Secretary's Advisory Committee on Infant Mortality

Meeting Minutes of June 13-14, 2007

Four Points Sheraton Washington, D.C.

GENERAL SESSION

WEDNESDAY, JUNE 13, 2007

WELCOME AND OPENING REMARKS

James W. Collins, Jr., M.D., M.P.H., Professor of Pediatrics, Northwestern University Medical School, Chairperson; Secretary's Advisory Committee on Infant Mortality
Anand Parekh, M.D., M.P.H., Senior Medical Advisor, Office of the Assistant Secretary for Health, Department of Health and Human Services
Dennis P. Williams, Ph.D., M.A., Deputy Administrator, Health Resources and Services Administration

Dr. Collins welcomed the participants to the meeting of the Secretary's Advisory Committee on Infant Mortality (SACIM). After the participants introduced themselves, Dr. Collins announced that Dr. Robert Sapien was promoted to the rank of full professor at the University of New Mexico. Dr. Collins requested a motion to approve the minutes from the November 2006 meeting. Dr. Frederic Frigoletto made the motion, which was seconded by Ms. Deborah Frazier, and the minutes were approved by a unanimous vote. [Point of clarification: The minutes were approved later in the meeting (beginning of Day 2) after Dr. Miller asked for time to review them.]

Dr. Collins reported that the SACIM subcommittee reports have been sent to the Secretary. [Point of clarification: The reports were finalized and at the time of the meeting were in the process of being sent to the Secretary. They will be sent by July 15, 2007.] He called the members' attention to the most recently updated infant mortality statistics from 2004 and noted that the preterm infant mortality rate for African American infants is 3.5 times higher than that for the general white population.

Dr. Parekh applauded SACIM for its holistic approach to the determinants of infant mortality and its ongoing support of cross-agency initiatives. He provided a short report from the Office of Minority Health (OMH), which recently launched an initiative called "A Healthy Baby Begins With You." The purpose of this national campaign is to raise awareness about infant mortality within the African American community. The initiative is part of a broader campaign called Closing the Gap on Infant Mortality for African American, American Indian, and Alaska Native Infants, which is a cross-agency initiative of the Health Resources and Services Administration (HRSA), Centers for Disease Control and Prevention (CDC), Indian Health Service, National Institutes of Health (NIH), and OMH.

In response to a question from Dr. Maxine Hayes regarding SACIM's recommendations to the Secretary, Dr. Parekh stated that the recommendations were submitted by Dr.

Collins to the Secretary's Office. Dr. Collins, HRSA staff, and staff in the Secretary's Office will communicate about the steps that the Department can take regarding the recommendations. The Department reviews the recommendations and attempts to incorporate them into existing programs.

Dr. Williams thanked the SACIM members and staff for their dedication and commitment to the Department's ongoing efforts to reduce infant mortality and improve the health of pregnant women and their babies. He also recognized Dr. Peter van Dyck, Dr. Ann Drum, Ms. Maribeth Badura, and the Maternal and Child Health Bureau (MCHB) staff for their commitment to and concern for mothers and families. Healthy Start projects are now sponsored in 99 communities in 37 States, the District of Columbia, and Puerto Rico. Dr. Williams also described a new HRSA booklet titled "Depression During and After Pregnancy: A Resource for Women, Their Families, and Friends." In addition, he acknowledged the value of SACIM's reports on improving birth outcomes and eliminating health disparities in infant mortality.

Dr. Williams provided a brief overview of some of HRSA's current activities and priorities, including the grants it has awarded to health centers across the country. HRSA is launching the High-Poverty County Presidential Initiative to bring the benefits of high-quality clinical care to poor counties. Up to 200 counties in 33 States will compete for 120 grants. HRSA will pursue a strategy that emphasizes clinical outcome measures and health information technology. The ultimate goal is to ensure that all of HRSA's programs work efficiently and effectively while achieving world-class clinical results.

Dr. Williams explained that HRSA recognizes the key role that information technology plays in delivering high-quality health care. The Office of Health Information Technology oversees an agencywide health information technology strategy that responds to the needs of the uninsured, underserved, and special needs populations. Dr. Williams described a Web portal that focuses on health centers, and he explained the role of health center networks that create opportunities for managing business operations. A new grant opportunity promotes the adoption and effective use of electronic health records.

Dr. Williams ended his presentation with a reference to the Ryan White HIV-AIDS Treatment Modernization Act, which aims to expand care and treatment into communities where the incidence of HIV infection is increasing. A number of new provisions are designed to deliver care more efficiently and more effectively.

Discussion

Dr. Williams' presentation prompted the following comments and questions:

- Dr. Ronald A. Finch asked about HRSA's attempts to engage the business community in its agenda, especially regarding the health centers and the use of private-public partnerships. Dr. Williams stated that HRSA does not engage aggressively with the business community; instead, HRSA gives grants to community-based organizations

to provide health services to specified populations and encourages these nonprofits to collaborate with their local institutions, especially through the use of health information technology. Dr. Finch noted that business coalitions and business organizations on health would be interested in a discussion of private-public partnerships.

- Dr. Robert Hannemann asked about the evaluation of communities' applications for community health centers. Are county medical societies, State medical associations, or existing medical facilities consulted before approval is granted for a new center or for expansion of an existing center? Dr. Williams referred to the HRSA Web site, which describes the grant application process, including letters of support in the community. The decision to award a grant is made by an objective review committee that deliberates, evaluates, and ranks the applications. Dr. Hannemann pointed out the importance of confirming the continuing need for community health centers through consultation with the State medical society. Dr. Williams stated that an eligibility requirement is that the center be in a medically underserved area.

- Dr. Bernard Guyer asked about the focus on information technology, specifically the issue of the lack of timeliness of vital statistics and the need for real-time data. Where does improving the vital statistics system fit into HRSA's priorities regarding information technology? Dr. Williams responded that the vital statistics system does not come under the direct purview of HRSA, but the Office of the National Coordinator for Health Information Technology at the Department is charged with putting new technology in place around the country. If the technology is in place around the country in hospitals and clinical settings, the ability will exist to capture data in an organized way. The President and Department are working steadily to bring this vision to reality over the next 10 years. Stating that the 3-year lag in data is unfortunate, Dr. Parekh referred to the attempts by the Office of the National Coordinator for Health Information Technology to develop standards for health information exchange and guarantee the interoperability of systems for data transfer. Dr. Guyer stated his belief that the problem is "imminently solvable" but will require leadership on the HRSA level. Dr. Hayes added that many States have been unable to adopt the standards for collecting vital statistics and that political will is needed to help these States meet the standards. Dr. Mary Lou de Leon Siantz referred to the possibility of creating partnerships with information technology businesses to solve the vital statistics problem.

- Dr. Frigoletto asked about the idea of an integrated medical records system and the possibility of gathering lessons learned, for example, from the successful attempt of Massachusetts General Hospital to establish such an integrated system. Dr. Williams acknowledged that Boston offers a model for using information technology to establish an integrated medical records system. He added that the Web site of the Agency for Healthcare Research and Quality was constructed to provide an electronic forum for sharing insights about the failures and successes of attempts at establishing integrated medical records systems.

- Dr. Ann Miller asked about the development of standards for the way in which States report information about births and deaths. Dr. Parekh responded that the National Center for Health Statistics is the source for information about the way in which individual States transmit vital statistics. He also described the establishment of the Certified Commission for Health Information Technology (CCHIT) to certify ambulatory care emergency medical records. CCHIT lists products approved on the basis of their interoperability. Another improvement involves the practice of hospitals providing information technology software to clinics in their region so that hospitals or health systems can be linked to individual clinics through electronic medical records.

MCHB UPDATE

Peter C. van Dyck, M.D., M.P.H., Associate Administrator for Maternal and Child Health, Health Resources and Services Administration, Executive Secretary for SACIM

Dr. van Dyck's presentation covered information about the 2008 budget, perinatal depression, and vital statistics. The House mark for the Maternal and Child Health Block Grant (MCHBG) is $750 million, which represents a substantial increase over the President's budget and therefore is a good early sign.

Dr. van Dyck stated that maternal depression affects infant mortality and prematurity. Although "baby blues" is common (affecting 60% to 80% of new mothers), it is of short duration. Clinical depression before, during, or after pregnancy is less common (affecting 5% to 15% of new mothers) and is a treatable disorder. Postpartum psychosis is rare (affecting 1 to 2 of 1,000 new mothers) and can occur for the first time within 4 weeks or up to 6 to 12 months after birth. Only one-half of depressions in primary care patients are detected, and even fewer postpartum depressions are detected. Women who suffer from depression while pregnant are 3.4 times as likely to deliver preterm and 4 times as likely to have low birth weight babies. They also are more likely to suffer obstetrical complications such as preeclampsia, excessive bleeding, placenta rupture, and premature rupturing of the waters. Dr. van Dyck announced that 300,000 copies of a booklet on perinatal depression have been distributed. In addition, the first complete revision of *Bright Futures: Guidelines for Health Supervision of Infants, Children and Adolescents* will be released in October.

Dr. van Dyck summarized information about vital statistics, in particular, matched birth and death certificates. The overall 2004 infant mortality rate from the linked file was 6.78 infant deaths per thousand live births, which was lower, but not significantly lower, than the 2003 rate of 6.84. Infant mortality rates for race and Hispanic origin groups were not different between 2003 and 2004. The infant mortality rate has not declined significantly since 2000 when it was 6.89. In terms of infant mortality by State, between 2003 and 2004, infant mortality rates ranged from 10.32 for Mississippi to 4.68 for Vermont. Infant death rates by race and ethnicity from 1995 to 2004 show that the rates for non-Hispanic black and American Indian and Alaska Native populations have increased significantly. Furthermore, the discrepancy to the Southeast is very pronounced, and a disproportionate amount of preterm infant mortality can be seen in the non-Hispanic black population. The

same disparity between the Northwest and the Southeast can be seen in the percentage of low birth weight by State.

Dr. van Dyck concluded his presentation by referring to the creation of two new Healthy Start sites, one in Nogales, Arizona, and the other in San Diego County, California.

Discussion

Dr. van Dyck's presentation prompted the following comments and questions:

- Dr. Ryan asserted that the most important social relationship that is compromised by maternal depression is the ability to parent. One of the challenges involves the fact that when women are identified with postpartum depression, after 60 days those who are eligible for Medicaid lose their Medicaid eligibility and their ability to receive appropriate followup services through the mental health system. He added that MCHB's leadership in Bright Futures has been exemplary.

- Dr. Hayes remarked on the contribution of place as a social determinant of health. Infant mortality can no longer remain a maternal-child health problem. She urged MCHB to exert "meta-leadership" to take itself beyond its own authority because the ability to resolve the problem of infant mortality lies outside the Bureau's purview. The question involves how the Bureau can influence other determinants such as poverty, education, housing, and so on, which contribute to infant mortality outcomes. The Federal Government can play an important role in pulling together the forces to affect these factors. Dr. van Dyck suggested that this topic might be a valuable presentation for the next meeting. He mentioned that 3-year studies of the contribution of place or geography to infant mortality and low birth weight are currently concluding.

- In response to a question from Dr. Jennifer Chernoch, Dr. van Dyck agreed to share the latest figures on the budget with SACIM when he receives them.

CMS NEONATAL CARE OUTCOMES IMPROVEMENT PROJECT
Jean D. Moody-Williams, R.N., M.P.P., Director, Division of Quality, Evaluation and Health Outcomes, Centers for Medicare & Medicaid Services

Ms. Moody-Williams delivered her presentation by telephone. She began with a number of announcements regarding current activities at the Centers for Medicare and Medicaid Services (CMS), including work on the reauthorization of the State Children's Health Insurance Program (SCHIP), implementation of the Value-Driven Health Care Initiative in State Medicaid programs, and acceptance of applications for the last round of transformation grants.

The Neonatal Care Outcomes Improvement Project is focused on care in neonatal intensive care units (NICUs). As a result of SACIM's recommendations, the seven original interventions have been extended to nine. Referring to the CMS Neonatal

Outcomes Project key change concepts, Ms Moody-Williams summarized the change package content involving maternal risk reduction, antenatal practices, use of antenatal steroids in pregnant women at risk of preterm delivery, immediate postnatal practices, prophylactic or early administration of the first dose of surfactant to premature infants at risk for respiratory distress syndrome, the nutrition care bundle in the NICU, and proper infection control practices in the NICU. The final two interventions involve coordinating NICU discharge planning and optimizing the followup care of high-risk infants. A 30-item measures package has been developed by professionals in the field for States to use in measuring their progress on these interventions.

Ms. Moody-Williams concluded her presentation by commenting on the limited funding for the change package. CMS is working with the States to find resources to implement the package. The target population is infants with a birth weight ranging from 401 to 1,500 grams and gestational age between 22 and 29 weeks.

Discussion

Ms. Moody-Williams' presentation prompted the following comments and questions:

- Dr. Ryan raised the issue of intensive home visitation by referring to a study in the most recent issue of the *Journal of Pediatrics*. This evidence-based initiative should be supported by Medicaid. Ms. Moody-Williams stated that CMS will inform States about the recommended interventions and provide them with resources such as toolkits to facilitate their decisionmaking. An effort also will be made to coordinate with other agencies in the community that offer home visitation services.

- Dr. Hayes suggested an edit to the systems change statement in the maternal risk reduction intervention, namely to "encourage prevention and healthy behaviors *before, during, and beyond* pregnancy." She also noted that the 32 Medicaid State medical directors should partner with maternal and child health medical directors to work together on the activities involving preconception care. In addition, Dr. Hayes stated that postpartum followup is often a failure of the system in the Medicaid community. Ms. Moody-Williams agreed that postpartum followup should be included in the change package content and that Medicaid medical directors are a rich source whose efforts should be coordinated.

- In response to a question from Dr. Frigoletto, Dr. Ryan reported that the *Journal of Pediatrics* article on home visitation described a retrospective case control study with robust results. The article was distributed to SACIM members during the meeting.

- Dr. Guyer asked about the deregionalization of neonatal intensive care. Regarding the interventions, did CMS discuss whether Medicaid policies should promote regionalization of perinatal care so that sick infants can be triaged to facilities where they can get the best care and experience the best outcomes? Ms. Moody-Williams responded that some States are farther along than others in looking at regionalization. CMS tries to implement policies to encourage consistency across the States, but

regional and statewide differences will exist based on varying needs. CMS is encouraging States to use the evidence-based measures as given. The available tools are fairly consistent with looking at a regional approach.

HEALTHY START UPDATE
Maribeth Badura, R.N., M.S.N., Director, Division of Healthy Start and Perinatal Services, Maternal and Child Health Bureau, Health Resources and Services Administration

Ms. Badura described the authorizing legislation for Healthy Start, an initiative to reduce the rate of infant mortality and improve perinatal outcomes. Healthy Start grants are issued for project areas with high annual rates of infant mortality. The grants require communities to partner with statewide systems and other community services funded under MCHBG. Communities also are required to have a community consortium.

After describing the grant cycle and referring to the Healthy Start logic model, Ms. Badura cited the impressive results reported from the Healthy Start national evaluation. She also referred to a report on high-risk interconceptional women. A total of 35 Healthy Start projects focus on outreach to these women during the 2-year time period after delivery. The report, which will cover best practices from the 35 sites, will be published in late fall or early winter. A complement to the Bright Futures for Women activity is a publication titled *Tender Loving Care for Mommy.*

REMARKS FROM THE ASSISTANT SECRETARY FOR HEALTH
Admiral John O. Agwunobi, M.D., M.B.A., M.P.H., Assistant Secretary for Health, U.S. Department of Health and Human Services

Dr. Agwunobi expressed his admiration for those who work in the field of public health and display a high level of commitment and compassion in their work. In particular, he praised SACIM and expressed his gratitude and that of the Secretary for the efforts of the Committee. Dr. Agwunobi stated that infant mortality is the most important measure of a community or country's commitment to public health in general.

Dr. Agwunobi stated his commitment to upholding all of SACIM's recommendations in spite of the slow pace at which the Federal Government works. Recognizing the extent of the disparities that exist in infant mortality and maternal mortality in terms of socioeconomics, race, and geographic settings, Dr. Agwunobi stated that the numbers can be changed just as they were changed regarding immunization rates. With persistence, passion, expertise, and patience, SACIM's goals can be achieved. With less than 2 years left in this administration, Dr. Agwunobi urged patience in progress toward the goals.

Discussion

Dr. Agwunobi's remarks prompted the following comments and questions:

- Dr. Hayes stated that SACIM has been thoughtful in its deliberations and recommendations. She expressed her hope that the political will could be found to focus on reducing infant mortality. The data systems must be fixed in order to be able to report accurate information on infant mortality rates. She urged Dr. Agwunobi to be a champion regarding the need to move infant mortality out of the restricted domain of maternal and child health. The pregnancy/biomedical paradigm must be replaced by the lifespan approach to improve infant mortality rates. A shift to an ecological model would consider the impact of poverty, racism, the absence of affordable housing, economics, and so on. African American women, in particular, must be prepared to bear children by achieving an optimal level of health beginning in childhood. Dr. Agwunobi stated that he will review SACIM's upcoming recommendations and its latest submissions. He reiterated that the Federal Government is built to change slowly over time and disagreed that the issue is political will in the sense of partisan politics or political priorities. Instead, he blamed society's failure to prioritize infant mortality. The public must be convinced to fight for maternal and child health.

- Dr. de Leon Siantz asserted that infants do not have a voice at the table except through SACIM and that racism and the perception of expendable people prevent the marketing of infant mortality as a problem. Dr. Agwunobi agreed that a marketing strategy is needed to address the problem and awaken people's awareness about infant mortality nationwide. The Federal Government alone cannot accomplish this task.

- Dr. Guyer raised the issue of the vital statistics system as a solvable problem even in a short timeframe. Vital statistics are a shared responsibility between the Federal and State governments. About one-third of the States have up-to-date electronic birth and death certificates and produce data in a timely fashion, while another third of the States lag behind and hold up the entire national record. SACIM needs current information to make pertinent recommendations. Dr. Agwunobi agreed and stated that he will discuss this issue with others in the Department. Vital statistics must be based on a common set of standards, and information technology must be fully leveraged in the health and public health arenas.

- Dr. Chernoch pointed out that children do not have the opportunity to vote and that part of the problem involves political will. She referred to the MCHBG budget, which lost $30 million in the past 2 years. The Administration and Secretary Leavitt must not cut these programs financially. Dr. Agwunobi explained that his comment about political will acknowledges that no one opposes maternal and child health; instead, different strategies can accomplish the goal of lowered infant mortality rates. The nature of a democracy is bound up with the existence of different perspectives. Instead of political opposition or a lack of political will, different opinions exist about how to reach the goal. Dr. Collins noted that a team approach, like that found in the NICU, especially in regard to outcome measures, is needed to prevent low birth weight. Dr. Agwunobi called for science to move from pilots to evidence-based processes.

- Dr. Hannemann asked about the release of information from the SACIM reports. The Low Birth Weight Subcommittee report has been released. The Interagency Workgroup report, however, is now 2 years old and is still on the Secretary's desk. Dr. Agwunobi stated that he will work to get a sense of where the Department is with the SACIM recommendation report.

- Ms. Renee Barnes thanked Dr. Agwunobi for his commitment and restated SACIM's concern about what happens to its recommendations. She stated her agreement that responsibility lies at the Federal and individual levels regarding infant mortality and disparities. Dr. Agwunobi called for individuals, communities, churches, and businesses to participate in the solution to the problem. He stated that a large part of the Federal Government's role is to inspire everyone to do their part to solve the problem.

INFANT DEATH—THE STATE OF THE SCIENCE
Marian Willinger, Ph.D., Health Scientist Administrator, National Institute of Child Health and Human Development, National Institutes of Health

Dr. Willinger presented information on "SIDS: State of the Science and Initiatives in Perinatal Research." Over the years, there have been critical landmarks in improving the rates of sudden infant death syndrome (SIDS) and understanding its etiology and pathogenesis. A number of case-control studies in high-risk communities in the United States and worldwide have identified modifiable risk factors in the postnatal sleep environment. Public health campaigns launched to modify sleep position have been successful in reducing SIDS rates. In addition, specific anatomic and neurochemical abnormalities identified in the brainstem are responsible for vulnerable infants dying in an adverse sleep environment.

A rapid decline in SIDS rates after 1993 occurred in conjunction with a campaign to reduce stomach sleeping, but racial disparity remains. As infant mortality rates plateau, so do SIDS rates. Unacceptable high rates of infant mortality exist among African Americans and American Indians. Since 1992, a telephone survey in the 48 contiguous States has covered information about infant care practices, in particular, sleep position. A dramatic rise in back sleeping can be seen among infants from birth to 8 months of age, but a racial disparity exists in the adoption of supine sleeping.

Dr. Willinger described studies funded to discover the barriers to the adoption of supine sleeping in high-risk communities. The studies revealed the importance of focused campaigns to reduce stomach sleeping, the issue of trust between mothers and their doctors and nurses, and the value of networks of female friends or relatives in recommending back sleeping. The studies also revealed information about the existence of myths about back sleeping and about overlay and entrapment.

Recommendations released by the American Academy of Pediatrics in 2005 involve keeping the baby's sleep area close to, but separate from, where others sleep and using a

clean, dry pacifier when placing the infant down to sleep. Studies will continue at WIC clinics, new sites will be added, and nationwide face-to-face interviews will be conducted.

Dr. Willinger reported on several studies involving new brainstem findings, developmental changes in physiology, and genetics. The ability to use serotonin effectively appears to be significantly impaired in SIDS infants. The results based on brainstem findings suggest that the observed abnormalities in the brainstem of SIDS infants originate in pregnancy while the baby is developing in utero. Other research has been conducted to link the neurochemistry findings with a physiologic phenotype. One study found that infants between 2 and 4 months of age, the peak age of SIDS risk, did not increase their heart rate in response to a head-up tilt, and there was a smaller increase in brain wave activity compared with newborns (*Acta Paediatr* 2005;94:1758–1763). The reasons for this developmental difference in response are being investigated. The researchers suggest that the tilt test might be a good way to assess the brain's control of blood pressure during the peak age of risk for SIDS (*Acta Paediatr* 2006;95:77–81). Research in genetics has shown that a number of genes are associated with the serotonin system. Polymorphisms in the promoter region that enhance the efficacy of the transporter are significantly in excess in SIDS cases, and those reducing efficacy are reduced in SIDS (*Pediatrics* 2001;107:690–692 and *Am J Med Gen* 2003;117A:268–274). Another polymorphism that also increases transporter efficacy is increased in African American SIDS cases. The combination of these two polymorphisms might confer greater SIDS risk among African Americans. Other studies involve genes associated with long Q-T syndrome and IL-10-anti-inflammatory cytokine.

Dr. Willinger cited opportunities to build on the existing knowledge generated over the past 20 years. Research in the SIDS infant could focus on how the observed brainstem deficits translate into altered physiological function and what the mechanisms are whereby the physiological response becomes deadly. New opportunities related to the maternal-fetal environment involve the origin of vulnerability in both the mother and the baby. The challenges for SIDS research are its low incidence and the fact that the heterogeneity of cases makes new research studies more difficult and expensive. In addition, the funds available for research are very confined.

Dr. Willinger described the Prenatal Alcohol in SIDS and Stillbirth (PASS) initiative, which involves a network of six cooperative agreements with the National Institute on Alcohol Abuse and Alcoholism and the National Institute of Child Health and Human Development (NICHD). The study found that binge drinking early in pregnancy is strongly associated with SIDS and that visits by public health nurses have a protective effect. In phase II, careful documentation of alcohol exposure will reveal the timing, quantity, and mediators of the toxic effects of alcohol.

The NICHD Stillbirth Collaborative Research Network (SCRN) comprises five clinical sites. The use of standardized surveillance in a geographic catchment will show that the stillbirth rates are greater than those reported in the vital statistics catchment. This population-based, hypothesis-driven, case-control study captures more than 90 percent of

deliveries. A number of hypotheses address racial disparity. A total of 58 hospitals participate in the SCRN protocol at the 5 clinical catchment sites.

Dr. Willinger described a number of other research networks. The Maternal-Fetal Medicine Unit (MFMU) network conducts randomized controlled trials to improve maternal, fetal, and neonatal health. The MFMU progesterone trial revealed the effectiveness of progesterone in reducing rates of preterm birth at all of the gestational age segments examined and in preventing recurrent preterm delivery. The Community Child Health Research Network (CCHRN), which involves community partnerships, is planning a study that examines how community, family, and individual-level factors interact with biological influences and result in health disparities in pregnancy outcome and infant mortality and morbidity. The purpose of the Genomic and Proteomic Network for Premature Birth (GPN) is to use wide-scale, high-output genomic and proteomic strategies to accelerate knowledge of the mechanisms responsible for premature birth. The GPN study designs include three separate studies: (1) a longitudinal cohort study, (2) a case-control study, and (3) an expression profiling study.

Discussion

Dr. Willinger's presentation prompted the following comments and questions:

- Dr. Guyer mentioned sudden unexplained death in infancy (SUDI) and asked to what extent the pathological diagnosis of SIDS is still an issue in interpreting data. Are SUDI deaths pathologically different from SIDS deaths? Dr. Willinger explained that diagnostic shifts since 1998 resulted in a decline in the SIDS rate without a true decline in postneonatal mortality. Since 1999, among whites, there has been no decline in SIDS; for African Americans, there was a slight decline but now a plateauing of SIDS cases. Both an autopsy and a scene investigation are required to rule out any other possible causes besides SIDS. Medical examiners rule deaths as SUDIs for a number of reasons and under a number of circumstances. It is likely that some SUDIs are SIDS, but a good pathologic marker is needed to verify a diagnosis of SIDS. Dr. Willinger's opinion is that, in the meantime, SIDS and SUDI cases should be considered as a conglomerate because the interventions to reduce them are very similar in most cases.

- Dr. Miller asked whether ethical implications were considered in the PASS study in regard to creating disincentives to counseling women against alcohol use during pregnancy. Dr. Willinger stated that counseling and referrals are provided to women in this study. Because cigarette smoking and alcohol use are often seen together, an attempt is being made to get some biological documentation of the exposures that the women report. Dr. Willinger added that women have been surprisingly open about reporting their alcohol use and that another adverse health behavior reported in the study involves the use of methamphetamine.

- Dr. Sapien reported that a child fatality review in New Mexico compared SUDIs with infants who died in car crashes and from SIDS. He stated that 30 percent of the

SUDIs had an open file with Child Protective Services compared with 2 to 3 percent of the transportation deaths and SIDS deaths. Dr. Willinger stated that this finding is very interesting if the SIDS diagnosis is being applied rigorously.

- Dr. Hayes expressed her interest in the CCHRN and urged Dr. Willinger to look at SACIM's recommendations, in particular, those in the area of preconception care. Dr. Willinger stated that she will ensure that the program scientists speak with Dr. Guyer about those recommendations.

- Dr. Ryan expressed admiration for the breadth of the research conducted by NICHD, which demonstrates that infant mortality is a common endpoint for an extraordinarily multifactorial set of events.

- Dr. Collins asked how the rate of SIDS for whites in this country compares with that for whites in other parts of the world. Dr. Willinger stated that the rates are currently very close. Before the evidence was released about prone sleeping and other countries instituted back-sleeping campaigns, U.S. SIDS rates were actually lower by about half than those for the rest of the world. That fact contributed to the slower adoption of the belief that stomach-sleeping was an issue in the United States. However, as other countries implemented their campaigns, their rates dropped. Now the U.S. SIDS rates are almost the same as rates for whites in other countries.

- Dr. Guyer commented on the discussion of stillbirth. The evidence shows a high racial disparity for stillbirth early in pregnancy, which disappears and then increases again at the end of pregnancy. Does that occur because of the increased proportion of preterm birth among black conceptions, which reduces the disparity in stillbirth deaths? If more preterm births occur among black pregnancies, it would look as though there is less disparity, but that would not be true. Dr. Willinger stated that she will explore this possibility in her paper.

CESAREAN DELIVERY AND THE RISK-BENEFIT CALCULUS
Frederic D. Frigoletto, Jr., M.D., Department of Obstetrics, Harvard Medical School; SACIM Member

Dr. Frigoletto presented "Perspective on 'C' Birth: 1940 to Present" to address the gap in the understanding among various disciplines about the causes of the cesarean birth rate. The insights of public health workers, midwives, and other providers are different from the insights of direct providers of obstetrical care.

In the 1940s, a major change occurred in where births take place. Before World War II, 50 percent of U.S. births were at home. After the war, 99 percent of births occurred in hospitals. Maternal mortality associated with cesarean birth has changed dramatically over the decades. In 1937, the primigravid cesarean maternal mortality rate was 6 percent, whereas the cesarean rate was quite low at 3.5 percent. In the 1950s, as births occurred more frequently in hospitals, cesarean delivery became safer because of the

introduction of antibiotics; as a result, the cesarean maternal mortality rate dropped to 1 percent.

In the 1960s, other developments affected the cesarean birth rate, such as the use of anesthesia, epidurals, blood banks, intensive care, and additional antibiotics. In the 1970s, recognition of the fetus as a patient resulted in the development of the disciplines of maternal-fetal medicine, high-risk obstetrics, and neonatology. The 1970s saw a marked increase in the cesarean delivery rate. At the end of the decade, NIH convened a consensus development conference on cesarean birth that lead to other observations and actions. In the 1970s, the cesarean maternal mortality rate continued to fall to 4 per 10,000.

In the 1980s, international comparisons revealed that in Dublin, where active management of labor was practiced, the cesarean section rate was half that of the United States. At the same time, the increasing threat of malpractice affected the practice of obstetrics. The maternal mortality rate associated with cesarean delivery was 4 times greater than the maternal mortality rate associated with vaginal delivery, but it was not known if the higher rate was due to the procedure itself or to the condition that required the procedure.

In the 1990s, as the cesarean section rate continued to rise, another approach developed, namely, to encourage women who had a previous cesarean section to attempt a vaginal birth after cesarean (VBAC). As a result, the VBAC rate rose rapidly. However, by the end of the 1990s, the unintended consequences of VBAC were recognized; considerable fetal and neonatal risks were associated with VBAC and maternal death. By the end of the 1990s, enthusiasm for VBAC began to wane, and it has fallen considerably at the present time. In addition, during the 1990s, changes occurred in patient characteristics, including increasing maternal age, weight, and birth weight. In vitro fertilization and increasing maternal age lead to increasing multiple births, which lead to increased risk of cesarean delivery. A change also occurred in the standards of practice involving forceps and vacuum deliveries, which were viewed as not being in the best interest of the fetus. The use of operative vaginal delivery was lowered.

In the current decade, patients' access to considerable information regarding pelvic floor morbidity has contributed to the increase in the cesarean section rate to 40 percent since 1996. Cesarean delivery on maternal request has appeared, and pregnant women's attitudes toward cesarean birth have changed.

Dr. Frigoletto summarized the information presented by saying that the period from the 1950s to the present has seen an increase in the medical management of pregnancy, changes in the management of labor pain and the use of forceps, growth of subspecialty areas, and changes in patient characteristics.

After providing data to support the previous assertions, Dr. Frigoletto stated that a first-time mother's risk of cesarean section in the United States is currently about 1 in 4. However, for second and subsequent deliveries, the risk is 1 in 20. A great range exists in that rate for hospitals that have similar patient populations. Furthermore, the phenomenon

of rising cesarean rates has occurred in Europe as well as America. As the cesarean section rate at the National Maternity Hospital in Dublin increased, the rate of first-time women delivering babies increased by almost 4 percent. At the same time, the percentage of induction, another risk factor for cesarean section, increased. Therefore, from 1994 to 2004, the cesarean rate increased from 8.8 to 17.0 percent at the same time that the percentages of inductions and first-time mothers increased.

The multifactorial nature of the issue of cesarean delivery is apparent. Dr. Frigoletto pointed out several non-obstetrical factors that contribute to cesarean rates. Although only limited data exist to substantiate the relationship between cesarean rates and *hospital volume*, cesarean delivery rates appear to be lower in teaching and county hospitals than in community and private hospitals. Data also show that *24-hour in-house obstetrical coverage services* are associated with lower cesarean birth rates. *Individual practice style* among obstetricians is probably the variable that is the most difficult to understand and control; one study showed rates that varied from 5.6 to 19.7 percent, and another study revealed rates that varied from 9.6 to 31.8 percent. Likewise, variation in cesarean rates exists among the patients of *intrapartum nurses;* one study revealed that cesarean section rates among women cared for by labor-and-delivery nurses ranged from 4.9 to 19 percent. Another factor that contributes to cesarean rates involves *payer source;* women with private insurance are more likely to have a cesarean section. In addition, *Fear of litigation* can influence the obstetric decisionmaking process, although the data to support threat of litigation as a factor are qualitative. Dr. Frigoletto also pointed out that significant variation exists among States regarding rates of cesarean section.

Various obstetric factors affect cesarean section delivery rates. Increasing *maternal age* is associated with increased risk of cesarean section. Prepregnancy *weight*, weight gain, and birth weight are other important determinants. Obesity is related to the complications of pregnancy: gestational diabetes, preeclampsia, and eclampsia. The distribution of body mass index (BMI) greater than 30 by State in 1991, 1996, and 2004 shows dramatic changes. Obesity is significantly related to outcome for both mother and fetus. *Diagnosis of dystocia* is the most common indication for cesarean section birth in nulliparous patients. Two studies of *active management of labor* versus usual and customary care revealed no difference in the incidence of cesarean section, although both studies showed a significant difference in the length of labor. The cesarean rate with *elective induction* is more than twice the rate with spontaneous labor; between 1990 and 2003, the incidence of induction of labor doubled. From 1980 to 1998, the rate for triplets rose from 37 per 100,000 to 193 per 100,000 live births; *multiple births* clearly create a risk for cesarean section.

Cesarean section is the most common surgical procedure in the United States. Forty percent of Federal Medicaid dollars go to obstetrical care. Payers identify cesarean section as a way to save, and low-risk patients receive expensive intervention. The rate of cesarean section in the 1990s was about 23 percent. VBAC changed the rate by as much as 3 percent. A California study showed that the cesarean rate fell from a peak rate of 25 percent to 21 percent in 2004, virtually all attributable to the decrease in repeat cesareans. The decision was not made on clinical criteria regarding the progress of labor or fetal distress. However, VBAC had unintended consequences, and the rate fell from 20 percent

in 2000 to 9 percent in 2004. Early studies of VBAC probably underestimated maternal and perinatal morbidity and mortality.

In one study, hospitals with lower cesarean section rates had much more perinatal morbidity than hospitals with higher cesarean section rates. In this decade, changes in attitude and culture, the perception that cesarean section might be safer for the baby, wide acceptance of a safe intervention, and pelvic floor morbidity are all factors involved in the phenomenon of cesarean section on maternal request. However, data on maternal risk is not available at this point. The trend toward cesarean section will most likely continue because of the influence of a number of factors. Opportunities to effect a change include induction. However, the appropriate cesarean rate cannot be established by a task force; instead, more intensive local, regional, and national peer review might be effective. The best route of delivery for a given patient is decided by the doctor, patient, individual circumstances, and available resources. Patients must be thoroughly and accurately informed as they participate in the decisionmaking.

Discussion

Dr. Frigoletto's presentation prompted the following comments and questions:

- Dr. Miller asked whether data exist to substantiate the notion that going through the birth canal has beneficial effects on the health or future outcomes for infants. Dr. Frigoletto mentioned the notion of imprinting and stated that at one time it was thought that the movement of the chest wall during the fetus's transit through the birth canal had beneficial effects in terms of moving fluid out of the lungs. However, this mechanical benefit might be more properly related to gestational age. Dr. Collins added that the medical reason for the cesarean section is the pertinent point. A healthy term infant benefits from going through the vaginal canal. For a clear-cut, small subgroup of infants, cesarean section makes a difference. The concern is for the child who should come out for other reasons; the increased risk of transient tachypnea of the newborn (TTN) might be minor compared with the elective cesarean section.

- Dr. Hayes commented that the historical view of how cesarean section has changed over time is very enlightening and that the ability to pay is a major issue for consideration. Dr. Frigoletto stated that county hospitals, which treat indigent patients, almost always have 24-hour coverage to accommodate residency training programs. Therefore, the payer source and the systems associated with the public institutions are factors in the issue. Dr. Yvonne Moore added that babies are smaller in indigent populations, thereby lessening the need for cesarean section. She also pointed out that in some communities, malpractice carriers will not cover VBACs. Dr. Frigoletto responded that the reduction in the use of VBAC is confounded by imposed regulations with which many community hospitals cannot comply.

- Dr. Hannemann asked about the possible relationship between the outcome for infants and the presence of a resuscitation team during cesarean delivery. Is there any evidence that the presence of a pediatrician trained in neonatal resuscitation plays a significant part in the infant's outcome? Dr. Frigoletto stated that he is not aware of

any study that differentiates the outcomes when either a pediatrician or a nurse practitioner experienced in neonatal resuscitation is present. Dr. Moore reported that as a result of a study by a neonatologist in one of the hospitals where she is on staff, the hospital now requires that a neonatologist be present at any primary cesarean section delivery. Dr. Hannemann stated that there is a difference between the cesarean section baby and the vaginally delivered baby. Infants born by cesarean section do not look or breathe as well as infants born vaginally. He added that during the interval of time that elapses before performance of the cesarean section, the infant is not monitored. Therefore, cesarean sections must be done as quickly and efficiently as possible.

- Ms. Barnes asked Dr. Moore for clarification about the study she referred to. Did the study involve the presence of a person trained in neonatal resuscitation versus the absence of such a person at the delivery or did it involve the difference between that person being a doctor versus a nurse practitioner. Dr. Moore responded that the study involved the former case. The level of training of the person was not specifically addressed.

Late Preterm Birth

Marvin Wang, M.D., Director, Newborn Nurseries, Massachusetts General Hospital, Instructor, Department of Pediatrics, Harvard Medical School

Dr. Wang's presentation, titled "The Late-Preterm Infant," began with a statement about elective cesarean section at 35 or 36 weeks of gestational age. The term "late-preterm infant" instead of "near-term infant" is used to emphasize the need for caution concerning these infants. Dr. Wang reviewed the statistics on premature births, which have increased by 30 percent. Premature infants (less than 37 weeks of gestational age) make up 12.3 percent of U.S. births. Seventy-four percent of those births fall into the late-preterm category.

Dr. Wang's study, which was based on Massachusetts General Hospital's obstetrical electronic medical records system, involved 120 late-preterm infants and 125 full-term infants. The study, which excluded infants with major anomalies, triplets (or higher), maternal substance abuse, and incomplete records, found that late-preterm infants fare worse than full-term infants regarding several morbidities. Compared with full-term infants, late-preterm infants are at higher risk for hypoglycemia and hypothermia, have slower lung fluid clearance, are twice as likely to suffer SIDS, have slower peristalsis and immature sphincter controls leading to poorly developed coordinating suck/swallow, and have more prolonged physiologic jaundice. They also have smaller and more immature brains and immature kidneys and livers.

A cost analysis comparison of late-preterm and full-term infants reveals a significant difference between mean and median newborn hospital costs, which indicates the existence of outliers that create the high numbers. A study in 2003 (Gilbert et al., *ObGyn* 2003;102:488–492) found that neonatal hospital costs averaged $2,600 for a 36-week newborn and $1,100 for a 38-week newborn. The earlier the gestational age, the higher the number of outliers.

The question is whether late-preterm infants are "well" preemies or "sick" full-termers. Clinical dilemmas arise regarding the treatment of respiratory distress and temperature instability in these infants. Dr. Wang cited two studies on respiratory distress. One of the studies (Clark, *J Perinatol* 2005 Aug;25(8):501–502) concluded that neonates born at greater than or equal to 34 weeks gestational age who require mechanical ventilation represent a high-risk population who have significant morbidity and mortality. The other study (Roth-Kleiner, *Swiss Med Wkly* 2003 May 17;133:283–288) looked at respiratory distress in late-preterm babies after cesarean section and found that, compared with emergency cesarean infants, elective cesarean infants required more mechanical ventilation and high-frequency oscillation and had more pulmonary air leaks and higher need for catecholamine aid.

Full-term babies generally do better than late-preterm babies. The biggest issue with late-preterm infants is feeding difficulty. Higher costs are associated with late-preterm infants. Length of stay is generally the same, but the earlier gestational ages result in greater numbers of outliers with excess costs. Diagnoses must be considered from both sides of

the continuum (full-term and late-preterm). The issue of early discharge arises when late-preterm infants are treated like their full-term counterparts. Furthermore, it has been found that 20 percent of infants born between 24 and 37 weeks of gestational age had clinically significant behavior problems at 8 years of age, a percentage that is much higher than that for full-term infants. A study using data from Utah found an increased mortality rate for late-preterm infants, but the majority of those infants had birth defects. However, when birth defects are factored out of the data, a significant difference still exists in mortality rates for late-preterm versus full-term infants.

Late-preterm infants should be monitored for respiratory distress, hypoglycemia, and temperature instability. They also should be tested in their car seats and should be given feeding support. The American Academy of Pediatrics issued a number of directives for research on late-preterm infants: (1) assess the extent of respiratory distress and the cost of care; (2) identify cardiopulmonary factors that can affect TTN and respiratory distress syndrome; (3) better understand respiratory maturation to assess the apnea of prematurity and feeding; (4) study the potential increase of SIDS; (5)evaluate brain development and maturation; (6) conduct more extensive studies on hyperbilirubinemia and prevention; (7) examine gastrointestinal issues and the possible increased association of necrotizing enterocolitis, reflux, poor feeding, lifelong gut disorders, and milk allergies; (8) examine immune immaturity and the association with infections, allergies, and asthma; and (9) examine differences of drug metabolism and effect.

Discussion

Dr. Wang's presentation prompted the following comments and questions:

- In response to a question from Dr. Moore, Dr. Wang stated that his study did not include the area of steroids. One of the key areas of research is to examine the indication for delivery and determine whether the urgently delivered late-preterm infant has different clinical outcomes from the electively delivered late-preterm infant. In the short term, a standard of care is necessary after delivery; in the long term, the question of change of practice will involve the connection between the obstetrician, staff, and parent on the indication for delivery and weighing that indication with the risk of having a late-preterm infant. Thus far, there are no data to warrant a change in practice prenatally.

- Dr. Collins raised a question concerning the use of tocolytics after 36 weeks. Dr. Wang referred to evidence-based versus anecdotal information about the risks associated with tocolytics and the need for further research on late-preterm births.

- Ms. Frazier referred to elective cesarean section and asked about insurance companies' reaction to it. Dr. Wang explained that the population of women who schedule elective cesarean sections, that is, the "too posh to push" group, most likely can afford to pay for the procedure out of pocket.

- Dr. Chernoch pointed out that families, mothers, and obstetricians need to be educated on the issue of birth outcomes for infants born at 36 to 40 weeks of gestational age. Dr. Wang agreed and noted that data are now available to guide families and obstetricians in their decisions regarding late-preterm birth.

- Dr. de Leon Siantz referred to research on the feeding sequelae of preterm infants and interventions starting at the hospital before discharge to help parents adjust to the needs of these infants. Early intervention and then followup to ensure appropriate parent/caregiver interaction can facilitate the child's academic experience in preschool and beyond. She asked about the timing of the diagnosis of developmental problems noted in 8-year-olds who had been born in late preterm. Dr. Wang responded that the study authors decided to use 8 years as a benchmark most likely to get a higher yield of patients than at an earlier age.

- Dr. Ryan described SACIM's role as relating to optimal birth outcomes in general and noted that many late-preterm infants have either overt or covert morbidity that might not be immediately demonstrated. Dr. Wang noted that the Utah study involved children up to only 1 year of age.

- Dr. Hayes referred to Dr. Wang's assertion that 74 percent of all preterm births were late-preterm births. She asked what the strategic next steps will be for cataloguing information about these children through the use of surveillance tools. Dr. Wang confirmed the need for more research to categorize the epidemiological risks associated with late-preterm delivery.

- Dr. Frigoletto stated that the information regarding payer source and cesarean section rate is 20 years old and needs to be updated. He also clarified that reassuring pregnant women with Braxton Hicks contractions about preterm delivery is a legitimate practice.

- In response to a question from Dr. Guyer about the method for determining gestational age, Dr. Wang stated that gestational age as recorded in the obstetrical electronic medical record was determined by the obstetrician's best estimate and ultrasound data. Dr. Guyer pointed out that Dr. Wang's study dealt with a series of continuous variables (gestational age, birth weight, maturity), a completely arbitrary section of which was "lopped off" based on some historical boundaries. This practice turns continuous variables into categorical variables, which then generate guidelines, recommendations, rules, and regulations. It creates proxies for assessments of probability of immaturity, but other babies born later might be just as immature from an organ point of view. Dr. Guyer asked whether creating these categories, rather than teaching the principles of assessing maturity, helps to improve care to infants across a whole range of maturity measures. Do these categories create opportunities for insurance companies, school systems, etc., to stigmatize infants born in these age groups, with implications for their later life and development? Dr. Wang asserted that the continuum raises questions about the sensitivity and specificity of medical management and diagnosis. Narrowing a patient population results in efficacious

medical management and specificity, whereas increasing the number of patients within a group increases the level of sensitivity. Future research might indicate the balance between specificity and sensitivity. Dr. Guyer added that, instead of birth weight and gestational age categories, tools are needed to understand the development of various systems and organs, which probably all have different curves and important long-term implications.

- Dr. Collins mentioned Dr. Guyer's allusion to the Barker hypothesis regarding chronic diseases of adulthood, and Dr. Guyer clarified that, according to the Barker hypothesis, chronic diseases are distributed along a continuum of birth weight, not correlated with low birth weight alone. If a continuum of risk follows birth weight distribution, "something about birth weight in general…reflects something that goes on in utero, and that's what we need to understand." Dr. Collins agreed and stated that screening tools depend on a cutoff point in the continuum and proxy measures of maturity or immaturity that might differ for an organ or an organ system. This broad epidemiologic grouping of late-preterm infants captures those infants who are at increased risk of poor outcomes compared with a group of full-term infants, some of whom might have the same issues. Dr. Wang explained that this particular area of study is attempting to more narrowly define a specific population.

- Dr. Frigoletto asserted that preterm delivery is justified only when there are strong medical indications. The importance of this particular study is its clinical application in clinical management protocols.

- Dr. Chernoch stated that regardless of what term is used to describe these babies, they need social services support. However, social services, education, and family support will not be available for these children without a diagnostic category. Dr. Wang referred to the very subtle signs of a problem in the first years that do not become more pronounced until later in life.

SERVICES FOR CHILD AND FAMILY UPON DISCHARGE FROM NICU
Howard W. Kilbride, M.D., University of Missouri-Kansas City School of Medicine, Chief, Section of Neonatal Medicine, Children's Mercy Hospital and Clinics

Dr. Kilbride presented information about complex problems related to discharge from the NICU and opportunities for improvement. The goals of his presentation were to review the epidemiology of NICU admissions and discharges, discuss the acute and long-term medical and psychosocial issues affecting these infants and children, present some specific resources needed based on current or anticipated needs, and present a conceptual discharge program.

Dr. Kilbride reviewed the statistics on U.S. neonatal mortality, birth-weight-specific survival for very low birth weight (VLBW) infants, estimated annual births, NICU admissions by gestational age, and NICU admissions by birth weight. He noted that NICU discharges include preterm infants, those with congenital malformations, and those with transitional cardiopulmonary distress. It is interesting to note that 2 percent of babies

with gestational age greater than 37 weeks are admitted into NICUs. The VLBW infants have a high degree of medical complications, such as severe intraventricular hemorrhage (6 percent), chronic lung disease (26 percent), retinopathy of prematurity (40 percent), and periventricular leukomalacia (3 percent). Babies who weigh less than 750 grams have very high rates of all of these complications. Length of hospital stay for VLBW infants is 60 days, but more than 3 months for those less than 750 grams.

Discharge issues for preterm infants include poor growth and nutritional deficiency, increased health concerns, chronic respiratory disease, apnea and SIDS, cognitive and motor delays, neurosensory disorders, and emotional-behavioral issues. Regarding nutritional concerns, Dr. Kilbride noted that the nursery experience is a growth-retarding experience. Specific nutritional problems involve low bone mineral content, iron deficiency, and protein intake. Problems also exist with sufficiency of oral feeding and adequacy of intake. The nutritional problems include slow growth, short stature, micronutrient deficiency, delayed oral skills, and gastrointestinal reflux. The resources needed include special diets and lactation support, nutrient monitoring and supplements, nasogastric feeding, occupational therapy and physical therapy consultations, and antireflux medications and gastrostomy tubes.

Dr. Kilbride reviewed statistical information about the general health of low birth weight infants at 2 years of age, pulmonary outcome for preterm infants, respiratory problems after neonatal intensive care, apnea, SIDS and preterm delivery, and sleep position education at discharge. Opportunities for improvement involve the lack of clear policies for transitioning preterm infants to the supine position before discharge, insufficient parental education regarding sleep position specifically for preterm or NICU infants, and inadequate education and training for NICU nurses regarding the relationship of sleep position and environment to SIDS. Another opportunity for improvement involves car seat safety for preterm infants and the proper fitting of the car seat.

Dr. Kilbride mentioned the effect of preterm birth on cognition and low birth weight as a risk factor for the need for special education. Socioeconomic status also exerts a strong influence on cognition. Regarding IQ, the effect of preterm birth was equal to the effect of socioeconomic status. Intervention in this area might improve the IQ scores at least in the low socioeconomic group, and some studies suggest an influence in particular for the larger preterm babies. However, for cognitive followup, 2 years is not a sufficient period of time. In terms of neuromotor outcome, Dr. Kilbride cited two studies and stated that severe cases will be identified by 2 years. The behavioral effects of prematurity are seen in infants who are less adaptable, less persistent, more withdrawn, and at increased risk for attention deficit hyperactivity disorder. Conduct problems might be related to neurologic risk and additional environmental effects. Dr. Kilbride also commented on blindness and visual problems in low birth weight children. Low birth weight babies must be monitored throughout childhood at least yearly for visual impairment. In terms of audiology problems, NICU patients might be at 20-fold higher risk for hearing loss than other newborns. A position statement in 2000 supported universal newborn hearing screening with a goal of early intervention (before 6 months). It is important to note that some babies have delayed-onset hearing loss.

Severe neurological impairment following NICU includes diagnoses of cerebral malformations, severe perinatal asphyxia, metabolic disorders, and bacterial meningitis, which affect mainly full-term babies. The discharge issues for these babies are significant: feeding problems, reflux, seizures, multiple medications, short life expectancy, and family support. These babies suffer from discontinuity of care. They are often discharged from the NICU only to be readmitted to the pediatric ICU a month or 2 later. A palliative care team is needed to give these babies and families continuous support. Dr. Kilbride cited this situation as a much more significant ethical issue than dealing with a 500-gram baby.

Dr. Kilbride explained the neurodevelopmental risks for term infants following NICU hospitalization, including congenital heart disease, extracorporeal membrane oxygenation (ECMO), congenital diaphragmatic hernia, coronary heart disease with ECMO, and status/post surgery. When these infants leave the NICU, they are stabilized, but they remain children with special health care needs (CSHCN). The discharge plan for these babies must be based on the idea that families and providers will work as partners. These children should have access to ongoing comprehensive health care through a medical home. They and families also should have adequate sources of funding. CSHCN should be screened early and continuously for special health care needs and receive early intervention. Community services should be organized so that families can access them easily. In addition, services are needed so that youth can transition to adult health care, work, and independence.

A discharge program should include a medical home with a primary care physician and a variety of medical and surgical subspecialists. A special care clinic might include a pediatrician, developmental pediatrician, nutritionist, social worker, psychologist, and teacher. Dr. Kilbride added that the clinic also might include an obstetrician or an obstetrical nurse practitioner to provide services to mothers. The clinic can act as the primary care provider or can serve as a support to the primary care provider. A number of government programs exist for CSHCN and involve both nutritional issues and surveillance issues.

Dr. Kilbride underscored the importance of the parent-infant bond in discharge planning. Medically fragile infants are sent home with devastated parents who need support beyond education about how to use a machine and a monitor. Most NICUs involve some form of developmental care that is directed at helping the medically fragile child and supporting the parents before discharge. Issues such as poverty, poor maternal health, family instability, low parental education, drug use, smoking, and psychiatric problems have a significant impact on the baby's outcome and the family's response to providing care for the child. These issues must be addressed at the same time that the child is being stabilized.

Effective discharge planning starts with early identification for the family of the types of discharge criteria used. Psychosocial assessments might include a home visit. Parent-driven education is important, as is discussing emergency plans with parents and making

followup telephone calls. In addition to parent communication, the discharge plan should include communication with the primary care provider. A handoff tool is needed to guarantee the smooth transfer of information about the baby to the outpatient department or primary care provider. The primary care provider must be educated about the issues involving nutrition and other medical concerns, and home health nurses must be trained as well. Followup can be accomplished through involving parents as advisors and using parent surveys. Discharge planning and followup care can help to ensure that children reach their maximum potential.

Discussion

Dr. Kilbride's presentation prompted the following comments and questions:

- Ms. Barnes referred to a recommendation in the *Journal of Pediatric Nursing* that called for health care providers in the pediatric setting to include screening for maternal depression. This recommendation echoes Dr. Kilbride's reference to professional alliances to support parents and children released from the NICU.

- Dr. Miller commented that a baby discharged from the NICU might be a surviving twin or triplet. In those cases, grief issues arise, and careful discharge planning, as described by Dr. Kilbride, should include an awareness of possible resulting crises in faith within the family.

- Dr. Chernoch pointed out that a national center, funded by MCHB, exists for each of the Healthy People 2010 objectives related to CSHCN. For example, there is a national center for families and providers working together as partners and for community-based services. NICUs can use these centers as resources.

THURSDAY, JUNE 14, 2007

MARCH OF DIMES PREMATURITY CAMPAIGN—PREEMIE ACT (PUBLIC LAW 109-450)

Jennifer Howse, Ph.D., President, March of Dimes

Dr. Howse's presentation included information about the implications of preterm birth in the United States and the key provisions of the Prematurity Research Expansion and Education for Mothers who deliver Infants Early Act, or PREEMIE Act, which she pointed out originated in the SACIM report on low birth weight.

In 2003, the March of Dimes, together with its founding partners, launched the National Prematurity Campaign to address the fact that prematurity is common, serious, and costly. The campaign seeks to build awareness and education programs in the area of preterm birth. Dr. Howse stated that one in eight babies is born with a diagnosis of preterm birth and the rates continue to increase steadily. The issues that society faces regarding disparities in health outcomes originate in birth outcomes. The risk of preterm birth is most extensive in the African American community and will soon extend to the Hispanic community. In terms of the seriousness of preterm birth, the media fails to reflect the fact that 25 percent of preterm infants have chronic, serious, and long-lasting disabilities. The third consequence emphasized in the prematurity campaign is that premature birth is costly. The annual cost of preterm birth in the United States is $26.2 billion. The average first-year medical costs of babies with a diagnosis of prematurity is $32,325 compared with $3,325 for full-term babies, and the average length of hospital stay is 13 days for preterm babies compared with 1.5 days for full-term babies.

The March of Dimes National Prematurity Campaign goals are to reduce the rate of preterm birth from 12.1 percent in 2002 to 7.6 percent in 2010 and to raise awareness of the problems of prematurity. The campaign's six fields of action involve (1) raising public awareness, (2) educating women of childbearing age, (3) supporting affected families, (4) assisting practitioners to identify and reduce risks, (5) supporting new research on etiology, and (6) advocating for health care access.

The Prematurity Research Initiative began in 2005 with a focus on genetics and genomics. The March of Dimes has awarded $7.7 million in new research grants to study the etiology of preterm birth. Additional grants will be awarded each year. The March of Dimes also has cooperative agreements with CDC to reduce disparities in premature birth at various pilot sites by focusing on faith-based initiatives, preconception health, enhanced service delivery, risk identification, and risk reduction.

In partnership with Johnson & Johnson Pediatric Institute and the Kentucky Department of Public Health, the March of Dimes has launched a 3-year targeted intervention, the aim of which is to reduce rates of preterm birth by 15 percent in the intervention hospitals. The "Healthy Babies Are Worth the Wait" project bundles public health services, consumer education, and evidence-based intervention in clinical care in three hospitals. Other March of Dimes projects involving awareness are Prematurity

Awareness Day in November (Pink and Blue Day), the "I Want My 9 Months" campaign, and the Healthy Babies Healthy Business campaign. The March of Dimes Grand Rounds program is an example of outreach to the professional community. The March of Dimes also has started a NICU Family Support Program, which includes modules of information in English and Spanish, a funded staff person in the hospital, and volunteer parents who are graduates of the program.

Another aim of the March of Dimes is advocacy. The organization has redoubled its efforts regarding access to health care to uninsured women and children, focusing on the reauthorization of SCHIP by September 30. The March of Dimes is particularly interested in amending the legislation to allow coverage of pregnant women 19 years and older both during and after their pregnancies who meet the eligibility criteria of SCHIP. SCHIP has contributed to lowering the rates of uninsured low-income children.

Dr. Howse described how the PREEMIE Act began with SACIM's final report and recommendations to the Secretary on low birth weight in 2001. The bill was designed to address the four recommendations found in the SACIM report: (1) to create a coordinated approach to the development of a research strategy by establishing the HHS Interagency Coordinating Council on Prematurity and Low Birth Weight, (2) to improve the understanding of molecular, genetic, biological, and psychological mechanisms of preterm birth through clinical and psychosocial interventions, (3) to assess the content, quality, organization, and financing of service delivery that affects low birth weight and preterm birth, and (4) to guide program and policy investments that will contribute to healthy families.

The PREEMIE bill was introduced in 2003 and reintroduced in 2005. It passed the Senate unanimously on August 1, 2006, and passed the House unanimously on December 9, 2006. The President signed the bill into law on December 22, 2006. The purpose of the PREEMIE Act is to reduce the rates of preterm labor and delivery, establish an evidence-based standard of care for infants and pregnant women at risk of preterm labor and other serious complications, and reduce infant mortality and disabilities.

In terms of research, the Act provides for the expansion and intensification of CDC's overall research portfolio on preterm birth and studies on the relationship between prematurity and birth defects and developmental disabilities. The Act also provides funds for CDC to collect additional data related to the Pregnancy Risk Assessment Monitoring System (PRAMS) and to link PRAMS data with maternal-infant clinical and biomedical information. In terms of education, the PREEMIE Act authorizes grants for demonstration projects to test and evaluate educational outreach and materials, improve treatments and outcomes, and respond to the informational and emotional needs of families. The PREEMIE Act also codifies the Interagency Coordinating Council on Prematurity and Low Birth Weight, which was originally recommended by SACIM. In addition, the PREEMIE Act calls for a Surgeon General's conference on preterm birth to establish a public-private research and education agenda. The conference's target date is December 2007.

The implementation of the PREEMIE Act depends on appropriations of $8 million to CDC and $1 million for the Surgeon General's conference. Dr. Howse suggested two action areas for SACIM. SACIM should become involved in the Surgeon General's conference in terms of planning, participation, and dissemination of the resulting report. In addition, SACIM should oversee and stay connected to the activities of the Interagency Coordinating Council on Prematurity and Low Birth Weight.

Dr. Howse concluded her presentation by expressing her confidence that answers will be found to the problem of prematurity.

Discussion

Dr. Howse's presentation prompted the following comments and questions:

- Dr. Miller asked Dr. Howse to convey to her staff and volunteers SACIM's respect for their work and commitment to the welfare of the country's youngest and most vulnerable citizens. Dr. Howse responded that she will take this message to the Board.

- Dr. Hannemann mentioned that Dr. Howse was appointed as an honorary fellow of the American Academy of Pediatrics last year. He asked how long the March of Dimes National Prematurity Campaign will last. Dr. Howse replied that the March of Dimes "is sticking with this until the finish line." Dr. Hannemann recognized the value of the March of Dimes and other organizations, and Dr. Howse recognized the staff of the Office of Governmental Affairs who were present at the meeting.

- Dr. Hayes asked the Board of the March of Dimes to accept a new paradigm for birth outcomes by investing more in women's health, in particular, preconception care. The biomedical model has not worked. The ecological model, which goes beyond the maternal-child health community, entails social, political, and environmental changes. Dr. Howse agreed that a new paradigm is needed for thinking about preconception health, which is broader than the biomedical model of prenatal care, labor, and delivery. The March of Dimes has a strong interest in the subject of preconception care, including defining and clarifying the services associated with preconception health and determining the financial issues it involves.

- Dr. Chernoch raised the issue of the attention given to NICU graduates who have survived and are doing well and the lack of attention to other children who have disabilities and mental health needs along with a good quality of life. She encouraged the March of Dimes to work with the National Association of Children's Hospitals to promote that message. Dr. Howse stated that the March of Dimes partners with the National Association of Children's Hospitals on a number of projects and is aware of the need to "bust myths" and disseminate information about a variety of outcomes of preterm birth.

- Dr. Guyer expressed surprise at the fact that the PREEMIE Act contains no mention of MCHB. Mr. Emil Wigode from the March of Dimes Office on Governmental Affairs replied that it was envisioned that HRSA would undertake the provision spelled out in Section 3: Public and Health Care Provider Education and Support Services. Instead of mentioning specific agencies, the Act refers to "the Secretary." Dr. van Dyck added that MCHB's partnership with the States is important in the implementation of strategies to improve low birth weight.

- Dr. de Leon Siantz asked what active steps are in place for planning the Surgeon General's conference. Dr. Michele Kiely from NICHD and the Office of the Surgeon General announced that an active planning process is ongoing. The conference will probably take place in early spring 2008. The current acting Surgeon General is RADM Kenneth P. Moritsugu.

- Dr. Frigoletto stated that strong socioeconomic and demographic information can enrich the knowledge about the processes involved in preterm birth. Dr. Howse stated her hope that the planning stages for the Surgeon General's conference will emphasize the stratification of data. An obvious example is the relative weight of late-preterm versus early-preterm infants. The factors involved must be considered in isolation in order to understand their overall contribution to the problem. That idea should be articulated as part of the agenda for the Surgeon General's conference. Dr. Frigoletto mentioned that individual factors, such as the resurgence of tuberculosis in certain areas, might be contributing to the annual increase in preterm birth.

- Dr. Ryan commented on the lifecycle perspective and preconception care as topics for the Surgeon General's conference. Girls with poor nutrition, sedentary lifestyles, and other poor health behaviors will face difficulty when they encounter the physiological challenges of pregnancy. The Surgeon General's conference should devote some time to examining this critically important topic.

ORAL HEALTH AND PERIODONTAL DISEASE—RESEARCH TO POLICY AND PRACTICE: PERIODONTAL HEALTH AND BIRTH OUTCOMES

Ann Drum, D.D.S., M.P.H., Director, Division of Research, Training, and Education, Maternal and Child Health Bureau, Health Resources and Services Administration

Dr. Drum's presentation contained information about the first MCHB "Research to Policy and Practice Forum" conducted in December 2006. The forum concentrated on the area of periodontal disease and perinatal issues. After recognizing members of the planning committee and listing the agencies that collaborated with MCHB on the forum, Dr. Drum stated the three meeting objectives: (1) to review evidence-based research relevant to the relationship between periodontal disease in pregnant women and birth outcomes, (2) to review current policies, programs, and practices within the public and private sectors to address the oral health needs of pregnant women and improve birth outcomes, and (3) to offer public and private health leaders the opportunity to dialogue about future directions in research, policy, program, and practice related to women's periodontal health and birth outcomes.

Two background papers were commissioned for the forum, one to review the scientific evidence related to periodontal health and birth outcomes, and the other to review the policies, programs, and practices addressing the oral health needs of pregnant women. The forum also included other presentations, including an overview of periodontal health for women of reproductive age, a paper on the challenges of applying evidence-based methods to new and emerging research issues, and an overview of new findings from federally funded clinical research on the effects of periodontal therapy on preterm birth and other adverse birth outcomes. Workgroup discussions and reports explored future directions in policy and programming arenas and future directions in research related to periodontal health for pregnant women.

Dr. Drum presented the highlights from a selection of the presentations as well as the major findings from the workgroup discussions and reports. The first background paper, titled "Review of Scientific Evidence Related to Periodontal Health and Birth Outcomes," was a systematic review including 44 studies. The authors concluded that there is evidence of an association between periodontal disease and some birth outcomes but no definite conclusion can be drawn because of potential biases, such as variation in periodontal disease and pregnancy outcome definitions across studies, insufficient control of confounding variables in many studies, insufficient sample size in some studies, and limited number of randomized controlled trial studies. Therefore, there is insufficient evidence to support provision of treatment during pregnancy for the purpose of reducing adverse birth outcomes. Several randomized controlled trials are under way to test the hypothesis that periodontal treatment can reduce rates of adverse birth outcomes. More studies are needed to examine the association between periodontal disease and increased risk of maternal complications.

The second background paper, titled "Policies, Programs, and Practices Addressing the Oral Health Needs of Pregnant Women," entailed document reviews, phone interviews with State oral health program staff, Web searches, and information from oral health experts. The researchers found that eight major entities have addressed the perio-preterm relationship: (1) insurers, (2) companies manufacturing consumer oral health products, (3) health professional associations, (4) consumer advocates, (5) lay press, (6) think tanks, (7) Federal Government agencies, and (8) State government agencies. The researchers also found that the perio-preterm relationship has been subsumed under the oral-systemic health rubric, public and private insurance coverage of periodontal benefits for pregnant women has increased, scientific statements regarding the perio-preterm relationship vary significantly, competition and marketing is a key driver of public health awareness in the private sector, and the absence of national professional guidelines appears to hinder efforts and cause confusion in all sectors.

Another key presentation included in the forum concerned a randomized controlled trial to test the effect of nonsurgical periodontal treatment on several birth outcomes. The key findings were that although periodontal treatment improved clinical measures of periodontal disease, it did not significantly change the risk for any birth outcome. The results were inconsistent with those of previous studies, and direct comparisons were

difficult because of varying methodologies. Periodontal therapy delivered between 13 and 21 weeks of gestation was found to be safe and effective in treating periodontal disease.

Two workgroups discussed future directions in policy and programming related to women's periodontal health and birth outcomes. The overarching themes were that good oral health is important across the lifespan, with pregnancy as an opportune time to promote oral health and healthy behaviors; growing evidence shows a possible association between periodontal disease and increased risk of several adverse birth outcomes; more studies are needed to show possible associations between periodontal disease and birth outcomes; and scaling and root planning are safe for pregnant women with periodontal disease. Several other themes involved health education and training, outreach and public education, policies and programs, workforce development, and access to care.

The third workgroup discussed future directions in conducting research on the impact of pregnant women's periodontal health on birth outcomes. Some of the key recommendations were to determine which, if any, aspects of periodontal disease are most strongly associated with risk for adverse birth outcomes; determine which populations with periodontal disease are most at risk for adverse birth outcomes; develop a reliable and rapid method for screening pregnant women for periodontal disease; and partner with existing clinical and research networks.

Dr. Drum summarized Dr. van Dyck's comments on four overarching strategies that came out of the forum: (1) creation of a research agenda that supports multiple strategies to improve the oral health of pregnant women, (2) development and dissemination of practice guidelines for providing oral health care to pregnant women, (3) increased investment in oral health promotion and prevention, and (4) implementation of strategies that increase access to oral health care.

Discussion

Dr. Drum's presentation prompted the following question:

- Dr. Frigoletto asked about the quality of Dr. Michalowicz's federally funded randomized controlled trial, which included 413 patients in the treatment group and 410 patients in the control group. Dr. Drum replied that the quality of the study is considered to be fairly high. The next study will have double the number of patients in the treatment and control groups. Early information will be available in 24 months.

PREGNANCY RISK ASSESSMENT MONITORING SYSTEM (PRAMS)
Norma Harris, Ph.D., Division of Reproductive Health, Centers for Disease Control and Prevention

Dr. Harris provided an update on PRAMS, an ongoing, population-based, State-based surveillance system of women delivering live infants. PRAMS entails a self-administered

mail survey (with telephone followup for nonrespondents) that contains self-reported data on maternal behaviors and experiences before, during, and after pregnancy. The overarching goal of PRAMS, which was instituted 20 years ago, is to improve the health of mothers and infants by reducing adverse outcomes such as low birth weight, infant morbidity and mortality, and maternal morbidity. PRAMS has 39 project sites and represents about 75 percent of all U.S. live births.

One of the strengths of PRAMS is its strong methodology. The States use birth certificates as the sampling frame from which to draw. A standardized protocol is in place, and the data are weighted to reflect the population of live births in the State. Another strength of PRAMS is that the States in general are able to achieve at least a 70 percent response rate. In 2004, 90 percent of the States achieved that rate. Finally, PRAMS is a unique source of State-based and population-based maternal-child health data.

One challenge posed by PRAMS involves the 70 percent or better response rate, which has been declining in the past few years. Another challenge experienced by States is the difficulty in getting increased response rates in racial and ethnic populations. Because one of the qualitative attributes of a surveillance system is flexibility, PRAMS is in the position of needing to change or enhance its methodology. Another challenge involves the timeliness of the data, which is the most significant challenge to policy and program development. Weighted data sets are sent back to the States 2 to 3 years after the date of birth. Another challenge involves the frequency of changing the survey questions along with the lack of an efficient data management system.

Dr. Harris presented examples of how PRAMS data have been used to promote public health action. In one example, PRAMS data were used to implement a breastfeeding law in Alaska, and in other examples, PRAMS data were used to evaluate a social marketing campaign in Utah involving prenatal care adequacy and to evaluate the problem of low birth weight in Colorado and the resulting social marketing campaign called "A Healthy Baby Is Worth the Weight."

PRAMS data can be used to promote public health action. Some characteristics of States that are able to use data for public health action are the presence of staff to analyze data, strong collaborations within the health department and the maternal-child health community, skill in working with program staff and policy makers, and willingness to champion the data. The challenge at CDC has been to provide technical assistance to States to strengthen these skills.

The goal of the Maternal and Child Health Data Linkage Project is to promote collaboration between maternal-child health and chronic disease/health promotion professionals by increasing their awareness of the value of PRAMS data with chronic disease/health promotion directors, identifying issues of mutual concern in PRAMS, and working together to address those issues. Some important reasons to promote collaboration are the importance of preconception care, especially for women with chronic diseases; the fact that pregnancy can unmask a potential for disease; and the fact

that pregnancy is an entry point into health care and an opportunity for primary prevention. Utah's tobacco prevention and control programs are an example of how the collaboration is working.

Future directions for PRAMS involve helping the nine new States collect data, evaluating and revising the questionnaire, overhauling the PRAMS data management systems, examining methods to increase response rates in hard-to-reach populations, increasing the dissemination of data, increasing the utilization of data for public health action, and expanding the Chronic Disease Linkage Project to many more States.

Discussion

The presentation by Dr. Harris prompted the following questions and comments:

- Dr. Hayes asked how CDC is marrying PRAMS with the Behavioral Risk Factor Surveillance System (BRFSS). Behaviors and contextual issues surrounding a women's health must be captured and used to influence policy. Dr. Harris explained what PRAMS has done with BRFSS, which is a random digit dial telephone survey of households across States that asks a variety of health-related questions of the adult in the household. BRFSS collects some information on pregnancy, but the sample sizes are extremely small. PRAMS' collaborations with BRFSS to date have been limited to acquiring an understanding of how to improve the information technology systems. Dr. Hayes praised the significant achievement of getting 70 percent of U.S. live births accounted for with information from PRAMS.

- Dr. Guyer asked about the methods whereby CDC works with the States to fund the data collection effort. Dr. Harris explained that CDC has cooperative agreements in place with the 39 States. CDC gives the States money to collect data for PRAMS. The standard protocol includes State development task boxes that can be modified to each State's needs. The States use birth certificate data to draw a monthly sample of mothers who delivered a live birth. Questionnaires are mailed out to the sampled mothers up to three times; if there is no response through the mailed survey, then telephone followup is conducted. The mail and phone responses come back to the States, and then they transmit the data to CDC through a secure data network. CDC performs its data cleaning and weighting process. A weighted data set is sent back to the States in about 1.5 years. Dr. Guyer asked why a full year's data is needed within this surveillance system. Dr. Harris mentioned seasonal variations with births and the original design of the project to sample for a whole year. For States with low numbers of births, for example, South Dakota, data will be collected for less than a year, but it will be weighted to reflect a full year's worth of time.

- Dr. Ryan stated that in North Carolina PRAMS has been successful as a Federal/State partnership because of the technical assistance provided to States. Might there be lessons to be learned from a successful PRAMS partnership in terms of enhancing the technical assistance regarding vital statistics? Dr. Harris stated that she would confer with her colleagues in the National Center for Health Statistics to answer that

question. She added that when CDC gets the final birth tapes from States, it weeds out duplicate records and addresses other data quality issues, all of which affects the timeliness of the effort.

- Dr. Moore suggested that the PRAMS survey could be linked to the well baby visit. Dr. Harris mentioned that this idea is potentially possible but would result in increased costs because of the need to determine where the mother goes for the well baby visit. Dr. Moore mentioned that updating the technology might offset the need to know where the mother goes for the well baby visit; coding could be used instead.

- Dr. Guyer asked about the general way in which States use PRAMS data. Dr. Harris stated that the examples she gave are of active States that use their data to evaluate programs and policies. Other States produce surveillance reports and fact sheets based on their data back. The data also help States develop an analytic priority for the next year. CDC issues national PRAMS surveillance reports, Morbidity and Mortality Weekly Reports, and manuscripts. External researchers also can obtain a dataset for analysis. All of this information is available at www.cdc.gov/PRAMS. Dr. Guyer mentioned fetal/infant mortality reviews and suggested that PRAMS as a surveillance model can be used to improve perinatal outcome and perinatal service delivery. Dr. Harris agreed that the data can be used to promote public health action. CDC has examined PRAMS data to determine the range of topics collected and their correspondence to Healthy People 2010. In addition to various efforts at the national level, CDC provides States with technical assistance regarding their needs and health priorities.

- Dr. Ryan reported that North Carolina was able to get specific data about unintended pregnancies from PRAMS and then use the data as the cornerstone for a proposal for a Medicaid waiver to expand family planning services. He suggested that CDC publicize the ways in which States have used PRAMS data to garner further support for PRAMS.

- Dr. Sapien asked three questions: (1) Is the PRAMS survey available in other languages besides English? (2) Why are data from the States with a small number of births extrapolated, while data from States with a large number of births are not? (3) Is it possible to create a system whereby PRAMS surveys can be attached to birth certificates for pickup by mothers? Dr. Harris responded that (1) the PRAMS survey is available in English and Spanish, and New York City is implementing the survey in Chinese and providing a translator who can speak three dialects for the phone survey; (2) States with a small number of births (e.g., South Dakota, North Dakota, Montana) collect data for a shorter segment of time, but they have a larger sample or batch size than States with a large number of births that draw samples monthly; and (3) the idea of attaching the PRAMS survey to birth certificates is interesting; CDC could think about how to operationalize it with the amount of funding available.

- Dr. de Leon Siantz asked about methods being contemplated to increase the PRAMS response rate from underrepresented groups. Dr. Harris responded that South Dakota,

for example, will use a few different methods to try to increase the response rate of the Native American population. South Dakota will use the mail and the telephone surveys as well as hand-carry the surveys to women who live on reservations. In terms of other racial/ethnic groups, operations data show that more African American women respond by phone than they do by mail, and the case might be similar for Hispanic women. CDC would like to conduct focus groups on this topic.

COMMITTEE BUSINESS: NEXT STEPS AND DISCUSSION
James W. Collins, Jr., M.D., M.P.H., Chairperson, SACIM

In response to a question from Dr. Cernoch, Dr. Collins explained that the Committee's reports have been finalized and should be on the Secretary's desk by Monday morning. The subcommittee reports will be sent to the Secretary by July 13, 2007. SACIM members will receive a copy of the final version of the complete report. Referring to the Surgeon General's upcoming conference, Dr. Hannemann stated that SACIM should be represented on the committee. Dr. van Dyck suggested that Dr. Collins write to the Surgeon General requesting participation by SACIM on the planning committee.

Dr. Collins asked the SACIM members for input regarding the Committee's future plans and directions. The Committee members offered the following comments and suggestions:

- Dr. Ryan suggested that SACIM send a letter to Dr. Agwunobi thanking him for his presence at the meeting and his pledge to follow up on SACIM's recommendations. Dr. Ryan also suggested that a representative from the Interagency Coordinating Council on Low Birth Weight present information about its activities at a SACIM meeting. Dr. van Dyck reminded the SACIM members that, as a member of the Council, he reported on the progress of its activities on a regular basis at SACIM meetings. He explained that the completed task of the ad hoc committee was to produce a report. Dr. Hannemann stated that the report was presented to the Secretary 2 years ago and would not become a public document until its release by the Secretary.

- Dr. de Leon Siantz asked that the next meeting include a followup report regarding the SCHIP evaluation. She moved that SACIM endorse the upcoming legislation covering SCHIP's continuation. Dr. Hannemann seconded the motion, and discussion led to several additions. Dr. Hannemann stated that the letter to the Secretary should mention the importance of the legislation related to the issues of infant mortality and low birth weight, which are within SACIM's purview. Dr. Miller suggested that the final wording be left to Drs. van Dyck and Collins. Dr. Ryan suggesting adding SACIM's support for the increase in the MCHB block grant. Ms. Frazier mentioned that SACIM also should support an increase for the Healthy Start project. The motion was passed unanimously as amended.

- Dr. Chernoch asked that the next meeting include a broad update on the budget process and information about upcoming related legislation.

- Dr. Ryan suggested that another presentation could cover intensive home visiting, nurse-family partnerships, and the CMS role in those partnerships.

- Dr. Sapien proposed the topic of injury as a cause of infant mortality. Dr. Guyer suggested a presentation by the Baltimore Better Babies Leadership Action Program, whose goals include improved perinatal outcome and reduced infant death, or other similar programs in Delaware and Kentucky. The idea would be to focus on a particular locality, give the presenters some guidelines and boundaries, and encourage them to describe their program components that address issues such as preterm birth, infant mortality, financial mechanisms, and regionalization of perinatal care.

- Dr. Hannemann raised the question of recognition of SACIM by the Secretary. Dr. Collins mentioned the presence at this meeting of representatives from the Secretary's Office.

- Dr. Frigoletto suggested that a methodologist be invited to describe the quality of studies and thereby help SACIM members improve their ability to analyze scientific information.

- Ms. Frazier reminded the group that SACIM is the body that makes recommendations for Healthy Start. She called for a presentation that would concentrate on best practices in both urban and rural Healthy Start projects. Dr. de Leon Siantz stated that a useful presentation might be one that focuses on the cost of *not* providing care over time to this group of children.

- Dr. Hayes proposed that the next meeting's agenda include a presentation on CDC's evidence-based clinical guidelines on preconception care. She also suggested that SACIM use the upcoming Surgeon General's conference to highlight its current recommendations.

At the end of the discussion, Dr. Miller expressed appreciation to Dr. van Dyck and his staff for their dedication. Dr. Collins stated that a date has not yet been set for the next SACIM meeting but that it would most likely be in November 2007.

PUBLIC COMMENT PERIOD
James W. Collins, Jr., M.D., M.P.H., Chairperson, SACIM

Association of SIDS and Infant Mortality Programs (ASIP)
Sandra Frank

Ms. Frank shared ASIP's observations and concerns about the Nation's response to infant mortality. ASIP, which is celebrating 20 years of education, counseling, advocacy, and research, provides national leadership for professionals who respond to infant and child deaths. The organization is committed to bereavement support, risk reduction, and prevention services. In recent years, with support from MCHB, ASIP has linked

researchers and practitioners in an ongoing dialogue to ensure that families receive the best possible evidence-based care.

Ms. Frank referred to a diagnostic shift in SIDS. The decrease in SIDS rates has been offset by other causes of infant death, such as asphyxia, suffocation, sudden unexplained infant death, and sudden unexpected infant death. These changes require a different response. Five years ago they would have been called SIDS.

Ms. Frank stated six points. First, new language is needed to describe sudden and unexpected infant deaths that are largely preventable. Second, State data collection must be standardized with the Sudden Unexplained Infant Death Investigation Reporting Form (SUIDIRF). Third, infants are still dying even though the terminology has changed, and bereavement support is needed for the families as part of the continuum of comprehensive perinatal care. Fourth, support must be renewed for public and professional risk reduction education. Fifth, basic assumptions must be examined and new research on disparities must be explored. Sixth, ASIP provides leadership for a systems integration approach to replace the service delivery approach.

ASIP is deeply concerned with the perception that the problem of SIDS has been solved. It is prepared to partner with Federal, regional, and State maternal and child health programs to leverage resources and provide technical support to continue the transformation of SIDS/SUID programs from service delivery to systems integration.

Pregnancy Loss and Infant Death Alliance (PLIDA)
Sarah Kye Price, Ph.D.

The purpose of Dr. Price's presentation was to raise awareness of the importance of bereavement support for families experiencing the death of a fetus or baby at some time during pregnancy, birth, or infancy. PLIDA is a voluntary and collective community of health care practitioners, grassroots bereavement support providers, bereaved parents, researchers, and educators. PLIDA urges SACIM to consider not only medical risk reduction programs and funding but also programs and funding to increase the infrastructure for bereavement support for women and families experiencing many types of loss during pregnancy, childbirth, and infancy. Dr. Price referred to the need to promote the emotional, social, and reproductive health of grieving families. A bereavement support infrastructure is particularly needed for families whose socioeconomic, racial-ethnic, or geographic status prevents them from otherwise accessing support services. The infrastructure must include the provision of much needed education, support, and training for the professionals who work with bereaved families both in hospitals and in community-based settings.

Dr. Price stated that position statements are available on the PLIDA Web site at www.plida.org. A culturally competent and federally supported bereavement infrastructure would include (1) advocacy for inclusion of bereavement-related research into Federal funding priorities, (2) fiscal support for innovative public health interventions that encompass both risk reduction efforts and bereavement support for all-

cause fetal and infant mortality, (3) increases in funding to support the current public health infrastructure for bereavement support of SIDS and other sudden infant death, including miscarriage, stillbirth, and neonatal and infant death from multiple causes, and (4) programs that reward and support health care organizations in developing culturally relevant and responsive bereavement support protocols and policies for families that they serve.

Black Health Coalition of Wisconsin
Pat McManus

Ms. McManus reiterated the need to broaden the context of infant mortality. The Black Health Coalition of Wisconsin has worked for the past 20 years on a variety of disparities. Although biomedical science is extremely important, the disparities have not changed, and protective factors, as well as risk reduction, are important. Consumer awareness and an increase in consumer voice also are important. Self-empowerment is part of the solution. In addition, training of professionals coupled with accountability about service provision is crucial in terms of monitoring and care. Anecdotal information, such as the description that Ms. McManus gave of her daughter's experience, is extremely important to discover how families protect themselves or regroup after such experiences. Ms. McManus encouraged SACIM to pursue information outside the biomedical model.

The meeting adjourned at 2:23 p.m.

PARTICIPANT LIST

Advisory Committee Members

James W. Collins, Jr., M.D., M.P.H., Chairperson
Robyn J. Arrington, Jr., M.D.
David Ray Baines, M.D., FAAFP
Renee T. Barnes, M.S., R.N.
Yvonne Bronner, Sc.D., R.D., L.D.
Jennifer M. Cernoch, Ph.D.
Mary Lou de Leon Siantz, Ph.D. R.N., FAAN
Ronald A. Finch, Ed.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
Ann Miller, Ph.D.
Yvonne Moore, M.D.
Kevin J. Ryan, M.D., M.P.H.
Robert E. Sapien, M.D., FAAP

Ex Officio Members

John O. Agwunobi, M.D., M.P.H., M.B.A.
Assistant Secretary for Health
Department of Health and Human Services

Jean D. Moody-Williams, R.N., M.P.P.
Director, Division of Quality, Evaluation, and Health Outcomes
Center for Medicaid and State Operations
Centers for Medicare & Medicaid Services

Advisory Committee Staff

Peter C. van Dyck, M.D., M.P.H.
Associate Administrator for Maternal and Child Health, HRSA
Executive Secretary, SACIM

David S. de la Cruz, Ph.D., M.P.H.
Senior Program Management Officer
Commander, U.S. Public Health Service
Division of Healthy Start and Perinatal Services, MCHB, HRSA

Michelle Loh
Staff Assistant
Division of Healthy Start and Perinatal Services, MCHB, HRSA

Presenters

John O. Agwunobi, M.D., M.P.H., M.B.A.
Assistant Secretary for Health, HHS

Maribeth Badura, R.N., M.S.N.
Director, Division of Healthy Start and Perinatal Services, MCHB, HRSA

Ann Drum, D.D.S., M.P.H.
Director, Division of Research, Training, and Education, MCHB, HRSA

Frederic D. Frigoletto, Jr., M.D.
Department of Obstetrics, Harvard Medical School

Norma Harris, Ph.D.
Division of Reproductive Health, CDC

Jennifer Howse, Ph.D.
President, March of Dimes

Howard W. Kilbride, M.D.
University of Missouri-Kansas City School of Medicine
Chief, Section of Neonatal Medicine, Children's Mercy Hospital and Clinics

Jean D. Moody-Williams, R.N., M.P.P.
Director, Division of Quality, Evaluation and Health Outcomes, CMS

Anand Parekh, M.D., M.P.H.
Senior Medical Advisor
Office of the Assistant Secretary for Health, HHS

Peter C. van Dyck, M.D., M.P.H.
Associate Administrator for Maternal and Child Health, HRSA

Marvin Wang, M.D.
Director, Newborn Nurseries, Massachusetts General Hospital
Instructor, Department of Pediatrics, Harvard Medical School

Dennis P. Williams, Ph.D., M.A.
Deputy Administrator, HRSA

Marian Willinger, Ph.D.
Health Scientist Administrator, NICHD, NIH

Other Attendees (THE YELLOW HIGHLIGHTS IN THIS SECTION REFER TO ILLEGIBLY WRITTEN NAMES ON THE SIGN-UP SHEETS.)

Benita Baker
MCHB, HRSA

Sandra Barnes
SACIM

Janice Berger
MCHB

Fred Butler
OA-CQ, HRSA

Barbara Braden
BPHC, HRSA

Christine Bransford
MCHB, HRSA

Christopher DeGraw
MCHB, HRSA

Pamela De la Cerda
MCHB, HRSA

Triesta Fowler-Lee
PICB, NICHD

Sandra Frank
ASIP

Brenda Fuentes
HRSA

Christine Hager
MCHB, HRSA

Karen Hench
MCHB, HRSA

David Heppel
MCHB, HRSA

Michele Kiely
OSG, NICHD

Lisa King
MCHB, HRSA

Michael Kogan
MCHB

Eve Lackritz
CDC

Cassie Lauver
MCHB

Lauri Levin
AMCHP

Marina Levin
March of Dimes

Henry Maingi
AMCHP

Bresni Maldonado
HRSA Intern

Dan Mareck
BHPr, HRSA

Amelia Manderschul
Project IMPACT

John McGrath
NICHD, NIH

Patricia McManus
National Healthy Start Association

Peggy Sanchez Mills
National Healthy Start Association

Julie Moreno
OMH, HHS

Carolyn Mullen
March of Dimes

Sarah Kye Pine
PLIDA/Virginia Commonwealth University

Madelyn Renteria
MCHB, HRSA

Dan Ricketts
Project IMPACT

Paul Rusinko
MCHB, HRSA

Phillip Smith
IHS

Cathy Spong
NICHD, NIH

Emil Wigode
March of Dimes

Beverly Wright
MCHB, HRSA