

**Secretary's Advisory Committee on
Infant Mortality**

**Meeting Minutes of
July 13–14, 2006**

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GENERAL SESSION

THURSDAY, JULY 13, 2006

WELCOME AND REMARKS

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

Dr. Collins welcomed the participants to the meeting of the Secretary's Advisory Committee on Infant Mortality (SACIM) and thanked the Committee members for their work since the November 2005 meeting. He extended a special welcome to two ex-officio members: Wendy DeCoursey, Ph.D., and Jean Moody-Williams, R.N., M.P.P., who represented Mark McClellan, M.D., Ph.D., at the meeting. After the SACIM members introduced themselves, Dr. Collins commended the subcommittees for their contributions to the process of formulating recommendations to be submitted to the Secretary of the Department of Health and Human Services (HHS). He also announced that the next SACIM meeting will take place on November 29–30, 2006. In addition, Dr. Collins referred the participants to tab 1 in the meeting notebook, which contains the letter forwarded to the Secretary at the end of last year and the Secretary's response to that letter.

MATERNAL AND CHILD HEALTH BUREAU UPDATE

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

Dr. van Dyck presented an update on several Maternal and Child Health Bureau (MCHB) initiatives and new grant competitions and provided some budget information. He referred to two reports in tab 3 of the meeting binder: (1) *Infant Mortality Statistics from the 2003 Period Linked Birth/Infant Death Data Set* and (2) the *National Institutes of Health (NIH) State-of-the-Science Conference Statement on Cesarean Delivery on Maternal Request*. Regarding the first report, Dr. van Dyck remarked that the infant mortality rate declined in 2003 to 6.84 from the 2002 rate of 6.95. Nearly half (49%) of infant deaths occurred in the less than 1 percent of infants whose birth weight was less than 1,000 grams. A wide range exists among States in the black infant mortality rate, but the range is not as wide in births to white mothers. The rate among whites in some States is as low as 3.9, whereas the lowest rate among blacks is 8.4. For multiple births, the infant mortality rate was five times the rate for single births.

Regarding the second report, Dr. van Dyck noted that the incidence of cesarean section without medical or obstetric indications is increasing in the United States. An important component of the increase is maternal request. Current evidence is insufficient to evaluate the benefits and risks of cesarean section on maternal request compared with planned vaginal delivery. However, other recommendations suggest taking a cautious approach to this subject.

Dr. van Dyck pointed out that three of the four presentations on the agenda were partially or fully funded by MCHB: (1) the Institute of Medicine (IOM) study on preterm birth, (2) the National Academies workshop on prenatal weight, and (3) the Health Resources and Services Administration (HRSA) perinatal and patient safety pilot.

Current MCHB activities include (1) grants for a program to reduce the risk of overweight or obesity in women of reproductive age; (2) State grants for perinatal depression; (3) a cooperative agreement or grant for fetal alcohol spectrum disorders to coordinate an ongoing demonstration program between the National Organization on Fetal Alcohol Syndrome and HRSA's community health centers to improve the prevention, identification, and support of individuals with fetal alcohol syndrome; and (4) the Program Assessment Rating Tool (PART) review to examine Healthy Start's purpose and design, strategic planning, management, and results and accountability. Dr. van Dyck announced that Healthy Start is expected to receive a very high PART rating. The Office of Management and Budget Web site (<http://expectmore.gov>) contains the results of the PART ratings.

Dr. van Dyck presented information about the maternal and child health block grant budget process for 2007. The information included the 2006 President's budget, the final congressional budget for 2006, and the 2007 House mark under the following categories: State, Special Projects of Regional and National Significance (SPRANS), Community Integrated Service Systems, earmark, Healthy Start, hearing screening, emergency medical services for children, traumatic brain injury, sickle cell, and Family to Family. The SPRANS congressional earmarks involve oral health, sickle cell, epilepsy, genetics, mental health, fetal alcohol, and vision screening. Dr. van Dyck noted that, in general, MCHB is pleased with the House mark.

Discussion

Dr. van Dyck's presentation elicited the following comments and questions from the participants:

- Fredric Frigoletto, Jr., M.D., speculated that the data on infant mortality might be more positive than they look at first glance because the mortality associated with multiple births is five times greater than the mortality associated with term births. Given the epidemic of multiple births, the infant mortality rate must be decreasing for term births. Dr. van Dyck agreed that the rate of multiple births affects the infant mortality rate among single births.
- Dr. Frigoletto added that the rising cesarean section rate and numbers of cesarean births by maternal request might have some relationship to the falling infant mortality rate, especially if the decrease occurs in the subset of neonatal mortality. The speculation surrounding this subject should be addressed, particularly in light of the alarm generated by media reports based on an incomplete understanding of the phenomena. Dr. van Dyck mentioned that the NIH consensus report addresses this problem.

- Ann Miller, Ph.D., noted that the PART review of Healthy Start indicates that the program is remarkably successful. She called for a round of applause for Dr. van Dyck and the MCHB Healthy Start staff for their good work.
- Bernard Guyer, M.D., M.P.H., commented that the Committee should never feel satisfied with hearing the 2003 infant mortality rate in 2006. SACIM should demand better and more timely data instead of merely speculating about what happened 3 years ago.
- Ms. Moody-Williams added her congratulations to the Healthy Start program and announced that the Centers for Medicare & Medicaid Services (CMS) will launch a program targeted to Medicaid clients to examine the infant mortality rate for low birthweight infants. The program's purpose will be to determine ways in which to decrease that rate. More information will be forthcoming about the program in 3 to 4 weeks.
- Maxine Hayes, M.D., M.P.H., asked about the earmark for newborn screening. Dr. van Dyck stated that the earmarked money has been used to fund seven regional collaboratives for newborn screening across the United States. Every State is tied to a collaborative. The purpose of the collaboratives is to establish a referral center, network, education center, or data collection point for the States in the region.
- Renee Barnes asked about the significant increase in funding for sickle cell disease. Dr. van Dyck explained that the new funding demonstrates congressional interest in sickle cell disease. The interest in newborn screening affects attention to sickle cell screening programs as well. One of the programs funds a sickle cell national organization to coordinate and collect data for sickle cell disease. Other funding supports 17 community centers to screen clients for sickle cell disease, including collection, identification, and followup. In addition, three major clinical sickle cell centers are funded to perform diagnosis, treatment, and referral services.

IOM REPORT ON PRETERM BIRTH: CAUSES, CONSEQUENCES, AND PREVENTION

Richard E. Behrman, M.D., J.D., Executive Chair, Pediatric Education Steering Committee, Federation of Pediatric Organizations, Inc., Chair, IOM Committee on Understanding Premature Birth and Assuring Healthy Outcomes

Dr. Behrman presented information about the IOM report on preterm birth. He explained that the task of the IOM Committee on Understanding Premature Birth and Assuring Healthy Outcomes was to assess the state of the science with respect to the causes of preterm birth, address the consequences for infants and their families, and establish a framework for action. The committee undertook four tasks: (1) review and assess the factors contributing to preterm birth; (2) assess economic and other societal burdens; (3) to address the research gaps, including barriers to clinical research; and (4) explore changes in public policy that might benefit from more research. Three themes guided the committee's approach: (1) clarity of terminology, (2) racial-ethnic and socioeconomic

disparities, and (3) preterm birth as a complex cluster of problems with a final common pathway.

The Committee's Four Tasks

Task 1 involved the review and assessment of behavioral and psychosocial factors contributing to preterm birth, such as the use of tobacco, alcohol, and illicit drugs; the role of nutrition, physical activity, and employment; and the impact of stress, life events, anxiety, depression, and racism. Sociodemographic and community factors also were reviewed and assessed, including maternal age, marital status, race, ethnicity, and adverse neighborhood conditions. In addition, the committee examined medical and pregnancy conditions contributing to preterm birth, such as hypertension, diabetes, weight, interpregnancy interval, and infertility treatments. The report also covers biological pathways, such as systemic and intrauterine infections, maternal stress, uteroplacental thrombosis and decidual hemorrhage, and uterine overdistension; the potential genetic research related to the problem of preterm birth; and the literature on environmental toxicants.

Task 2 entailed economic consequences, mortality and acute complications, and neurodevelopmental disabilities. This task also assessed health and growth problems, such as the issues of rehospitalization, quality of life, and the relationship to adult diseases. In addition, the committee assessed the impact on families, including maternal distress, family functioning, marital stress, and resilience.

Task 3 called for the committee to identify research needs by reviewing the causes and consequences of preterm birth, including barriers to clinical research on preterm birth. The committee identified the following barriers: available workforce, career development, funding for research, ethical and liability issues, training of scientists, and academic leadership challenges.

Task 4 required the committee to examine public program expenditures and the role of public policies and programs in reducing preterm births. Topics covered included health insurance, education, health care financing, and the organization and quality of care, among others.

Framework for Action

One of the major recommendations of the committee was the establishment of multidisciplinary research centers. The objective of these centers will be to focus on understanding the causes of preterm birth and the health outcomes for women and their preterm infants. These research centers will engage in basic, translational, and clinical research; provide sustained intellectual leadership; foster mentored research training programs; and use sustained funds from funding agencies to investigate the complex syndrome of preterm birth.

The framework for action also involves priority areas for research, including (1) a better definition of the problem of preterm birth with improved data, (2) the conduct of clinical and health services research investigations, and (3) the conduct of etiologic and epidemiologic investigations. To better define the problem of preterm birth, a national mechanism is needed to collect, record, and report perinatal data; the use of ultrasound should be encouraged early in pregnancy to establish gestational age; reliable and precise indicators of maturational age should be developed; and the economic consequences of preterm birth should be investigated.

To conduct clinical and health services research investigations, the following measures must be undertaken: (1) improve methods for the identification and treatment of women at increased risk of preterm labor, (2) develop guidelines for the reporting of infant outcomes, (3) investigate the causes of and consequences for preterm births that occur because of fertility treatments and institute guidelines to reduce the number of multiple gestations, (4) establish a quality agenda, and (5) conduct research to understand the impact of the health care delivery system on preterm birth. To conduct etiologic and epidemiologic investigations, research must be supported on the etiologies of preterm birth, multiple risk factors must be studied to facilitate the modeling of the complex interactions associated with preterm births, and research must be expanded into the causes and methods for the prevention of the racial-ethnic and socioeconomic disparities in the rates of preterm birth. In addition, the framework for action described in the report calls for the study of the effects of public programs and policies on preterm birth and the conduct of research that will inform public policy.

Future Plans

A prepublication copy of the report can be viewed at <http://nap.edu>. The report will be published in its final form in the fall of 2006. Preliminary plans for dissemination include sending report summaries to professional organizations, distributing report briefs to representatives in Congress and other lay audiences, and offering presentations by committee members at conferences to develop public awareness of the problem of infant mortality.

Discussion

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

- Robert Hannemann, M.D., praised Dr. Behrman and the IOM committee for a very concise and comprehensive presentation and commented that the IOM report used information supplied by SACIM. Referring to Dr. Behrman's statement about modeling complex interactions to study multiple risk factors for preterm birth simultaneously, Dr. Hannemann stated that these research capabilities are available now but lack adequate funding because they are not well recognized. He asked whether the IOM committee has any suggestions for gaining recognition of the newer capabilities. Dr. Behrman reiterated that quantitative methodologies are available to

address complex multifactorial risk systems. However, the political will is needed to allocate resources for this endeavor.

- Dr. Hayes stated that the IOM report seems to have a bias toward the medical component of preterm birth. She asked Dr. Behrman to address the social determinants of health that are “outside the 9-month window,” have the strongest impact on positive birth outcomes, and occur long before the pregnancy is conceived. Dr. Behrman remarked that other criticism aimed at the IOM report has cited it as being too focused on the social, behavioral, and community sides. He pointed out that over half of the report focuses on the nonmedical components of preterm birth. Furthermore, the report stresses that research in this area must be planned by multidisciplinary groups, consider the stress in communities that creates vulnerabilities, and examine the generational effects of immigration.
- Dr. Guyer asked about the changing pattern in preterm births. Different populations display different trends in preterm birth. Traditionally, preterm birth has been a problem with disadvantaged African American populations in the United States, but those rates seem to be improving somewhat. In other subpopulations, the problem seems to be worsening. Dr. Guyer asked whether the committee perceived preterm birth as one problem emerging in new populations or as a different problem from population to population. Dr. Behrman referred to rapidly occurring demographic changes across the country and mentioned that risk factors vary from group to group. For example, genetic risk factors should be explored in more detail. One of the areas that the committee focused on was later-gestational-age premature infants. Some disturbing suggestive information indicates that these individuals might have adverse consequences at school age and in their subsequent development, particularly if they are reared in a high-risk environment. Among highly educated, affluent African Americans, the rate of preterm delivery still is higher than that of their counterparts in the white population. Clearly, a different mix of factors is involved. The final report contains a discussion of this topic. Bioinformatics might be helpful in sorting out large databases with complex social and biological information.
- Dr. Guyer asked about the role of infertility treatment. Dr. Behrman responded that, in this country, assisted fertility has resulted in a greater proportion of multiple embryo transplants than in a number of other countries in which the focus has been on developing a standard of medical practice involving the transfer of single embryos. Therefore, infertility treatment contributes to the overall problem. Other problems involve the use of medications to induce superovulation and the lack of nationwide reporting of information. In fact, the information gap might indicate a significant part of the problem. The American College of Obstetricians and Gynecologists (ACOG) and other fertility organizations should address this concern.
- Dr. Hannemann asked whether the committee offered any suggestions about how to bring the problem of preterm birth to the public’s attention. The problem must be recognized before legislatures will allocate funding for research. Neonatal intensive care units (NICUs) save premature and sick infants at a rate unknown in the past.

Without NICUs, the infant mortality rate would soar. Dr. Behrman stated that the committee believes that the general public must recognize preterm birth as a public health problem. Strategizing with foundations and governmental support is ongoing.

- Dr. Collins asked whether the tendency to perceive preterm birth as a minority problem has been a major impediment to addressing the problem. Dr. Behrman responded that preterm birth is a majority problem and that major demographic changes in the country have resulted in a number of other groups being significantly affected by the problem. These circumstances might result in increased media attention and general public acknowledgment that will in turn prompt some political activity. The multifaceted nature of the problem of preterm birth is another factor that must be recognized and addressed.
- Yvonne Bronner, Sc.D., R.D., L.D., pointed out that Dr. Behrman's presentation did not address a strategic plan for problem solution. She asked whether any attention has been given to a systems approach toward developing a model that will enable continued monitoring of progress and strategic funding of the outcomes that show an impact on the problem, in particular, the gap. Dr. Behrman responded that the committee made a number of specific recommendations about uniform national data collection. The model needed for making progress in this area includes the multidisciplinary centers to study the problem. An investment by the Federal Government and private foundations is needed to create these centers, which might be virtual centers, with sustainability and talented intellectual leadership.
- Robert Sapien, M.D. noted that part of public education involves insurance companies and third-party payors. He asked whether the committee addressed the issue of reimbursement for ultrasound. Dr. Behrman responded that the committee did discuss reimbursement for ultrasound and the liability issue. The insurance industry was not represented on the committee. However, the obstetric and gynecologic input indicated possible hesitation based on the reimbursement issue. Moreover, Dr. Behrman noted that there did not seem to be a sense of concrete obstruction to early ultrasound. It was thought that reimbursement for ultrasound before 20 weeks to gain knowledge that would lead to the prevention of preterm delivery was a good possibility.
- Mary Lou de Leon Siantz, Ph.D., R.N., stated that the interdisciplinary centers will require the establishment of partnerships with local communities to put research into practice. These partnerships will facilitate the integration of public service prevention messages into local communities in a cost-effective manner. Dr. Behrman noted the attempts to encourage minority group entry into the health professions and to establish community partnerships related to the health professions.
- Dr. de Leon Siantz mentioned community health care workers who could be mentored and educated to enter the health care professions. Dr. Behrman agreed but stated that the committee report does not discuss this topic.

- Dr. Guyer referred to the 1985 report on low birthweight, which focused on the simple response that early prenatal care and the risk factor approach would solve the problem. The current IOM report seems to have a much more complicated message. He asked about the immediate translational steps of the report's recommendations by public policymakers, especially regarding preterm birth in emerging populations. Dr. Behrman noted that the media role will be important. The standards for assisted fertility and superovulation will provoke some tension and movement. Early ultrasound to assess fetal health is another possible focus within the infrastructure of the prenatal care system. The mixed causes of preterm delivery constitute a complex issue.
- Dr. Bronner asked about the input of committee members with expertise in nonmedical areas. Dr. Behrman responded that this group upheld the notion that studies that examine isolated risk factors are not needed. Instead, committee members favored interventions that consider a complex of social, behavioral, and biological risk factors. They called for intervention studies to evaluate that complex of factors and result in recommendations about public policy changes.
- Dr. Hayes asked whether the IOM committee received any funding for dissemination of the report findings. She stated that the findings must be articulated to organizations such as the March of Dimes and other working bodies. A thoughtfully planned communication strategy and an articulate statement are needed. The HHS Secretary could use the report as a platform on which to make a statement to the public and to Congress about the complexity of the problem of preterm birth. Dr. Behrman responded that the committee has no funds for dissemination of the report's findings. SACIM's involvement in communicating the message to the general public would be a major help, along with assistance from various sponsoring groups and foundations.
- Joyce Roberts, Ph.D., asked whether the committee addressed the merit of the use of progesterone. Dr. Behrman stated that progesterone use is discussed in chapter 9 of the report. The committee found progesterone to be a useful modality but not a "silver bullet" for the problem of preterm birth.
- Dr. van Dyck asked whether the report addresses the fact that one preterm birth is considered a risk factor for subsequent preterm birth. He also inquired about its effect on the overall preterm birth rate and asked about possible differential recommendations for first versus subsequent preterm births. Dr. Behrman verified that a preterm birth is one of the best predictors of another preterm birth and noted that it puts a woman in a high-risk category in terms of prenatal care and the need for early ultrasound. The report discusses microchip technology for investigating potential genetic or epigenetic factors that might be influential in those pregnancies.

THE NATIONAL ACADEMIES' WORKSHOP ON THE IMPACT OF PRENATAL WEIGHT ON MATERNAL AND CHILD HEALTH

Maxine Hayes, M.D., M.P.H., FAAP, State Health Officer, Washington State Department of Health, Chair, Workshop Planning Committee

Rosemary Chalk, Director, Board on Children, Youth, and Families, The National Academies

Ms. Chalk presented some background information about the Board on Children, Youth, and Families within the Division on Behavioral and Social Sciences and Education of The National Academies. The board is the only joint structure between IOM and the National Research Council (NRC). The National Academies has launched a series of projects, including one on emergency services for children and another on maternal depression. IOM has established the Kellogg Fund, which helps translate IOM reports into information and guidance for communities.

The Workshop on the Impact of Pregnancy Weight on Maternal and Child Health, a joint venture of the NRC and IOM, was held on May 30–31, 2006, in Washington, DC. Dr. Hayes pointed out that the workshop was sponsored by MCHB. After recounting the history of interest in the topics of nutrition during pregnancy and lactation and maternal weight gain during pregnancy, Dr. Hayes stated that the workshop's planning committee included experts in nutrition, obstetrics and gynecology, pediatrics, public health, and nursing.

The fivefold task of the workshop was to (1) examine the research that describes the distribution of maternal weight (before, during, and after pregnancy) among different populations of women in the United States; (2) examine the research on the effects of different weight patterns during pregnancy on maternal and child health outcomes; (3) examine the research on the individual, community, and health care system factors that impede or foster compliance with recommended gestational weight guidelines; (4) explore opportunities for Title V maternal and child health programs to help childbearing women achieve and maintain their recommended weights before, during, and after pregnancy; and (5) inform future research and data collection needs.

The workshop was organized into three panels: (1) gestational weight gain and maternal health consequences; (2) maternal weight and gestational weight gain and child growth and health; and (3) the role of individual, community, and health care system interventions to promote appropriate weight during pregnancy and postpartum. Dr. Hayes pointed out that the purpose of the workshop was to produce findings, not recommendations.

Overview and Trends

Improvements in maternal, fetal, and child health are key public health goals. Since the 1970s, American women have gained 8 to 10 pounds more weight during their pregnancies than in earlier reporting periods. Gestational weight gains are related to short-term fetal, infant, and maternal health outcomes. However, the relationship between high weight gain during pregnancy and maternal obesity is relatively unknown. The

guidance for maternal health during pregnancy must be tailored, and more information is needed about specific racial and ethnic groups.

Workshop participants reviewed the trends and status of weight gain before, during, and after pregnancy through several national databases supplemented by the California maternal and infant health system database. Key findings include the following: (1) there is no national surveillance system to monitor pregnancy weight gain, (2) there is limited information on different populations of women (e.g., adolescents, racial/ethnic groups, immigrant populations, overweight versus underweight women), and (3) there are limited data on prepregnancy weight patterns.

Panel 1: Predictors of Gestational Weight Gain and Maternal Health Consequences

The first panel reviewed the biological, metabolic, and social predictors and their relationships to gestational weight gain and considered the short-term and long-term maternal health consequences of gestational weight gain. The panel found that (1) new data do exist, but they are limited in scope; (2) limited data exist for minority populations; (3) gestational weight gain has both biological and social determinants and consequences; (4) gestational weight gain frequently is associated with prepregnancy body mass index (BMI); (5) a balance must be struck between the risk/benefit of gestational weight gain on the maternal side versus the infant/child health consequences; and (6) this issue requires a lifespan approach.

Panel 2: Infant and Child Health Consequences

The panelists reviewed information about the infant/child short-term and long-term health consequences of maternal weight and gestational weight gain. The panel found that the number of large-for-gestational-age infants is increasing, whereas the number of small-for-gestational-age infants is decreasing. One question involves the meaning of gestational weight gain, and another asks why the focus should be on gestational weight gain. A third question involves infant health, preterm birth, and both low and high BMI. In terms of body composition, BMI and gestational weight gain predict fat mass in newborns, but the meaning of this finding is not clear. In the area of children's health and weight, BMI and gestational weight gain predict overweight in children. The panel repeated the emphasis on the importance of taking a lifespan approach to this issue and balancing the risk/benefit of gestational weight gain on the maternal side versus the infant/child health consequences.

Panel 3: Insights to Interventions

The third panel reviewed the individual, psychosocial, community, and health system approaches to promote appropriate maternal weight during pregnancy and the postpartum period, including infant weight. The key presentation findings from the *individual* viewpoint involve energy balance and behavioral strategies. Individual interventions are effective at preventing excessive weight gain and reduce postpartum weight retention. However, they focus on pregnancy and the postpartum period only. More research must

address the importance of planning for pregnancy. The *psychosocial* approach to weight gain focuses on stress, social support, depression, and attitudes. Observational data are available, but data from intervention trials are lacking on the implications of psychosocial issues. The results are inconsistent for gestational weight gain and postpartum weight retention, and methodological issues involve understanding the validity of indicators. In addition, there is a lack of effective prenatal interventions.

A great deal of work remains in this area. Likewise, there is limited research in the area of *community* approaches, and the existing research has shown mixed results. However, there is evidence of the effectiveness of health workers, action-promoting material, goal-setting, and self-monitoring. Also, social marketing needs to be better understood in terms of community. Regarding *health system* factors, guidelines are available for clinicians, but it is unknown how well-used they are and they use different cutpoints for weight gain. There are virtually no available studies on clinician or health system interventions.

In general, the workshop participants found that interventions should take place before, during, after, and between pregnancies. The approaches should differ by subgroup, and individual and environmental approaches should be combined. Weight management must be integrated throughout the lifespan. All three panels found gaps in knowledge about maternal weight gain and gestational weight gain. A summary of the workshop proceedings now is in preparation and will be released in the fall of 2006.

Michelle Lawler commented on the workshop as an important project that will lay the groundwork for followup efforts to update prenatal weight gain recommendations.

Discussion

The presentation on the workshop elicited the following questions and comments from the committee members:

- Kevin Ryan, M.D., M.P.H., asked whether the increasing prevalence of adult onset diabetes, with its implications for maternal and fetal health, was a topic of discussion during the workshop. Dr. Hayes responded that the topic was addressed in terms of large-gestational-weight infants and the subsequent risk for type 2 diabetes during childhood. The issue underscores the importance of preconceptional care during the lifespan.
- Dr. Guyer asked about the basis for referring to an increasing population of large-for-gestational-age infants. Dr. Hayes responded that these infants outnumber low birthweight infants and that mean birthweight is definitely increasing. In fact, a large number of women who want to get pregnant are undergoing bariatric surgery.
- Dr. Collins asked whether data suggest that obese women need to gain less weight during the first half of pregnancy compared with nonobese women. Dr. Hayes responded that the understanding now is that fat is an organ with implications in

terms of insulin. Dr. Frigoletto added that there is an epidemic of pregnant women with BMIs greater than 30 who are at risk for maternal complications of preeclampsia, eclampsia, and diabetes. Since diabetes is associated with macrosomia, the result is an increase in large-for-gestational-age babies. He also stated, from a clinician's observations, that obese women tend to gain less weight during pregnancy than nonobese women and yet do not have low birthweight infants as a consequence.

- Dr. Roberts expressed concern about the paucity of data in light of the complexity of the problem. She emphasized that it is encouraging that action-promoting material and maternal goal-setting and self-monitoring are potentially effective in helping women control their weight gains.
- Dr. de Leon Siantz remarked that the most culturally and family-based approach to intervention deals with food, particularly among Latino families. Teaching people in a cost-effective manner how to change their cooking habits and encouraging people who engage in hard physical labor during the day to increase their exercise in the evening are interventions that must be tailored to the target population. Dr. Hayes confirmed that these points were recognized in the workshop discussions. The community is the key in terms of the environments in which people find themselves that either impede or support some of the desired behaviors. Strategies must be devised to encourage community involvement.
- Robyn Arrington, Jr., M.D., reported that Michigan has been designated the most obese State in the Union and the Detroit area the most obese part of Michigan. Most of the problem pregnancies he deals with involve obesity. Outreach to chronically obese patients early in pregnancy through the use of home nurses is an effective intervention.

Dr. Hayes concluded the discussion by calling for the calculation of BMIs on pregnant as well as nonpregnant women. She stated her hope that the workshop will instill the importance of BMI calculation. Dr. Chalk added that adolescent medicine also is important, especially concerning nutrition and exercise. Two other IOM reports might be of interest to the committee members: one concerns the reduction of childhood obesity and the other concerns food marketing to children and youth.

MEDICAID POLICY CHANGES AND THE IMPACT FOR MATERNAL AND CHILD HEALTH

Deficit Reduction Act of 2005: Provisions Affecting Providers Working To Reduce Infant Mortality

Regan Crump, M.S.N., Dr.P.H., Director, Health Systems and Financing Group, Office of Planning and Evaluation, Health Resources and Services Administration

Dr. Crump focused on the sections of the Deficit Reduction Act (DRA) that affect safety net providers. The DRA of 2005 became law on February 8, 2006. Its stated purpose is to increase flexibility for State Medicaid programs and reduce the rate of growth in spending.

Section 6001: Pharmaceutical Provisions

This section of the DRA changes the way in which manufacturers price drugs. In determining average manufacturers price (AMP), the purchaser (wholesaler, individual pharmacies, mail order companies) must be considered. Pricing, cost, reimbursement rates paid by State Medicaid agencies, and rebates depend on the AMP. The determination of AMP is significant when purchasing drugs at the patient level. The DRA mandates monthly disclosure of AMPs to States and quarterly posting on the Internet. As a result, the AMP will have greater transparency.

The pharmaceutical provision of DRA could result in Medicaid cost-containment strategies that initially target high-cost drugs and later apply to all Medicaid reimbursed drugs. Another result might be decreased operating margins for small, independent pharmacies.

Section 6004: Children's Hospitals

The DRA makes children's hospitals eligible for participation in the 340B drug-pricing program. This allows them to purchase outpatient drugs at a significantly discounted rate compared with purchasing drugs on the open market. Some legislative and policy issues have slowed down the implementation of this section of the law. This is because DRA made changes in the Social Security Act but the 340B drug-pricing program was authorized by the Public Health Service Act. A technicality must be addressed before children's hospitals will be able to purchase drugs through the 340B drug-pricing program.

Section 6101: Additional SCHIP Allotments to Eliminate Funding Shortfalls

This section of the DRA appropriates \$283 million for fiscal year (FY) 2006 to handle projected shortfalls in the State Children's Health Insurance Program (SCHIP). Section 6102 establishes a prohibition against CMS approving further Medicaid waivers that brought nonpregnant, childless adults into care under SCHIP using SCHIP funds. A grandfather clause is in place for States that already allow coverage of nonpregnant childless adults. However, new requests to cover nonpregnant childless adults using SCHIP funds would not be approved. Caretaker relatives are not considered childless adults.

The DRA's implementation occurs over the course of a year, with different implementation dates for different provisions of different sections of the law.

Section 6037: Documenting Proof of Citizenship

This section of the DRA is mandatory for all States. It requires that beneficiaries newly applying for Medicaid or people whose eligibility is being reconsidered must provide documentation of their identity and citizenship or lose Medicaid eligibility. Part of the intent is to deny Medicaid benefits to individuals who are not documented U.S. citizens.

The impact is likely to be a reduction in the number of eligible individuals. Some people who were receiving Medicaid benefits will become uninsured.

States are concerned about the administrative burden of the documentation. CMS issued a regulation, effective on July 6, 2006, that affects an estimated 8 million Medicaid recipients. According to the new regulation, these individuals will be exempt from some of the documentation requirements of Section 6037 because the Social Security Administration's State Data Exchange Database contains information to confirm the citizenship of individuals who applied for Medicare benefits or Supplemental Security Income. Another provision in the regulation allows individuals who receive Medicaid because of presumptive eligibility to receive Medicaid benefits up until the time that they file an application in which they declare themselves to be citizens. At that point, the citizenship documentation requirements would become effective.

Section 6041: Cost-Sharing

States have new options to impose cost-sharing (e.g., premiums and copayments) for many new groups and types of services. Premiums are permitted for people who are over 150 percent of the Federal poverty level (FPL). Increased cost-sharing is permitted for people who are over 100 percent FPL. For people who are under 100 percent FPL, the nominal cost-sharing provisions still will apply. They will not be subjected to the higher cost-sharing that the DRA allows if a State chooses that option.

Cost-sharing is limited to 10 percent of the service cost for people under 150 percent FPL, but some States enroll people in Medicaid at higher levels. For those over 150 percent, the cost-sharing can be 20 percent of the service cost. The cap on premiums and cost-sharing still exists. In aggregate, family payments cannot exceed 5 percent of family income.

The greatest impact of the cost-sharing provision will be on nonpregnant adults and children brought into Medicaid as optional or expansion populations. Much will depend on the State and how the State implements the options offered.

Another cost-sharing provision concerns enforceability. States have the option to allow providers to deny care if a person fails to pay the cost-share. This is a significant reversal of longstanding Medicaid policy.

Section 6042: Cost-Sharing—Prescription Drugs

This provision is consistent with what States have been doing for some time. States have the option to impose higher copayments on nonpreferred drugs to provide incentives for providers to write prescriptions for the lower cost or preferred drugs. Prescription copayments are subject to a medical necessity override, which then would apply the copayment for preferred drugs.

Section 6043: Copayments for Nonemergency Care in Emergency Rooms

This provision allows emergency services providers to deny access to care if an individual who presents to an emergency room could be cared for in a primary care setting. However, the emergency room must identify nonemergency providers in the community and have referral arrangements with those providers.

Section 6044: Benchmark Coverage

Benchmark coverage is the concept that a State can enroll certain categories of individuals into a different type of Medicaid plan from what is in place. The plan is called a benchmark plan. States can select from four types of plans that have actuarially equivalent coverage and that look like (1) the BlueCross BlueShield Standard Federal Employee Health Benefits Program, (2) State employee coverage, (3) coverage offered by the largest commercial health maintenance organization (HMO) in the State, and (4) Secretary-approved coverage. States that enroll individuals into a benchmark plan must ensure access to services at federally qualified health centers (FQHCs) and rural health centers (RHCs) either through the benchmark plan or directly. If individuals receive care directly from FQHCs or RHCs, the State must reimburse those entities at a congressionally determined rate, which is called the Prospective Payment System. In addition, the Early and Periodic Screening, Diagnosis, and Treatment Program (EPSDT) benefit is protected in full.

Section 6052: Case Management and Targeted Case Management

This provision eliminates the Federal match when other payers can pay for case management services. Third-party liability rules under HIV health care services and Indian Health Services are not affected.

Section 6064: Family-to-Family Health Information Centers

This grant program rests with HRSA and provides grants to assist families of children with special health care needs (CSHCNs) to access and coordinate resources typically available through separate and difficult-to-navigate systems. It identifies successful health delivery models and conducts outreach activities to families, health professionals, schools, and other appropriate entities. Specific amounts are set forth for the grant program in FYs 2007 through 2009, with an increase of \$1 million each year.

The DRA provides a great deal of flexibility and significant new options for States, yet many States have indicated that it does not go far enough. The Medicaid Commission will issue a second set of recommendations to HHS for long-term changes to the Medicaid program. It is expected that States will make greater use of the flexibility through State Plan Amendments. Some States still might choose the Section 1115 waiver process. The extent to which States will take advantage of the DRA flexibilities will be determined by a variety of factors, including the 2006 gubernatorial elections. States are awaiting further CMS guidance.

Dr. Crump concluded his presentation by mentioning the potential impacts of the DRA. Medicaid enrollment might decrease as a result of new documentation and premium and cost-sharing requirements. Also, the number of people who are uninsured might increase, and safety net providers might experience an increase in the number of people seeking care. In addition, providers might see reduced reimbursements due to more restrictive benefit plans and lower pharmacy payments, more people might delay or forego prenatal care, and more people could be covered with streamlined benefit packages. Finally, State Medicaid programs might be better able to reduce the increase in the rate of spending.

Impact of the Deficit Reduction Act on Maternal and Child Health Programs and Populations

James Resnick, M.H.S., Public Health Analyst, Office of Data and Program Development, Maternal and Child Health Bureau, Health Resources and Services Administration

Mr. Resnick began his presentation by pointing out the linkages between public health programs and Medicaid. The Title V maternal and child health services block grant program is structured into a pyramid of four ascending categories: (1) infrastructure-building services, (2) population-based services, (3) enabling services, and (4) direct health care services. The Federal, State, and local commitments total about \$5 billion. Public health programs affect 32 million people. Strong linkages exist between Title V and Medicaid.

DRA's impact on maternal and child health populations is not always clear because States have the option of implementing some of the provisions involving eligibility, premiums and cost-sharing, benchmark coverage, and targeted case management. However, an analysis of premiums, cost-sharing, and flexibility shows that the DRA provides protections for pregnant women and low-income children. Exempted cost-sharing services include emergency, family planning, and other services to mandatory Medicaid women. The benchmark plans must include well-baby and well-child care, including age-appropriate immunizations; Secretary-approved preventive services; and EPSDT wraparound.

Mr. Resnick touched on several topics: (1) issues involving eligibility; (2) the Family Opportunity Act, which provides an option to States to allow families of disabled children to buy into Medicaid; (3) the 2003 Medical Expenditure Panel Survey, which revealed that a high percentage of costs are paid out of pocket; and (4) another study that showed that costs for children are relatively low. Data from the Congressional Budget Office show that 9 million Medicaid enrollees—half of whom will be children—might face cost-sharing for the first time by 2015. Mr. Resnick summarized the findings of a Kaiser Commission research report on the impact of cost-sharing. The report found that when States impose cost-sharing, people with lower incomes are affected disproportionately, many people choose not to continue in the public programs, and unmet medical needs result. Coverage losses and affordability problems stemming from increased out-of-pocket costs can lead to increased pressures on providers and the health care safety net. Furthermore, the impact of benefits flexibility is unclear on services such

as family planning, hearing, vision, mental health and behavioral, and CSHCN services. It remains to be seen how the wraparound for EPSDT will be implemented on the State level.

Case management presents complicated issues in terms of Medicaid because the guidance in the past was not very clear. The DRA defined what case management services are. However, targeted case management is not explained very well in the DRA, especially with regard to third-party payers. It is unclear whether changes to the Medicaid law will affect reimbursement of services performed by maternal and child health programs. Mr. Resnick concluded by discussing increased flexibility, the Title V monitoring role, and Title V coordination.

Discussion

The presentations offered by Dr. Crump and Mr. Resnick elicited the following comments and questions from the Committee:

- Dr. Miller commented on the onerous effect on pediatric hospitals of the documentation of citizenship requirements. Health care providers in those hospitals should not be made to act as border guards, which is what the Federal legislation requires. Regardless of whether the borders are opened or closed, they should not be “put at the front door of a children’s hospital.”
- Dr. Hannemann asked whether any predictive modeling was done to determine the results of the DRA on individual States or whether any funding was allotted to the States to monitor their individual Medicaid programs. The fear is that as soon as health care services are denied for any reason, emergency rooms will be overloaded. Dr. Crump stated that he is not aware of any requirements in the DRA or any funding for evaluations of its impact. The official estimates of impacts are from the Congressional Budget Office and involve dollars saved and care averted. Ms. Moody-Williams added that the DRA includes no specific evaluation funds. However, CMS encourages States to evaluate the impact and they have a vested interest in doing so.
- Dr. Hannemann used the term “unfunded mandate” to characterize the law because of the lack of funding for evaluation, monitoring, or addressing the overloading of emergency rooms. Mr. Resnick noted that HRSA has data sources on its programs and that the various data sources taken together could provide a way to analyze the situation. Dr. Crump added that the definition of safety net providers in the IOM report includes those who are mandated to provide services and those who provide services because of ethical policy. The “intact but endangered” safety net will have to handle this deluge of patients.
- Dr. Hayes reiterated the fact that the National Governors Association (NGA) lobbied for the DRA because of the budget impacts and implications of the programs addressed. Many of the changes in the law are optional, and the States will choose the options that reduce the pressure on their budgets. The maternal and child health

programs, which are responsible for articulating the health of this population, will monitor the implications of the DRA in every State. However, a systematic monitoring system is needed. Dr. Hayes asked whether the States are mobilizing to identify the types of indicators that should be monitored over time. Mr. Resnick responded that the block grant program is reviewed every year. Data and the narrative are online. Therefore, the infrastructure for analysis exists and the data can speak for themselves. Dr. Crump added that the impetus for some of the assessment, monitoring, and evaluation came from strong recommendations from advisory committees to the Secretary, professional organizations, and others.

- Dr. Frigoletto asked about the exempted services and protected services for women and children, including family planning. Mr. Resnick responded that the DRA indicates that States cannot apply cost-sharing to family planning services.
- Deborah Frazier, R.N., expressed concern that a family unable to make a copayment can be dropped by a provider. Dr. Crump affirmed that the law allows a State the option of changing the State plan so that providers of Medicaid services can deny access to services, or can no longer provide services, to individuals who are unable to make their cost share or to comply with payment arrangements. Ms. Frazier pointed out that this situation is contrary to the recommendations of SACIM and will eventually lead to increased stress and poor health outcomes for the poorest of the poor. Dr. Crump shared the written justification for the DRA provisions and quoted the concept of “self-responsibility,” that those individuals above a certain percentage of the poverty level must invest their fair share in the system of care. Mr. Resnick quoted an official from the NGA who said that “Medicaid is an option for the States.” Mr. Resnick stated that the governors support Medicaid even though they have the option to eliminate it. Likewise, the States can use or not use the options that are offered. Dr. Crump added that the flexibility allows States to expand coverage. For example, Massachusetts is moving to expand Medicaid coverage, as are Vermont and West Virginia. Significant improvements in the quality and comprehensiveness of care are possible. The law does not require that States reduce coverage. They can choose to expand it.

HEALTH DISPARITIES COLLABORATIVE: PERINATAL AND PATIENT SAFETY PILOT

Ada Determan, M.P.H., Public Health Advisor, Division of Clinical Quality, Bureau of Primary Health Care, Health Resources and Services Administration

Jennifer R. Ustianov, B.S.N., R.N., IBCLC, Project Director, National Initiative for Children’s Healthcare Quality, Vermont Child Health Improvement Program, University of Vermont College of Medicine

Ann Elrington, M.D., Ph.D., Chair, Department of Obstetrics and Gynecology, and Chief Medical Officer, Detroit Community Health Connection, Inc.

Ms. Determan explained that HRSA’s Bureau of Primary Health Care (BPHC) focuses on providing care to underserved populations through a network of federally funded health centers. The Health Disparities Collaborative is a quality improvement program within the bureau that focuses on the operational, financial, and clinical systems in the

health centers. HRSA embarked upon the Perinatal and Patient Safety Pilot when it received funding through the Office of the Secretary's Office of Minority Health (OMH) and the other HRSA Bureaus to focus on the disparities and devise ways to narrow the gap. The pilot also addressed the Federal Tort Claims Act (FTCA), which covers health care providers in the health centers.

Strategies for Change: Forming Better Partnerships for Better Outcomes: Reviewing the Outcomes of HRSA's Perinatal and Patient Safety Pilot Collaborative

Ms. Ustianov explained that the pilot translated evidence-based practice into doable work within a practice, which leads directly to better outcomes for patients. The pilot concerned strategies for change.

Background of BPHC's Health Disparities Collaboratives

Ms. Ustianov mentioned that the collaborative model is based on a design that first defines a disparity or gap in care and then engages health care professionals and staff. Next, the model calls for outlining current best practice guidelines or best knowledge. Then, improvement strategies are designed, tested, and implemented at a practice level based on evidence and experience. Work with all of the players includes a patient advocate, and data are collected on improved outcome and process measures. The health disparity collaborative strategy is intended to transform care through a care model, improvement model, and learning model. The infrastructure of the community health centers and the support system outside the community health centers are examined, along with the strategic partnerships that are essential for high-quality care. An essential element is that the leadership at the community health centers must buy into and be engaged in the work of the collaborative.

Measures involved in the health disparities collaborative are aligned with the Health Plan Employer Data and Information Set and the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). Collaborative topics include diabetes, cardiovascular disease, asthma, depression, and cancer screening and followup. The key elements for breakthrough improvement are (1) the will to change to a new system, (2) ideas on which to base the design of the new system, and (3) execution of the ideas.

Overview of HRSA's Perinatal and Patient Safety Pilot Collaborative

The aim of the pilot was to enhance partnerships that would reduce disparities and ensure safety in pregnancy outcomes. These changes will occur by targeting reductions in the primary areas of infant mortality disparities for the African American population through low birthweight, preterm delivery, and sudden infant death syndrome (SIDS). The participants included five health center teams, with faculties of national experts that include clinicians, public health professionals, and health center representatives. This pilot was the first in which all four of HRSA's Bureaus worked on one particular project. Other involved organizations were the Institute for Healthcare Improvement and the

National Initiative for Children’s Healthcare Quality. The Federal partners Centers for Disease Control and Prevention and OMH also were involved.

The process began with a vanguard group meeting that resulted in a decision to concentrate on the quality of prenatal care as a foundation in the community health centers. Numerous preparation meetings followed, as well as site visits, a harvest meeting of all of the teams, and creation of a “change package.” Core measures included outcome measures (preterm birth and low birthweight) and process measures (early prenatal care visits, risk assessment index, risk screening index, self-management goals, followup index, and availability of medical records).

A perinatal change concept is a general, or high level, idea for changing a process. It usually is developed by an expert panel based on literature and practical application of evidence. An example of a change concept is “to foster communication with partners.” A change idea is an actionable, specific idea for changing a process that can be tested in the local environment to determine whether improvements are gained. An example of a change idea is “to meet with State maternal and child health officials.” Innovations created through the pilot included a psychosocial screening tool, an intimate partner violence card, a “footprint card,” and partnerships. The top seven change concepts were (1) foster communication and coordination, (2) organize and share information between hospitals and community health centers, (3) form partnerships with community organizations and specialists, (4) develop a registry system and process, (5) provide ongoing in-service training for providers and staff, (6) embed evidence-based guidelines into daily clinical practice, and (7) use effective self-management support strategies.

The pilot resulted in the following accomplishments: (1) outreach to community and health care partners to coordinate care, resulting in patient linkages to community services and resources, improved efficiency of the health care system, and reduced duplication of needed resources; (2) enhancement of patient safety through communication and transfer of information and records; (3) development of a comprehensive psychosocial tool; (4) increased adherence to ACOG guidelines; (5) improved health care center credibility and reputation; and (6) strong connection with JCAHO patient safety standards.

Challenges and insights from the pilot included an awareness of the complexities of the perinatal topic. Multiple health issues must be addressed, two patients become one, and the absence of guidelines requires relying on best knowledge in some areas. Partnership development is essential to form a complete team to coordinate care from the prenatal to the intrapartum stages.

Plans for Dissemination of Learning

The small sample size (just five health centers) should be expanded before national dissemination. This pilot was the first to have hospital partners as team members. The teams recommended that next steps should include the establishment of 15 to 20 new

health centers with mentoring from the original 5 health centers. Any group organization could start with the top seven change concepts to help improve outcomes.

Dr. Elrington described the Detroit Community Health Connection (DCHC), an FQHC that has been in existence since 1988. DCHC has expanded to five sites, delivers a large percentage of Hispanic patients, and handles more than 70,000 patient encounters a year. With regard to DCHC, Dr. Elrington reiterated that the safety net is intact but in danger.

DCHC will participate in a collaborative with Hutzel Hospital, a premier research institution in Detroit, to become part of a maternal/fetal network of research and organized care, thereby following in the footsteps of the perinatal collaborative. DCHC takes care of patients ranging from infants to the elderly, giving it an opportunity to perform care across the lifespan. The health center thinks of obstetrics and delivery of prenatal care as part of community-organized obstetric care. The community setting allows for collaboration with various organizations. Omnicare, a Detroit-based HMO, asked DCHC to participate in a mobile Women, Infants, and Children program.

Dr. Elrington raised the issue of delivery system design, including the transfer of perinatal records to the delivery hospital. DCHC provides a continuum of care for undocumented immigrants. A Problem-Oriented Pregnancy Risk Assessment form asks a series of psychosocial questions and results in a specific plan of care for the patient. In addition, coordination of care meetings occurs at Hutzel Hospital as part of a risk reduction measure to ensure FTCA provisions for malpractice.

The perinatal collaborative has opened doors for community health centers across the Nation to partner with tertiary care centers involved in research and delivering a disproportionate amount of labor and delivery care to improve outcomes for women with low socioeconomic status.

Ms. Determan referred to next steps for the pilot. HRSA is determining the mechanics for continuing the work of the pilot teams and spreading to other health centers across the Nation. There is a definite commitment to building on the lessons learned during the pilot. In particular, the collaborative process focused on separate conditions or diseases. Moving forward will involve thinking in a more integrated, comprehensive way in a primary care improvement initiative in the health centers. The final documents will be posted on the <http://healthdisparities.net> Web site.

Discussion

The presentation on the pilot collaborative elicited the following comment from Dr. Hayes:

- Collaboratives are very effective because people can return to their settings and apply what they learned to make a difference in practices. SACIM should consider the feasibility and effectiveness of collaboratives as it produces its report.

SUBCOMMITTEES' REPORTS AND COMMITTEE FEEDBACK

James W. Collins, Jr., M.D., M.P.H., Chairperson, Secretary's Advisory Committee on Infant Mortality (SACIM)

In the absence of any public comment, Dr. Collins asked the three subcommittee chairpersons to deliver their reports.

Subcommittee on Eliminating Health Disparities

Yvonne Bronner, Sc.D., Chairperson, Subcommittee on Eliminating Health Disparities

After acknowledging the efforts of the subcommittee members, Dr. Bronner presented the subcommittee's three recommendations.

The first recommendation, a state-of-the-science conference, involves convening leading scientists who would focus on increasing the understanding of the determinants of the racial disparity in infant mortality. Another component of the conference would be to develop a strategic action plan to set the agenda for problem-solving research and demonstration project funding. Dr. Bronner stated that the emphasis of the state-of-the-science conference would not be on current research. Instead, the emphasis would be on research designed to elucidate the racial gap in infant mortality rates. One research question might involve what is known about the factors that determine the disparity in infant mortality. An indepth epidemiological study might result in a clear picture of these particular women and their pregnancies, including their prepregnancy health status, weight gain, energy transfer, infant well-being, and the timing of the loss of the products of conception. All of these issues should be examined relative to the gap.

Another question might address what is known about the impact of the following factors on the disparity in infant mortality: behavioral and lifestyle factors, psychosocial factors, environmental and contextual factors, racism, and intergenerational effects. The outcomes of the conference would include (1) a clear statement of what is known about the multiple determinants of the disparity in infant mortality, (2) identification of gaps in the research to increase the understanding of the multiple determinants of the disparity in infant mortality, and (3) a strategic action plan with clearly stated goals and objectives that would facilitate the monitoring of outcomes.

The second recommendation calls for increasing funding for the identified research initiatives set forth in the strategic action plan and developed during the state-of-the-science conference. The research initiatives would be designed to affect the disparity in infant mortality by focusing on behavioral factors (diet, physical activity, smoking, alcohol consumption, and substance use and abuse), psychosocial factors (stress and domestic violence), environmental and contextual factors (inequalities in education, income, and housing; unsafe versus stable neighborhoods; incarceration; and environmental toxins), and racism (institutional, internalized, and personally mediated).

The third recommendation, to celebrate and expand funding for Healthy Start, would be based on findings from comprehensive evaluations and findings from research identified

and designed to affect the disparity in infant mortality. Dr. Bronner pointed out that Healthy Start allows for testing the paradigms discovered through the research and can be used to monitor changes that could lead to the problem solution. Another component of the third recommendation involves providing technical assistance to at-risk communities to increase their opportunities for preparing successful proposals. By reaching out to unfunded high-risk communities, Healthy Start can affect the disparity in infant mortality. Technical assistance to these communities could help them prepare qualified proposals.

Dr. Bronner asked the subcommittee members for any additions to her presentation. Dr. Sapien mentioned that the subcommittee discussed the fatherhood initiative in Healthy Start. Dr. Miller added that eliminating racial disparities is a moral imperative not merely a budgetary consideration. After thanking Dr. Bronner for her efforts in guiding the subcommittee deliberations, Dr. Frigoletto highlighted three specific suggestions that could be included in the draft report: (1) the statement concerning the climbing prematurity rate should be qualified by an explanation of the reasons for the increase, in particular, the epidemic of multiple pregnancies and the obesity/overweight problem; (2) the statement that two-thirds of the disparity can be explained by the 1 percent of very low birth weight (VLBW) infants should be given serious consideration in the effort to understand and solve the problem of the disparity in infant mortality; and (3) the statement that the disparity is evident even in college-educated African American women who have improved socioeconomic status deserves careful investigation. The research initiatives mentioned in the second recommendation might focus on these three areas. Dr. Bronner and the other Committee members agreed that the area of biological factors should be added to the second recommendation.

Discussion

The discussion that followed the presentation of recommendations included the following points:

- Healthy Start has not been shown to reduce disparities in infant mortality. However, the program can provide the milieu in which to conduct research designed to address the gap. The gap is not being addressed by research conducted under the medical model.
- The first and second recommendations, which concern the state-of-the-science conference and research, strive to identify successful strategies for reducing the gap in infant mortality. The Healthy Start initiative is a viable means of implementing those strategies.
- Two-thirds of infant deaths occur in the neonatal period, and one-third occurs in the postneonatal period. Sudden infant death syndrome (SIDS) and death due to injuries and infections comprise the vast majority of postneonatal deaths, and there is a 2.5 to threefold racial disparity in postneonatal mortality rates. Therefore, the emphasis is on nonmedical issues because the gap is more prominent there.

- National centers might be established to accumulate data regarding pregnancies ending before 28 weeks. An opportunity for synergy exists in relation to the preterm birth report, the weight gain report, and preconception work. A strategic plan could be based on findings from the state-of-the-science conference, the research component, and the demonstration or application continuum to measure progress.
- Healthy Start should be expanded and celebrated because it is a community-based initiative. The community approach, as seen in Healthy Start, the Northern New Jersey Maternal and Child Health Consortium, and certain Special Projects of Regional and National Significance (SPRANS) grants, is significant and complements the traditional medical approach. The importance of community-based work in these programs must be articulated to the Secretary of the Department of Health and Human Services (DHHS).
- Interdisciplinary approaches, that is, the efforts of a health care team working collaboratively, are crucial to community-based initiatives.
- Discussion about disparities in the report should include multiple racial/ethnic groups.

Subcommittee on Improving Clinical and Public Health Practice

Kevin Ryan, M.D., M.P.H., Chairperson, Subcommittee on Improving Clinical and Public Health Practice

After acknowledging the efforts of the members of the subcommittee, Dr. Ryan commented on the large number of recommendations generated by the subcommittee and asked for the full Committee's help in narrowing down the list. The subcommittee's analysis of the history of infant mortality in the United States showed that for several decades there were relatively rapid declines in infant mortality followed by a slowdown in that improvement. Outcomes have been improved by increasing advances in the field of neonatology that lead to improved outcomes in neonatal intensive care units (NICUs). However, at this point, the rescue paradigm must be replaced with a different paradigm that involves the lifespan approach to improving birth outcomes (the temporal axis) and community-based and intervention-based public health practices (the strategies axis).

The subcommittee report on clinical and public health practice is divided into four areas: (1) prereproductive care and preconceptional care, (2) pregnancy-related recommendations, (3) improvements in public health practice, and (4) promoting excellence in clinical service provision. Area 1 involves the prevention of unintended pregnancies and the variety of ways in which better health for women can be promoted throughout the lifecycle. Area 2 concerns evidence-based strategies in prenatal care (e.g., regarding smoking cessation, reduced periodontal disease, and infant sleep positioning) that, if fully implemented, would improve birth outcomes. Area 3 focuses on the issue of organizing public health practice around the new paradigm and acting on its implications, including factors such as stress, chronic disease, obesity, marital status, and violence. Area 4 recognizes two main areas for improvement: (1) clinical implementation of

evidence-based and other recommended obstetrical practices and (2) patient acceptance of those practices.

Recommendations

In light of the large number of recommendations, Dr. Ryan extracted the research-based recommendations from the four areas of the report and asked for members' suggestions on ways to pare them down. The following suggestions and comments were offered:

- One criterion for paring down the Area 1 recommendations should be the ability of the Secretary to act on them.
- The Area 1 recommendations seem to fall into three main categories: (1) provider education, (2) patient and community education, and (3) assessment and research.
- Preconception care as an important area of focus should be apparent. The reports can cover many elements in the recommendations in the report itself.
- The message of the Area 1 recommendations must reflect an awareness of the growing diversity of the population of the United States. Education of women must be part of a family perspective. Similarly, the reproductive plan for life must be culturally competent or culturally inclusive. The emphasis must be on both men and women, and cultural competence should be a thread throughout the recommendations.
- The issue of communication through electronic medical records is an overriding concern and should be applied to all three subcommittees.
- Another study as originally suggested is not needed; rather, a conference should be convened to establish what already is known and what should be done on the basis of what is known. One could use such models as an Institute of Medicine (IOM) Roundtable or a Surgeon General's Workshop to address and ensure the translation of research into practice at the community level.
- The time is right to tie together all the reports completed to date (i.e., the IOM report, March of Dimes activities, the SACIM report on low birthweight, last year's Interagency Coordinating Council report to the Secretary) to gain public awareness and the Secretary's attention on the issue of infant mortality.
- The recommendations in Area 4 could be summarized by using the words "encourage, facilitate, and incentivize," and the details regarding them could be included in footnotes or an appendix. DHHS is interested in the alignment of clinical practices with best practices.
- A number of national alliances are interested in gaining consensus on performance measures and best practices.

- The adoption of evidence-based, culturally competent practices should be integrated into the Area 4 recommendations. Paraprofessionals should be included as part of the team approach. Partnerships should be developed with the private sector. A strategic plan must be developed.

Dr. Ryan explained that the SACIM policy memorandum on reengineering vital statistics is based on input from the National Center for Health Statistics (NCHS) and the National Association for Public Health Statistics and Information Systems. These two entities are in agreement about the nature of the problem. The important issues involved in the discussion of reengineering vital statistics concern structure and cost. The structural issue involves the adoption of the 2003 revised birth certificate and the development of electronic birth and death records. The cost issue involves startup costs, maintenance costs, and the need for additional staff at the Federal level. Six specific recommendations are given regarding vital statistics.

Dr. Guyer added that the recommendations call for the Secretary to lend moral support and financing to the efforts involving vital statistics. Although half of the States are doing a decent job in the effort, a national data set cannot exist until all of the States are involved. Each of the States is deficient in some aspect. The six recommendations could be packaged into a single recommendation for the Secretary's action in the area of vital statistics.

Discussion

The following comments were made regarding the memorandum on reengineering vital statistics:

- The 2003 revised birth certificate proposed for adoption by the States expands the data collected (e.g., it is significant for the issue of maternal weight gain because it records height and weight and therefore enables calculation of a person's body mass index). Promoting linkages of the revised birth certificate with other datasets as a long-term priority for all of the States will strengthen the health statistics systems .
- NCHS raises the issue of vital statistics each year in its budget submission and requests funding to improve and develop the system.
- Federal funding to States could be based on linking noncompliance or timeliness to withholding funding.

Subcommittee on Maternal and Child Health Funding and Financing

James Resnick, MCHB Staff for Subcommittee on Maternal and Child Health Funding and Financing

In the absence of Dr. Cernoch, Mr. Resnick began his presentation by acknowledging the contributions of the subcommittee members to the report. The six recommendations of the subcommittee concern (1) the consistency of Centers for Medicare & Medicaid Services (CMS) policies across States, (2) safeguards on benchmark plans, (3) targeted case management services, (4) the Maternal and Child Health block grant program, (5) the *Healthy People 2010* goals, and (6) evidence-based practices.

Discussion

The subcommittee presentation elicited the following comments from SACIM members:

- Regarding the fourth recommendation, the committee should be more explicit about the need to target the problem and consider a specific earmark. For example, knowledge about community involvement, such as what has been learned from programs like Healthy Start and the SPRANS grant, should be applied to the block grant. Evaluation, understanding, learning, and application must be accomplished with the available money. The question is “What are we doing with what we have?”
- If the state-of-the-science conference were used to set priorities, then the priorities would be funded.
- The SPRANS grants are tied to the MCHB’s strategic plan, which is developed every 5 years with broad national input from all of the State directors. The SPRANS grants mimic the strategic plan, and best practices from the SPRANS grants are used and disseminated. In the block grant portion, the law allows for recommendations but not for specifications.

With regard to the overlap that exists among the subcommittees’ recommendations, Dr. Collins explained that the plan is to keep the subcommittees separate through the revision process. Ideas for condensing the final recommendations may be raised during the next day’s Committee business session.

Dr. van Dyck specified the expectations for the next day’s session. During the morning session, the three subcommittees will revise their recommendations based on the full Committee’s comments. They then will submit their recommendations on a disk for printing and distribution to the Committee members during the afternoon Committee business session.

The day’s meeting adjourned at 5:10 p.m.

FRIDAY, JULY 14, 2006

COMMITTEE BUSINESS: DISCUSSION OF THE SUBCOMMITTEES' REVISIONS AND VOTING ON THE SUBCOMMITTEES' RECOMMENDATIONS

James W. Collins, Jr., M.D., M.P.H., Chairperson, Secretary's Advisory Committee on Infant Mortality

After spending the morning in subcommittee meetings, the full Committee reassembled to discuss the subcommittees' revisions and to vote on their recommendations.

Subcommittee on Maternal and Child Health Funding and Financing

Joyce E. Roberts, C.N.M., Ph.D., Professor and Director, Nurse-Midwifery Program, University of Michigan School of Nursing

Dr. Roberts reviewed the six recommendations from this subcommittee concerning: (1) CMS development of consistent policies for approval of State plans in reference to the needs of women and children, (2) safeguards on benchmark plans approved by CMS for State Medicaid services, (3) targeted case management services in Medicaid, (4) restoration of the fiscal year 2005 level of funding to the Maternal and Child Health Services Block Grant program, (5) coordination of efforts among Federal agencies to reach the *Healthy People 2010* goals, and (6) promotion of evidence-based and service-focused programs and services.

Discussion

- Discussion of the first recommendation resulted in its being amended by deleting the second sentence.
- Discussion of the third recommendation resulted in the following revision: "We strongly recommend that the match for targeted case management services within Medicaid not be reduced for maternal and child health services and that consumer input be sought on developing program variables and definitions of targeted case management."
- Discussion of the fourth recommendation concluded that it should include a statement about not compromising other needed public health MCH services. It was decided to integrate some of the detail involved in this recommendation into the full text of the report.
- The sixth recommendation, which involves funding, is related to the recommendation involving data from the Subcommittee on Improving Clinical and Public Health Practice. In fact, funding statements appear in a number of recommendations. This type of overlap is acceptable.

Dr. Collins asked for a vote on the six recommendations. The full committee voted unanimously to accept the recommendations as amended.

Subcommittee on Improving Clinical and Public Health Practice

Kevin Ryan, M.D., M.P.H., Chairperson, Subcommittee on Improving Clinical and Public Health Practice

Dr. Ryan reported that the subcommittee condensed its report into four recommendations and one recommendation for reengineering vital statistics. The first recommendation focuses on the paradigm shift to the lifespan approach for the prevention of infant mortality. The second and third recommendations, which can be viewed together, concern the two major ways of approaching progress in infant mortality: (1) by fully implementing evidence-based strategies that already exist (recommendation 2) and (2) by conducting research in areas in which further research is required (recommendation 3).

Discussion

- Discussion of the first recommendation centered on the use of the term “the Secretary of DHHS” and the notion of his recognition of the lifespan approach. The word “recognize” will be replaced with “promote,” and the word “his” will be replaced with “the.”
- Discussion of the second recommendation centered on the notion of convening two conferences, one involving research and the other involving intervention, rather than one conference that covers both topics. If two conferences are convened, their names can reflect the difference between them.
- Discussion of the third recommendation (an interagency group to prioritize a research agenda to reduce infant mortality) involved the work of the DHHS Interagency Coordinating Council on Low Birth Weight and Preterm Birth, which also dealt with the topics of SIDS and racial disparities. The report of this group was submitted to the Secretary in June 2005 and should be used to inform the work of the recommended interagency group. Another point of discussion involved the suggestion by the IOM study for multidisciplinary research centers to study certain customized focused issues that require a coordinated national effort.
- Discussion of the fourth recommendation resulted in adding the word “core” before “measures” in the first sentence and substituting “determine” for “discuss” in the second sentence. A question was raised regarding the need to mention colleges of public health, medical schools, and nursing schools in the recommendation. These concepts will be included in the text of the report.

Dr. Collins’ call for agreement on the recommendations resulted in a unanimous vote in favor of approving all four of the recommendations as amended.

Dr. Ryan presented the revised version of the vital statistics recommendation.

SACIM members offered the following comments and suggestions regarding the revised recommendation on vital statistics:

- The sentence structure should be changed to reflect that the proposed legislation, not the States, would provide the funding to implement and maintain the reengineered systems.
- Both the States and NCHS will require resources to implement and maintain the reengineered systems.
- Because the Federal Government does not have authority in this area, the recommendation must entail an action that the Secretary can actually take. The structure and the cost issues involved in the recommendation must be addressed with Federal legislation. The Federal Government also would need support to fulfill its responsibilities in this regard.
- Linking reengineered vital statistics with national security might generate the political capital needed to create a national standard.
- The lack of a national vital statistics imperative is most likely linked to the States rights issue. In addition, States lack the resources to improve their vital statistics systems. If funding accompanies a mandate to reengineer the systems, the idea will be well received.
- “Should consider seeking” should be stated more strongly.
- The revised recommendation reads as follows: “Because the reengineering of the Nation’s vital statistics system is a matter of national security and of critical importance to the Nation’s health, the Secretary should seek Federal legislation that will set national standards for the timeliness and accuracy of vital statistics data with which all States would need to comply. The proposed legislation also should provide the funding needed by the Federal Government and the States to implement and maintain the reengineered system.”

A vote to approve the revised recommendation was unanimous.

Subcommittee on Eliminating Health Disparities

Fredric Frigoletto, Jr., M.D., Department of Obstetrics, Massachusetts General Hospital

Dr. Frigoletto mentioned that most of the work of the subcommittee involved revising the text that accompanies the recommendations. The recommendations are essentially as they were when Dr. Bronner presented them to the group during the previous day's session. The second recommendation was changed to reflect a focus on the subgroup of VLBW infants. Dr. Frigoletto added that a multidisciplinary research center might be most effective in focusing on the VLBW group. Adding a sentence or two to the second recommendation on that issue might be appropriate.

Discussion

The full Committee added the following comment on the subcommittee's recommendations:

- The title of the state-of-the-science conference probably should refer in some way to the notion of disparities in infant mortality. This wording should be added to the first and second recommendations.

Dr. Collins' call for a vote on the recommendations resulted in a unanimous decision to approve all three of them as amended.

Dr. Frigoletto mentioned that certain points are omitted from the recommendations. For example, there is no mention of creating a universal medical records system. He suggested making an inventory of omitted items so that they can be added to the report. Dr. Sapien suggested including a list of stand-alone recommendations. Dr. van Dyck mentioned that SACIM members could make suggestions about omitted items when they review the final draft reports.

ADJOURNMENT

Dr. van Dyck congratulated the Committee members for their work on the recommendations and the text of the reports. The final draft of the reports (narrative and recommendations) should be ready for review by August 18, 2006; the review process should be completed by September 8, 2006, and the final reports should be submitted for SACIM approval at the November 2006, meeting.

The meeting adjourned at 2 p.m.

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