materials. Dr. Cernoch responded that family-friendly materials are very readable, have more pictures than words, and contain terminology that families can understand.

— Dr. Bronner stated the importance of studying the science of dissemination.

— Dr. Ryan pointed out that, in addition to families, childcare centers and childcare in general are important avenues for promoting the "back to sleep" message.

- *Attempt to develop methods to screen newborn infants for elevated SIDS risk.* In response to a question from Dr. Frigoletto, Dr. Alexander commented that apnea in the newborn is no longer considered a major risk factor for SIDS.

- *Intensify the Back to Sleep campaign to emphasize back rather than side sleeping.*

The following comments were made about this recommendation:

— Dr. Tu emphasized the importance of identifying a channel of distribution in marketing this message. She referred to Dr. Miller's observation that a substantial amount of faith-based type of instruction in childrearing is under way.

— Ms. Frazier asked about discussion on the "back to sleep" position with families in Native American or African American populations to determine why they choose not to put babies on their backs to sleep. Dr. Collins responded that the problem is the lack of information that back-sleeping is best. Another association involves the resistance to change on the part of maternal grandmothers who provide care. Provider communication with maternal grandmothers also is an issue. Dr. Alexander noted the reluctance on the part of the black community to accept a message delivered largely by the white community. Ms. Ryan added that the mechanism and methods used by hospitals in post-delivery classes should be examined.

- *Enhance the pursuit of the pathophysiologic mechanisms underlying SIDS that may provide a means of prevention beyond the back-sleeping position.*

- *Identify the small subgroup of genetic metabolic disorders that can cause SIDS and include them in any expanded newborn screening programs that are developed.* As a result of a suggestion by Dr. Ryan, Dr. Alexander stated that the wording of this recommendation would be amended to eliminate the ambiguity about the concept of etiology.

- *Develop and implement improved, standardized death scene investigation of sudden unexplained infant death syndrome (SUIDS), including SIDS, to increase the accuracy of national SIDS data.*

Input from the participants on this recommendation included the following comments:

— Dr. Sapien suggested that this recommendation include autopsy standardization and coroner and medical examiner standardization. Ms. Frazier noted that an accurate diagnosis of SIDS depends on both the death scene investigation and the autopsy. She called for education of first responders, coroners, and medical examiners on the standardization of the investigation and the autopsy. Dr. Hayes agreed with this suggestion and pointed out that it is another example of implementation.

— Dr. Sapien also asked about adding language concerning the use of child fatality review teams.

The Prioritization Process

Dr. Alexander noted that the recommendations apply to different agencies. He asked for input from the participants on how to go about the prioritization process.

The following comments were made concerning prioritization:

- Dr. Ryan commented that the prioritization process should look at the magnitude of impact and the strength of the evidence about the efficacy of the intervention or the research.

- Dr. Tu suggested that the chair and co-chairs undertake the task of prioritization.

- Dr. Cernoch asked how the committee will make its recommendations.

- Dr. Hayes stated that the committee must consider what the Secretary can actually take action on and must recognize that the implementer of those recommendations is MCHB. Dr. Alexander responded that the implementer is actually HHS.

- Dr. Collins suggested that the chair and co-chairs carry out the prioritization and disseminate that information by e-mail to the members of SACIM for their review. The Secretary will receive a written report.

- Dr. Miller suggested that a deadline be set for SACIM members to send their input, if they so desire, to the chair and co-chairs concerning the prioritization of the recommendations. The revised recommendations will be sent to the members by August 1, and their input will be due by August 17. By September 1, the members will receive the draft list of recommendations for review.

SETTING THE AGENDA FOR THE FUTURE
James W. Collins, Jr., M.D., M.P.H., Chairperson, Secretary's Advisory Committee on Infant Mortality

Dr. Collins explained to the new members that this session of the meeting is devoted to setting the agenda for the next meeting as well as discussing the committee's long-term goals. He asked for the participants' suggestions on topics and speakers.

Translation of Research Into Practice

- Dr. Hayes remarked on the IOM's interest in dissemination and communication to the public and to policymakers regarding messages pertaining to scientific research. Colleagues within the IOM, in particular, the Board for Children, Youth, and Families, may be able to speak on the optimal ways of translating research into practice and disseminating scientific messages to the public and to decisionmakers. An appropriate speaker on this topic is Ms. Rosemary Chalk.

- Dr. Bronner called for establishing a system for the activity. Because information is always emerging, the field of maternal and child health might benefit from a systematic approach. Panels of experts could write consensus reports that are developed into guidelines and then result in public dissemination materials.

- Dr. Roberts mentioned that Dr. Murray Enkin, from Canada, has addressed the implementation of care practices. The Cochrane Collaboration studied the meta-analysis of perinatal care practices and generated data about implementing the evidence through the use of influential individuals as well as other strategies. Dr. Enkin has written about strategies for implementing effective care in pregnancy and childbirth in various domains, including the practice domain, the public domain, professional organizations, and educational institutions.

Assumptions About Infant Mortality

- Dr. Hayes explained that she would like to have time for the committee to examine some of the assumptions underlying SACIM's approach to infant mortality, including what is known about preterm birth and low birth weight. The committee must include in its recommendations to the Secretary the need for interventions that address the gap between knowledge and practice. Geographical differentials and population differentials must be taken into consideration. It would be helpful to have information about what was learned from the first evaluation of Healthy Start. Progress depends on systems changes and on policy rather than on unimplemented recommendations. Dr. Collins expressed an unwillingness to guarantee that the committee's recommendations will actually result in policy decisions. Instead, he called for issuing recommendations that, if followed, can be beneficial.

- Dr. Hayes called for tying some of the recommendations to policy development at the State and community levels as well as at the Federal level. Hearing the point of view of a local or State official might be helpful.

- Dr. Guyer mentioned the value for SACIM of sharing a strategic approach to reducing infant mortality. Such a strategic framework has been considered in the literature published by Drs. Patricia O'Campo, Donna Strobino, Paul Wise, and Brian McCarthy. Dr. Guyer remarked that the Maryland Commission on Infant Mortality devised a blueprint for reducing infant mortality and packaged it for the Governor's office and the legislature.

- Ms. Frazier reemphasized the importance of implementation at the State level. She asked Dr. Hayes for her recommendation for the implementation of the recommendations. Dr. Hayes referred to having perinatal systems in place within States. For example, the First Steps evaluation was translated into policy for the entire State of Washington. SACIM might benefit from hearing about some examples. Reducing infant mortality at the local level will affect infant mortality rates at the State and Federal levels. Dr. Hayes repeated that examining assumptions about infant mortality can lead to strategic approaches to solving the problem.

- Dr. Collins asked for the name of a person whom SACIM could approach about giving a presentation. Dr. Hayes responded that both Title V and Medicaid are involved in the issue. Dr. Collins stated that SACIM will seek a speaker who is a front-line, State-level person who has successfully translated research into policy or at least knows the system and how to do so.

Electronic Surveillance System

- Dr. Guyer mentioned the possibility of developing an electronic vital statistics system that would provide numerator data on infant deaths in the United States in a very simple format by location, population characteristics, etc. The Georgia prototype is one such system. Possible speakers might be Dr. Michael Kogan from MCHB, Dr. Eve Lackritz from CDC, or engineers who specialize in the Geographical Information System (GIS) or bioinformatics. Having to wait 2 years to learn the infant mortality rate stymies SACIM's work. Technical experts must be empowered with the authority and resources to solve this problem so that the data can be applied to policymaking.

- Dr. Hayes raised the question of whether the data can become available with one stroke at the Federal level or whether the issue entails "a 50-piece puzzle." The question goes beyond an engineering issue and resides in the necessity of receiving data from 50 States. Dr. Guyer disagreed and pointed out that the incidence of infant deaths should be determined by a surveillance model, not a vital statistics or diagnostic model based on State borders.

- Dr. Baines pointed out the link between this idea and bioterrorism surveillance. In support of Dr. Guyer's idea, Dr. Bronner stated that the technology exists to communicate quickly and that infant mortality can become a part of a system of communication. Ms. Ryan raised the question of whether standardized definitions exist from State to State to guarantee consistent reporting of the basic surveillance information. Ms. Frazier suggested that the proposed system might be developed with bioterrorism dollars. Dr. Guyer pointed out that the classic use of the term "surveillance" implies indicators and that an investigation can be carried out in real time depending on the indicators. Dr. Bronner pointed out the iterative nature of the model under discussion.

- Dr. Eve Lackritz reported that CDC has linked databases on its Web site for GIS mapping. Therefore, the interactive method is already available. For example, the system has revealed that high teen pregnancy rates are clustered in the Mississippi Delta area; therefore, target populations can be determined geographically. CDC is working directly with States to reduce barriers to reporting, and MCHB epidemiologists are assigned to States to obtain data about infant mortality. CDC's NCHS has been advocating for an electronic system to help inform policy. The current systems are archaic and outdated. CDC's concern is rapid response and quick data collection. The CDC's NCHS system relies on States' budgets and personnel to put vital records together.

- Dr. Hayes asked if SACIM has seen any of the GIS information. Dr. Lackritz responded that CDC can provide a presentation if that would be useful. Dr. van Dyck mentioned that this information is available in the Title V Information System on MCHB's Web site. Dr. Hayes mentioned that the information would be helpful to SACIM as a committee.

- Dr. Ryan stated that his understanding of the model under discussion is that it would bypass State biorecords. The point of entry would be hospitals that fill out death certificates. He mentioned the Health Alert Network, which identifies emerging disorders very quickly. Opportunities might exist to use a piggyback strategy.

- Dr. Lackritz mentioned the importance of the quality, accuracy, and speed of information retrieval on the birth certificate. Births occur in hospitals, but prenatal care takes place in clinics, and links between the two are not always automatic. Dr. Sapien pointed out that some deaths do not occur in hospitals; therefore, using only hospital-based information would not be appropriate, and EMS systems are not universal in their reporting and are not electronic in many States. Dr. Collins concluded that the surveillance model depends on death certificates, not birth certificates.

- Dr. Tu asked about the channeling of data from the point of origin to the data bank. SACIM should be educated about the barriers and filters to the information. Dr. Baines agreed that it would be interesting to hear from some of the States regarding the barriers they face in the information flow. Dr. Tu mentioned that if the majority of the data come from hospitals, the American Hospital Association can be the first-entry point of contact. Dr. Hayes cited this issue as an example of testing assumptions to determine interventions.

- Dr. Guyer asked whether a committee could be formed of technical people from NCHS, MCHB, and CDC to brainstorm about this issue, answer questions about how the system works across the entire country, and propose a realistic solution to the problem.

Miscellaneous Topics

- Dr. Cernoch reiterated the topics that were touched on at the meeting, namely, obesity, bioterrorism, postnatal family support and medical home, putting research into practice and focusing on policy, and payment for services. Dr. Collins mentioned a presentation on stressors associated with preterm delivery in the Arab American population after 9/11. Ms. Ryan reinforced the idea of learning more about how CMS assigns weights for providers to determine reimbursements.

- Dr. Sapien noted that infancy extends up to 1 year of age and urged that SACIM consider themes beyond the perinatal period at each meeting. He identified domestic violence as an example.

- Ms. Frazier called for the committee to be mindful of a secondary audience, namely, those individuals at the governors' and health directors' levels who influence Medicaid policies, as well as money and resources, in the States. Dr. Guyer asked whether the committee could have access to an inventory or matrix of activities in the States related to infant mortality.

- Dr. Bronner suggested thinking about the life cycle in an organized way, starting with preconception (family planning). SACIM could solicit some reports on the state of infant mortality in the United States. Data could be compiled on pregnancy (programs, issues, budgets), delivery, and the first year of life. Once the state of infant mortality is ascertained, the problems to be solved can be determined. Following this organized strategy for determining data will allow the committee to "put a detailed window on" African American infant mortality. The resulting planned strategy can be measured in a report card format.

- Dr. Arrington mentioned that compliance is the source of frustration for practitioners in the Detroit area, in particular. A major component of the infant mortality problem in Detroit and Miami is that patients do not take advantage of available prenatal care, the WIC programs, and other existing programs. He would like to hear presentations about new and creative outreach methods that have been successful in the area of compliance.

- Dr. Roberts mentioned the issues of redundancy, fraud, and corruption in the system.

- Ms. Ryan proposed the topic of respiratory syncytial virus and its implications in infant mortality, especially in different geographic areas.

COMMITTEE BUSINESS

Dr. Collins announced that the next meeting of SACIM will be on November 11 and 12 in Washington, D.C.

He thanked the SACIM members for their participation in the meeting.

The meeting adjourned at 2:50 p.m.

PARTICIPANT LIST

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Robyn J. Arrington, Jr., M.D.
David Ray Baines, M.D., FAAFP
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Yvonne Bronner, Sc.D., R.D., L.D.
Jennifer M. Cernoch, Ph.D.
Deborah L. Frazier, B.A., R.N.
Fredric D. Frigoletto, Jr., M.D.
Bernard Guyer, M.D., M.P.H.
Robert E. Hannemann, M.D.
Maxine Hayes, M.D., M.P.H., FAAP
C. Renee Elmen Hollan, R.N., B.A.N.
Ann Miller, Ph.D.
Joyce E. Roberts, C.N.M., Ph.D.
Christina M. Ryan, R.N., M.P.A., B.S.N.
Kevin J. Ryan, M.D., M.P.H.
Robert E. Sapien, M.D.
Betty K. Tu, M.D., M.P.A.

Ex-Officio Members

Patricia Daniels
Food and Nutrition Services
United States Department of Agriculture
(for Peter S. Murano, Ph.D.)

Howard Zucker, M.D.
Deputy Assistant Secretary for Health
Department of Health and Human Services
(for Cristina V. Beato, M.D.)

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Lead Statistician, Reproductive Statistics Branch
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Other Attendees

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Office of the Assistant Secretary for Planning and Evaluation, HHS

Barbara Braden
BPHC, HRSA

Leanne Cusumano
CRC Consulting, Inc.

David de la Cruz
MCHB, HRSA

Angela Hayes-Toliver
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