

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

**Meeting Minutes of  
March 1–2, 2005**

**The Sheraton National Hotel  
Arlington, Virginia**

## **GENERAL SESSION**

**TUESDAY, MARCH 1, 2005**

### **CALL TO ORDER**

*James W. Collins, Jr., M.D., M.P.H.*

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

*Associate Professor of Pediatrics, Northwestern University Medical School*

### **WELCOME AND INTRODUCTIONS**

Dr. Collins noted that the inclement weather has impacted the locals more than members who have traveled to the meeting from far away, so some people may be delayed and will arrive as the morning progresses. He welcomed the participants to the Secretary's Advisory Committee on Infant Mortality (SACIM) meeting, a very important one that will build on the previous meeting. For the benefit of new people in the audience, he asked members and observers to introduce themselves.

Dr. Collins reminded members of the packet they had received from Ann Koontz, Dr.P.H., C.N.M., that included a summary of the most recent Committee business session, November meeting minutes, and a set of previous agendas. Each member also received the handout for the current meeting that outlines the Committee work. The task for the next year to year and a half is to identify and work on issues that deserve further exploration and concentrated subcommittee work, with the goal of providing recommendations to the Department of Health and Human Services (HHS). Subcommittee issues should focus on program deficiencies that could benefit from further departmental efforts aimed at improving maternal and infant health. The subcommittees will assist the Committee examine several issues in depth and make practical recommendations to the Secretary that can be easily implemented.

Dr. Collins announced a public forum scheduled for Wednesday, March 2, 2005, where the public will have the opportunity to address the Committee. He also referred to a summary in the members' packets from the National Center for Health Statistics (NCHS) that highlights the increase in the 2001–2002 infant mortality rate. According to the summary, which is an update of an earlier presentation to SACIM in the past year, there were more births of infants who weighed less than 750 grams. The increase was not limited to a particular race or age range—it was evenly distributed among women aged 20 to 34 years. Charles Rothwell, M.S., M.B.A., Director of NCHS's Division of Vital Statistics, is on the agenda for March 2 to discuss the issue.

Dr. Collins reminded attendees who are not on the Committee that they may attend all of the sessions as observers only.

Dr. Collins shared that he is a liaison between SACIM and the Advisory Committee on Heritable Disorders and Genetic Diseases in Newborns and Children (ACHD), which is moving forward

with recommendations on universal newborn screening. Peter van Dyck, M.D., M.P.H., is also an active member of that Advisory Committee and he was asked by Dr. Collins to present an update of the most recent meeting.

**HEALTH RESOURCES AND SERVICES ADMINISTRATION  
AND MATERNAL AND CHILD HEALTH BUREAU UPDATE**

*Peter C. van Dyck, M.D., M.P.H.*

*Associate Administrator, Maternal and Child Health Bureau, HRSA*

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

Dr. van Dyck extended greetings for Elizabeth M. Duke, Ph.D., Administrator of HRSA and from himself for the Maternal and Child Health Bureau (MCHB). This is SACIM's first meeting since the appointment of HHS Secretary Michael Leavitt, whose biographical sketch is included in each participant's meeting binder. Dr. Duke has had several meetings with the Secretary, and she and Dr. van Dyck will take part in budget hearings next week with the Secretary and the appropriations committee; the Secretary is therefore eager to quickly learn about the Department and its programs.

HRSA is responsible for the President's Health Care Center Expansion Initiative, which is designed to establish or expand a total of 1,200 health center sites that will serve an additional 6.1 million patients annually by 2006. The Initiative continues to be a priority because 100 percent of the funds will provide direct health care services to people who need them the most, including pregnant women.

In 2004, the Community Health Centers System served an estimated 13.2 million people (3 million more than in 2001 at more than 3,600 delivery sites, an increase of about 500 sites since 2001). It is a rapidly expanded program. HRSA's Fiscal Year 2006 budget, which begins on October 1, 2005, increases funds to health centers to complete the President's 5-year growth initiative. The increases are intended to help reach key goals by developing new health center sites in 40 of the Nation's poorest counties, and by placing new sites in 25 other high-poverty counties. One of the biggest challenges of an expansion of this size and scope is to find the right people to fill the estimated 36,000 new health center staff positions through 2006, including more than 11,000 clinicians.

National Health Service Corps (NHSC) clinicians have a fundamental role in the staffing strategy. As part of this health center system, President Bush also directed the agencies involved to reform and extend the NHSC, which continues to do a very good job placing thousands of health care professionals in the field. Since 1972, the NHSC has placed almost 26,000 primary care or mental or behavioral health clinicians in areas with shortages of health professionals across the country.

Dr. van Dyck then discussed the President's recently released budget and the 2006 allocation for the MCHB. The money essentially remains flat from 2005 at \$724 million for the maternal and child health block grant, which constitutes a formula that allocates to each State an amount of money tied to the percentage of poor children in that State. A grant program, called SPRANS,

allocates grants of regional and national significance, about 800 in total, to agencies, community groups, and universities for programs related to professional training, sudden infant death syndrome (SIDS), children with special health care needs, maternal care, and infant mortality prevention. Because the block grant is flat, that discretionary budget is relatively flat as well. Healthy Start had about \$98 million in 2004 and increased to around \$103 million for 2005, the current year, and returns to the 2004 level in 2006. Dr. van Dyck noted that this Committee is responsible for advising the Secretary on the implementation of the Healthy Start Program. He then mentioned several small programs, about \$10 million for newborn hearing screenings, about \$20 million for emergency medical services for children, and around \$9 million for the traumatic brain injury program in 2006.

Congress can allocate money that is not in the President's budget. These provisions are called earmarks. According to Dr. van Dyck, Congress has earmarked money for oral health, sickle cell disease, epilepsy, genetics or newborn screening, and mental health. These funds have been congressional earmarks, not presidential allocations, for the past 2 to 3 years.

In 1997, about 2 million pregnant women out of an estimated 4 million pregnancies a year were served by the MCH block grant in the United States. In 2003, almost 2.5 million pregnant women were served, which equates to serving about 65 percent of all pregnant women in the United States in some way during pregnancy or delivery.

About 3 million infants were served in 1997 compared with an estimated 3.9 million infants in 2003. The MCHB basically serves 100 percent of all infants born in this country. The newborn screening program is a partnership between the States and the Federal Government that reaches every newborn. There is also high-risk screening and many other services specifically for infants.

In 1997, an estimated 16.5 million children received services, compared with an estimated 18 million in 2003—approximately one-quarter of the Nation's 80 million children from 1 to 18 years old. An estimated 900,000 children with special health care needs received services in 1997, compared with approximately 1.2 million in 2003, comprising 12 to 15 percent of this population.

The total number of individuals served by MCH programs increased from 24 million to more than 28 million in that 6-year period. Dr. van Dyck emphasized that the MCHB, in concert with its State and local partners, provides an immense amount of services to children, mothers, and families across the United States, despite a flat budget in some years.

Dr. van Dyck also discussed the activities of the Low Birth Weight Coordinating Council (LBWCC). At the urging of SACIM when it chose low birth weight as a long-term strategic issue on which to advise the Secretary, the Secretary formed an internal committee within the Department to better understand and coordinate research projects studying low birth weight and then make a set of recommendations to agencies in the Department. Recommendations were sent to the LBWCC, minor changes were made, and the LBWCC has finished and reviewed the final report. Dr. Koontz is finalizing the edits. Ten days ago the Secretary's office called Dr. van

Dyck to ask when it would be completed; he noted that the interest in the report had carried over to the new Secretary, who was told to expect the report in 3 or 4 weeks. Dr. van Dyck praised the report and the work of the members, especially Dr. Koontz and Susan Meikle, M.D., M.S.P.H., of the Agency for Healthcare Research and Quality (AHRQ). Duane Alexander, M.D., Director of the National Institute for Child Health and Human Development, and Dr. van Dyck co-chair that committee.

This week, the Objective Review Committees began a competitive review of all 68 Healthy Start sites for the approximately \$73 million that will be allocated in June or July 2005. Two projects for border health are also applying for funds under the racial disparities component, which will divide \$1 million between them.

Dr. van Dyck also discussed the national evaluation by MCHB of the Fetal and Infant Mortality Review (FIMR), which was presented in the December 2004 issue of the *Maternal and Child Health Journal*. He characterized the issue as an excellent review of the entire process and noted Johns Hopkins University faculty were involved. Dr. van Dyck passed one copy around and indicated that each member will be mailed a copy. The evaluation examined the effectiveness of local health departments in communities with and without FIMR programs. The delivery of essential MCH public health services received special attention. In the overall findings, local health departments in communities with FIMR programs were more likely than communities without a program to implement several essential MCH services such as data collection and quality assurance activities. A significant component of FIMR was designed to improve these activities. The review also found that implementation of essential MCH services was enhanced in local health departments and in communities that had the FIMR program in conjunction with another type of perinatal systems initiative (e.g., grants for Healthy Start or to decrease infant mortality). Positive evaluations reflect the good work in communities with the FIMR program, an active program from the Bureau that continues to serve communities.

Dr. van Dyck referred to the Secretary's ACHD, which Dr. Collins had mentioned earlier. It is similar to SACIM in status and was established by the Secretary last year to advise him mainly on newborn screening issues and services around the country.

At the last SACIM meeting, Dr. van Dyck had presented an update on newborn screening that included inequities among States, rapidly expanding technology, and the need to provide equal access for all parents whose children have rare conditions. He had also discussed a report commissioned by the MCHB and conducted by the American College of Medical Genetics that recommended a minimum panel of newborn screening tests that every State should be using and should have to implement these changes.

The report recommends how to address issues such as when to add tests and effectively expanding a State program. Dr. van Dyck noted that the report will be released the week of February 28 to March 4, 2005, and a *Federal Register* notice will announce a 60-day period for public comments. The report will be sent to selected organizations with a special interest in it, such as the Association of Maternal and Child Health Programs (AMCHP), State directors, State laboratory directors, geneticists, parents, and other groups. It will also be available from the

MCHB Web site. The *Federal Register* notice will also include Web addresses for the report, other ways to access it, how to comment on it, and where to call with questions. Dr. van Dyck characterized it as a very significant report with many recommendations that have a national impact on programs and States, and invited individual and collective comments. Dr. van Dyck added that Dr. Collins provides a formal liaison between ACHD and SACIM. Dr. van Dyck pointed out that newborn screening is a very timely issue with press coverage in newspapers such as *The New York Times* and the *Wall Street Journal* and members should stay well-informed because it relates clearly to infant mortality. The ACHD voted to send a draft of the report to the Secretary with a request to please pay attention to the data and take appropriate action when he receives the final report. Dr. van Dyck concluded by asking for questions.

## Discussion

- Maxine Hayes, M.D., M.P.H., FAAP, was pleased that Dr. van Dyck had mentioned the LBWCC's report and noted that the *Maternal and Child Health Journal* would be a good place to share the findings of the report. She reminded members that the National Academy of Sciences (NAS) also is convening a committee to work on low birth weight and is seeking participants; Dr. Hayes has submitted names from SACIM for consideration. She identified a connection between NAS objectives and the LBWCC report. Now that the report is complete, it presents a wonderful opportunity for NAS and SACIM to publicize and increase the visibility of the findings. Dr. van Dyck clarified that the report is complete but has not been cleared yet.
- Robert Hannemann, M.D., asked whether SACIM members will automatically receive a copy of the report. He also wanted to know the process for implementing any of the recommendations once the Secretary has received it. Dr. van Dyck did not know; he indicated that the Secretary makes that decision. Dr. Hannemann pointed out that the final paragraph of the *National Vital Statistics Report* (volume 53, number 12) states that "the prevention of preterm and low birth weight delivery, and especially very preterm and very low birth weight delivery, should be central to efforts to further lower the U.S. infant mortality rate." The report is an indication of the pressure that is needed but may not be found elsewhere, said Dr. Hannemann. He has been working on these issues for the past 4 or 5 years and is eager to see results.
- Betty Tu, M.D., M.B.A., thanked Dr. van Dyck for presenting such an excellent update especially for members who are in the consumer industry, thus bringing them up to date immediately.

Dr. Collins reminded members to review the minutes of the previous SACIM meeting. He then motioned for approval of the minutes. Dr. Hayes seconded the motion, and the minutes were approved.

## **FINANCING: PROVIDER REIMBURSEMENT/PAYER SYSTEMS**

*Panel discussion with:*

*Edith Hambrick, M.D., J.D., Medical Officer, Center for Medicare Management, Centers for Medicare and Medicaid Services*

*Linda A. Tavener, Team Leader, Non-Institutional Payment Team, Division of Reimbursement and State Financing, Center for Medicaid and State Operations, Centers for Medicare and Medicaid Services*

*James A. Scroggs, M.H.A., Director, Department of Health Economics, American College of Obstetricians and Gynecologists*

*Charles J. A. Schulte, III, M.D., FAAP, in private practice in Virginia and former Chairperson of the American Academy of Pediatrics Committee on Coding and Nomenclature*

### **Remarks by Edith Hambrick, M.D., J.D.**

Dr. Hambrick substituted for the scheduled speaker, Carol Bazell, M.D., who was unable to attend. Dr. Hambrick stated that many physicians are not paid under the Medicare Physician Fee Schedule (PFS), but she was told that SACIM wanted to know how the process works. She then explained that, historically, before establishment of the Medicare PFS, Medicare payments were based on the charging patterns of physicians, which were considered inflationary with unacceptably large differences among types of services, geographic areas, and physician specializations. The 1989 Omnibus Budget Reconciliation Act implemented the PFS, with a gradual transition from the reasonable charge to a resource-based fee schedule that took full effect in January 1996. Recent changes were mandated by the 2003 Medicare Modernization Act.

More than 7,000 services are reimbursed under the 3 PFS components: physician work, practice expenses (the costs to physicians for maintaining an office), and the malpractice expenses (referred to as professional liability insurance). There are uniform national resource-based relative value units (RVUs) for each component: physician work RVU (WRVU), practice expense RVU (PERVU), and malpractice RVU (MRVU) expenses. The payments vary among 92 localities and are based on geographic practice cost indices (GPCIs) that reflect different resource costs of providing services. Rent in Manhattan differs significantly from rent in a small rural area, and wages for employees may also be affected by geography.

The overall payment is determined by multiplying the WRVU by the work GPCI (WGPCI), adding the PERVU multiplied by the practice expense GPCI (PEGPCI), adding the MRVU and multiplying it by the malpractice GPCI (MGPCI); and then multiplying by the conversion factor, which amounts to about \$38 this year.

Dr. Hambrick explained that payments are based on the Current Procedural Terminology® (CPT) codes and on some G codes, which are created for special programmatic needs, such as implementing statutory guidelines for colonoscopy screening. That screening benefit can be satisfied by any of three tests. Therefore, a G code may be needed that describes such a specific service as opposed to that found in the CPT codes. The American Medical Association (AMA) CPT Editorial Panel annually revises and updates the CPT code set that forms the basis of PFS

payments. Of the 11 AMA-nominated representatives from specialty societies and 6 additional representatives, the Centers for Medicare and Medicaid Services (CMS) has 1 voting member. The Panel provides annual updates to CPT codes that reflect current medical practices. The Panel may also delete codes and provide some coding guidance within the CPT book and CPT coding assistance.

After the codes are passed at CPT, they go to the AMA Relative Value Update Committee (RUC) for physician services. The Committee has voting representatives from 23 specialty societies, including AMA, CPT, American Psychological Association, Health Care Professionals Advisory Committee, and political action committees. The RUC provides recommendations on an annual basis, usually in August, to CMS about WRVUs and PERVUs, and contributes to maintaining the resources-based relative value scale (RBRVS). The MRVUs have a different process and do not provide recommendations. CMS accepts more than 90 percent of the recommendations from the RUC. However, if there is a sense that some are “misvalued,” they may be referred to a refinement panel.

The Practice Expense Advisory Committee was charged with reviewing all 7,000 codes to develop or update practice expenses. The name was changed to the AMA Practice Expense Review Committee (PERC) and it is a subcommittee of the RUC. Except for an additional representative from nursing, its composition mirrors that of the RUC. PERC is a smaller committee that looks at all new codes and advises the RUC on direct practice expense input values. For example, there may be a question of how many minutes a nurse is with a physician during a certain procedure. The PERC may also discuss the types of supplies necessary for that procedure and forward the information to the RUC. The RUC will then vote on the code and work values and will also include a recommendation for the practice expense. These decisions are then forwarded to CMS.

The initial WRVUs were established through a Harvard University study headed by Dr. Hsiao, and are in the process of a PFS review required by law that refines the codes every 5 years. By 2007, there will be some new work values. Every year CMS publishes a Notice of Proposed Rulemaking, usually in the summer, on policy decisions and considerations for the upcoming year. CMS also publishes the WRVUs and PERVUs, usually in November.

The relative values for practice expenses are based on a statutory formula that was in use from 1992 to 1998. Beginning in 1999, the AMA was tasked with looking at all 7,000 codes to refine the practice expense inputs. As the AMA refines the codes in the current 5-year review, the practice expense will be reviewed as it relates to labor. However, the practice expense as it relates to inputs, such as the cost of a machine or how many minutes a technician is present, will not be reviewed.

Resource-based MRVUs were first implemented in 2000. They are also reviewed every 5 years and are based on actual malpractice premium data from surveys of insurance companies or State agencies that have malpractice data across a broad spectrum of States. The MRVUs account for 3.9 percent of the total RVUs. Obviously, for some specialties with higher professional liability insurance rates, the percentage is higher.

The GPCIs are updated every 3 years; revisions are phased in over 2 years. The MGPCIs were updated in 2004. The WGPCIs and PEGPCIs will be updated in 2005 to incorporate data from the most recent census.

Changes to the PFS are implemented through a regulatory process that was mentioned earlier. The statutory formula—the sustainable growth rate—adjusts physician rates to make actual spending equal a target and will make reductions in the PFS conversion factor if the target is not reached. If spending is higher than the target, there is a statutory maximum reduction that is equal to 7 percent in a year. However, the 2003 Medicare Modernization Act update permitted physicians a 1.5-percent increase for 2004 and 2005.

Dr. Hambrick repeated that the conversion factor for 2005 is about \$38. Anesthesia has a different methodology for determining the conversion factor, which is about \$17.75. The base rate is tabulated on minutes, with additional preprocedure and postprocedure rates depending on the type of procedure.

Dr. Hambrick suggested sources of further PFS information. The CMS Web site (<http://www.cms.hhs.gov/physicians>) has numerous drop-down menus; going to providers permits access for physicians, nonphysician practitioners, or hospitals. There are also open-door forums, where anyone may ask a question. The Web site is (<http://www.dms.hhs.gov/opendoor/>) for more information. Several files on the Web site provide tables for the CPT codes, scriptors, RVUs, GPCIs, and other components that are needed to calculate payments. Carriers can be located using Zip Codes. Dr. Hambrick can be reached [ehambrick@cms.hhs.gov](mailto:ehambrick@cms.hhs.gov). Dr. Bazell can be reached at [cbazell@cms.hhs.gov](mailto:cbazell@cms.hhs.gov), or 410-786-6960.

Dr. Collins said there was time for questions. Robert Sapien, M.D., FAAP, asked when the 2005 GPCIs will be available. Dr. Hambrick responded that a change in the census definition has caused a delay; she asked him to e-mail his question to her and she will forward it to the person handling the GPCIs.

### **Remarks by Linda Tavener**

Ms. Tavener provided an overview of how Medicaid pays for physician and other licensed practitioner services. Medicaid is a Federal-State partnership. There is a great deal of strain on the partnership currently, with much more flexibility on the Medicaid side, because it is a partnership, than on the Medicare side. States have a large amount of flexibility to set payment rates for physician and other licensed practitioner services within Federal guidelines that are usually broad, but are sometimes very specific.

Two overarching principles govern payment under Medicaid:

1. Payments must be consistent with efficiency, economy, and quality of care; and
2. Rates have to be sufficient to enlist enough providers so care and services are available to Medicaid beneficiaries to the same extent that services and care are available to non-

Medicaid beneficiaries in the general population. This principle is called the Equal Access Provision (EAP) and it serves as a floor for Medicaid payments.

For professionals not enrolled as managed care providers, States generally pay pursuant to a State-developed fee schedule. For individuals enrolled in managed care, providers would be paid as part of the capitated rate. Many Medicaid recipients currently are in managed care. Virtually all States have some recipients in managed care, and while results have been mixed, many States are moving more and more Medicaid beneficiaries into the managed care arena. Fee schedules can be Statewide or can vary by locality, and they should generally be the same for public and private community providers of the same service in the same locality.

This administration has a heavy focus on proper funding for the Medicaid program and is concerned about States paying their share; the Federal Government pays a portion of the cost and States pay the rest. How much each side pays depends on the per capita income of the individual State. The highest is around 85 percent now. The Federal Government pays roughly 80 to 85 percent of the maximum. States that are wealthy, such as New York and California, would be about a 50–50 match. Because of the administration's emphasis on funding, CMS looks at how public and private providers are paid. When it comes to fee schedules, the expectation is that when a State sets the fees, the State would pay the same rates pursuant to the fee schedule for public and private community providers to provide the same service in the same locality. Some but not all States base their fee schedules on a percentage of the Medicare fee schedule. The States are permitted to mix and match, to pay some providers at the Medicare rates, pay some at a portion of the Medicare rate, and, in some cases where there is a need to increase access to particular services or attract certain providers to enroll, pay more than the Medicare rate. That policy is currently being applied to university-affiliated professionals or those employed by safety-net hospitals.

Probably the biggest overarching principle for a State is how much Medicaid costs. In many cases, the cost combined with the type of budget a State has will determine reimbursement fees and services. During the past 2 or 3 years, States have had serious budget problems that have caused changes in programs by limiting eligibility. Under Medicaid, there are mandatory and optional eligibles as well as services. During the past 2 years, many States have implemented amendments to limit eligibility and eliminate optional State plan services such as chiropractic care. Many other licensed practitioner services are optional. States have also lowered the rates paid for particular services. States usually target expensive items such as inpatient hospital services, but occasionally target professional services provided by physicians and other licensed practitioners.

States are permitted to pay higher rates for particular kinds of professionals, physicians, and other licensed practitioners, or for particular services or CPT codes. Pediatric and obstetric services and codes are often paid at a higher rate than other codes because those populations are seen as the most vulnerable in Medicaid. States will often pay higher rates in rural or underserved areas to entice providers into the program and increase access. States may also negotiate with and pay higher rates to particular specialists whose services are needed but who are usually unwilling to

accept Medicaid rates that many providers, particularly among transplant specialists, consider very low.

Medicaid has upper payment limits (UPLs) for inpatient and outpatient hospital and clinic services, and this topic has received a great deal of attention in the last 2 years, noted Ms. Tavener. Technically, there is no UPL for physician or other licensed practitioner services. However, all Medicaid payments have to conform to the overarching principles mentioned earlier: they have to be efficient and economical. In the last 2 years, as part of the funding problems that have emerged in the Medicaid program, States have been asking CMS for approval to pay higher rates to professionals in group practices affiliated with university teaching hospitals and to hospital-based physicians employed in public safety-net hospitals. These requests all have to do with how Medicaid is funded. The States have to match funds and cover some of the costs. Regulations and statutes enable States to legally transfer money from State university teaching hospitals and public hospitals back to the Medicaid agency to pay for their share of Medicaid costs. States have a good reason for increasing payments to these categories of providers—it is a way to recycle the money back to the State. A State will typically increase rates paid to these professionals on paper by adding a supplemental payment to the base rate, but the provider never receives the additional money.

Funding in the university setting is rather complicated. Large pools of money are drawn from a range of sources such as grants, State appropriations, and patient care. Salaries for some of the professionals associated with these group practices are drawn from some of those pools. So when this payment is made, it goes back into that large pool of money and the universities do whatever they want with it.

Because the administration currently emphasizes funding, allowing those rates to become too high raised the concern that a significant portion of the money was not being used for the Medicaid programs, but was instead offsetting other costs at the university and elsewhere in the State's troubled budget. CMS has therefore set physician UPLs outside of the regulations, as a matter of policy. The UPL is the average commercial rate paid to the same types of providers in university-affiliated group practices for the same services in the same area. It is controversial because it is a policy and not a regulatory action under the broad statutory requirement for economy and efficiency. These efforts have enabled CMS to close loopholes in the statutes that allow States to inappropriately recycle Federal funds from the Medicaid program for other purposes.

## **Discussion**

- Dr. Guyer asked, in many States, particularly where Medicaid covers a huge proportion of the births in the State, how Medicaid pays the costs for some of those systems that are different than individual costs to a physician or a hospital. He also asked how CMS plans and coordinates with Title V maternal and child health services. Ms. Tavener said that at the Federal level in terms of Title V there is little coordination. There are supposed to be interagency agreements among the Title V and State Medicaid agencies that call for any

coordination that is necessary, but CMS does not typically monitor those agreements unless there is a problem with them.

- Ms. Tavener asked Dr. Guyer to clarify what he meant by “systems costs.” He responded with the following examples: movement of infants between levels of care, transportation of medical services, and all of the different kinds of services States are providing in the area. Ms. Tavener explained that transportation is a covered Medicaid service. It is a requirement; States have to provide transportation to medical services for any eligible beneficiary. It would not be any different for the populations Dr. Guyer mentioned than for an adult, a nonpregnant woman, or others.
- Kevin Ryan, M.D., M.P.H., suggested that Dr. Guyer possibly meant issues related to administrative claiming or Federal financial participation, and asked Ms. Tavener to comment on them. She indicated that there is a separate match for administrative costs related to the proper and efficient administration of the Medicaid program that can cover transportation, outreach, and eligibility activities. That match is normally 50 percent, and is separate from the match that would be paid for medical services such as inpatient and outpatient hospital and physician care.
- Dr. Hayes mentioned that members have discovered, from their experience on SACIM and from working with maternal and child health populations for years, the importance of and contributions from nonmedical components of care to improving health status and outcomes; she noted that there is no exception when it comes to perinatal issues. She is interested in achieving a better understanding of why some nonmedical services really should not be optional because many of them are at the State level and the States can pay for the services. She wanted to know if Ms. Tavener is aware of an emerging policy that would even out the situation where nonmedical services that are broadly understood, such as social determinants, would not be optional. In the 1980s, States learned that nonmedical services affected the most outcomes. In Washington State, Title V has a relationship with Medicaid, but because States can choose this policy status, Washington State is the exception more than the rule. She then spoke of a need for a balance in policies. Many families need more time and require more services than providers are paid to provide. Mothers for whom infant mortality could be a problem will not receive the support services they may need to get through a pregnancy and have a successful outcome.
- Ms. Tavener asked what Dr. Hayes meant by optional services, explaining that CMS can only pay for services that Congress has designated in the statutes as Medicaid services. Of those, there are some that Congress has mandated every State to provide and some services that Congress has permitted States to choose to provide. Ms. Tavener clarified that under current law, optional services include services from nurse practitioners other than family and pediatric nurse practitioners, which are mandatory under Medicaid. There is no current effort toward making any optional services mandatory; the Government is moving in the opposite direction. This administration is considering eliminating some of those optional services. Dr. Hayes was of the opinion that it is not

the right direction, and wondered what it will take to reverse that possibility because it will lead to more harm than good and will cost more later on. Dr. Collins and Ms. Tavener both noted that opinion should be saved for subcommittee work.

- Dr. Hannemann asked Ms. Tavener whether the EAP cited in her presentation is being enforced: “Payments must be consistent with efficiency, economy, and quality of care and sufficient to enlist enough providers so that care and services are available under the plan to the same extent available to the general population.” He does not see evidence of extensive enforcement and mentioned lawsuits pending in Michigan and other States. It is a simplistic problem: inadequate reimbursements to providers will leave States without enough providers. Dr. Hannemann asked why the EAP is not being enforced.
- Ms. Tavener explained that it is in many ways a political concern. Medicaid is a large program that is already very expensive. It is not politically palatable for the Federal Government to tell States with existing budget problems that they have to pay a certain rate or a higher rate. It is also problematic that the statute does not provide a workable enforcement mechanism. The compliance process under Medicaid entails taking additional funds back from a State. It does not make sense to some people to punish a State for not paying higher rates by taking money from the State budget and State Medicaid program, because that money eventually comes from the providers, the beneficiaries, and everybody else. Dr. Hannemann said that must be the reason for the problems some States are experiencing, and noted the need for a solution before a crisis situation results. States currently in a crisis are forcing patients into emergency room care that is more expensive and less efficient. It seems to be a disconnect not to recognize a regulation already in existence.
- Christina Ryan, R.N., M.P.A., B.S.N., mentioned maternal fetal medicine, and asked how, with only a few thousand in the country, an expansion can be put into place that would allow other providers or caregivers to benefit from these services if the accompanying access to dietitians and genetic counselors does not occur. Yet when those efforts and models are generated, these so-called optional services are eliminated, and efforts to expand the scope for that practitioner or physician are thwarted. However, Medicaid is in communities that need a perinatologist to reduce infant mortality and it is Medicaid that prohibits access to these other licensed professionals by not allowing reimbursement. Ms. Tavener agreed, but said there is little she can do about it even though CMS is well aware of these complaints and has heard them many times.
- Dr. Ryan characterized the difficulties as a process that is driven by many decisions made by the States and the problems may differ. Access to oral health services is a problem in North Carolina but may not be a problem in South Carolina. Traditionally, the remedy has been a legal one; access to oral health care involved a lawsuit in North Carolina, which is time consuming as well. Again, leaving many of these decisions at the State level does not appear to permit a broad and sweeping solution, he observed. The solution is more money, but the States and the Federal agencies share the same monetary concerns.

- Robyn Arrington, Jr., M.D., represents Michigan, and as a medical director of a primarily Medicaid health maintenance organization, he knows some of these issues are enormous problems in that State. He wondered whether Ms. Tavener anticipates any relief in terms of funding in the next several years. The Governor of Michigan just announced a \$1 billion shortfall in the Medicaid program, at the same time that the southeastern part of Michigan has mandatory managed care for the Medicaid population, thus leaving the State responsible for deciding who to pay—the hospital, the practitioner, or the pharmacy costs. The Governor also rescinded a 12.5-percent raise that had been promised to managed care for the upcoming year. Last year there was no increase to address inflationary concerns.
- Ms. Tavener responded that the situation will likely get worse before it gets better. However, this administration is very committed to proper funding. CMS recently reorganized to create a unit specifically for reimbursement and funding issues, and hired 100 new full-time equivalent employees across the country to audit State funding practices. The administration strongly believes that States have been violating the rules and taking advantage of the Federal Government for a long time. At the National Governors' Association meeting on February 28, 2005, funding was an important topic. The President's budget calls for \$50 billion in savings from addressing these funding loopholes. These are serious efforts to ensure that Federal dollars are spent correctly, which could cause some heartache at the State level in the short term. In the long term, there could be a major restructuring of Medicaid.

### **Remarks by James Scroggs, M.H.A.**

The American College of Obstetricians and Gynecologists (ACOG) is actively engaged in the process described earlier by Dr. Hambrick. ACOG has a representative on AMA's CPT editorial panel and on AMA's RUC. ACOG is very active within those committees. The committees recommend new codes when needed, survey members to determine relative values (including the current 5-year review), advise physicians on coding issues, advocate for appropriate payment policies by public and private payers, conduct coding courses to make sure physicians know how to code correctly (there were about 13 courses this year and the same number are planned for next year), and provide publications to ensure that people are following the procedures correctly. ACOG is satisfied with the process because the CPT and RUC are peer reviewed. The CPT codes define distinct procedures by ensuring that a code does not involve multiple procedures that are already defined elsewhere without overlapping. The RUC develops relative values based on CPT definitions. Hysterectomy is by itself. Treatment for flu is separate from treating someone who is pregnant. Medicare, using the RBRVS, does not pay the cost of providing the medical care. The RBRVS establish relative values. "We know which one is more; we know which one is less," explained Mr. Scroggs. Based on the physician work, the practice expense, and professional liability, the cost differences become apparent and these numbers are used to determine a pay scale. It does not necessarily mean that the pay scale pays for the cost of the care provided.

Most nongovernmental payers use CPT or some modified form of that code. The insurers use a

modified RBRVS. The CPT is now required under the Health Insurance Portability and Accountability Act (HIPAA), making it the universal form of coding, but that does not necessarily mean that the relative values are used uniformly. It does mean that the codes are used uniformly. Insurers modify payment and bundling rules. Although these procedures are distinctly defined, the insurers may indicate that different treatments occur together. For example, a pregnant woman visits an obstetrician, but she may need and receive treatments that are not obstetric.

The RVU process works relatively well, especially for physicians working with practice expenses. The liability expenses, however, are not appropriately documented. The method of determining the costs is flawed. The services use old data from unreliable sources. A 30-percent increase in liability costs over a year or two is not reflected by any changes in the relative value scale. Medicare payments are legislatively limited, and that is a significant problem. Trying to decide how much of an increase is needed to pay for liability costs is not going to have an overall positive effect for the physician, because money is limited. By bundling, insurers do not pay for all of the services that are provided.

Mr. Scroggs read from a contract submitted by an insurer to illustrate how insurers manipulate the codes to avoid payments.

The group agrees to permit rebundling to the primary procedure those services considered part of, incidental to, or inclusive of the primary procedure and to allow Company to make other adjustments for inappropriate billing or coding (e.g., duplicative procedures or claim submissions, mutually exclusive procedures, gender/procedure mismatches, age/procedure mismatches). As of the Effective Date, in performing rebundling and making adjustments for inappropriate billing or coding, Company utilizes a commercial software package (as modified by Company for all Participating Physicians in ordinary course of Company's business), which commercial software package relies upon Medicare and other industry standards in the development of its rebundling logic.

Mr. Scroggs then mentioned that arbitration and the arbitration clause essentially prohibit any group action on behalf of physicians to challenge the coding rules that insurers have arbitrarily developed. Physicians deal with these kinds of clauses every day, which can evoke an adversarial attitude toward insurers. With small practices especially, there is very little a physician can do to challenge these contracts—there is no opportunity for negotiations. Mr. Scroggs read a section of an e-mail that he received on January 17, 2005, from an ACOG member:

Since my liability insurance had continued to skyrocket over the past few years, why hasn't the malpractice portion of the RVU allocated to global OB gone up proportionally? If this were to occur, then the insurance companies and Medicaid payers who base their fee schedules on RVUs would be forced to pay more for OB, making the increase in liability insurance palatable. Since this has not happened, is the RVU system a farce? Who calculates the RVUs? And why haven't they

increased the RVU proportionally? Thanks, RS, M.D.

Mr. Scroggs said it is important to remember that the AMA and RUC do not have direct input into malpractice or professional liability expenses.

Using a chart, Mr. Scroggs provided an example of proposed factors used to calculate the liability portion of RBRVS. The risk factor of 1 is based on the allergy/immunology professional liability fees. Other services in the chart are then multiples of that number. The premium used for obstetrics and gynecology is about \$70,000 a year, whether it is prenatal care or the delivery itself. The obstetrician also provides gynecological care, so the premiums those payments are based on are about 50 percent less than those for obstetrics.

Mr. Scroggs explained an example from Missouri. The liability for 2004 was about \$103,000, which is about average for Missouri. For obstetric care, the RVUs for the physician work (23.03), practice expense (14.97), and liability (4.47) reflect about 10 percent for the liability portion, which is higher than the typical 3 percent. Using the conversion factor of about \$38 leads to about \$170 per delivery for the liability payment. (The geographic factor is not applicable to Missouri so it was omitted.) The obstetrician needs 607 deliveries a year to recover the \$103,000; the national average is 142 deliveries. The obstetrician is providing other services that pay even less for the liability portion. As a result, class action suits are in progress against major insurers; the cases against Aetna and Signa have been settled.

Liability costs have risen 30 to 50 percent, while liability payments increased by 1 to 2 percent. The rebundling is perceived as unfair, and there is dissatisfaction with the CPT and RUC processes—not widespread or hostile but questions about why payments do not match expenses. In some areas, especially in rural States with already few obstetricians, liability premiums are increasing significantly. The loss of a few doctors in some counties means there will be none. Mr. Scroggs presented four recommendations:

1. Adjust the physician fee process to include correct liability costs reimbursement. This would require a legislative change.
2. Adjust the RBRVS to allocate liability expenses appropriately across all obstetric and gynecological services, not only to obstetric services, which is the current policy. Obstetricians also provide a significant amount of gynecological care.
3. Address the liability system or tort reform.
4. Effect acceptance of CPT definitions by insurers to address issues that have resulted in lawsuits in the past few years. Acceptance can be voluntary, judicial, or regulatory. Efforts are ongoing with insurers to improve the situation and with McKesson, the developer of the software, to accept definitions that are appropriate.

## **Discussion**

- Dr. Guyer commented on how much has been learned about the importance of preconception care and its ultimate influence on the outcome of pregnancy; people also use the term preconceptional care. He asked what is needed to incorporate a funding

scheme of incentives for preconception care. Mr. Scroggs said that physicians could provide this care with the proper codes. It is not just counseling, but visiting the doctor before pregnancy to ensure a healthy status and to examine genetic and other factors. Many insurers cover those areas of care and there are CPT codes for them. Some of these efforts to motivate physicians to provide and the patients to seek this care are merely educational. He then asked Albert Strunk, M.D., J.D., FACOG, Vice President, Fellowship Activities, ACOG, for comments.

- Dr. Strunk reported that a large percentage of pregnancies remain unintended and unplanned, and therefore elude any impact in terms of preconception issues. Also, there is currently an attempt to determine the many factors that might be screened for if the money is available in a preconception setting. There is no uniform agreement or standard as to exactly what those factors should be. No one really knows which factors impact preconception, he added.
- Dr. Hayes noted that many of the things that may have a positive impact on pregnancy outcome probably do not have a CPT code. Creating those codes needs an agreement on standards, as Dr. Strunk indicated. Without a code, providers cannot be paid. Dr. Hayes asked that this topic be part of the subcommittee deliberations in the afternoon on reimbursements. She felt they had learned a lot about what can positively influence pregnancy in terms of outcome. But working on avoiding unintended pregnancies takes place before the obstetric stage; it is on the pediatric or family side of care.
- Dr. Ryan added that around 50 percent of pregnancies are unintended. He spoke of many missed opportunities by providers. For example, a family practice doctor or a doctor of obstetrics and gynecology may see a woman who is diabetic and receives care for her diabetes but is never told that optimal diabetes control before conception is critically important. Even in the course of routine visits to the doctor, there are opportunities to counsel a woman of reproductive age about what she needs to do before she becomes pregnant, such as smoking cessation. Dr. Strunk offered that this raises the broader issue of basic health care for all Americans and what that means in terms of the number of uninsured persons and the number who do not qualify for Medicaid, in the case of obstetric category patients. He has always viewed obstetrics as just part of the public health issue of a Nation. This country is not prepared to address health care in that fashion any more than the country is willing to provide the basic care to all citizens for diabetes, hypertension, or any other common diseases.
- Dr. Hannemann emphasized that he would rather prevent than treat a problem, which is the hallmark of pediatrics. Because speakers have suggested things will get worse before they get better, and because SACIM needs to advise the Secretary on possible actions, he wanted to know an estimate or prediction of when this critical funding point will arrive, either in the obstetrics or pediatric care setting. He suggested that perhaps there has to be a crisis before there is a change in funding. How far does funding go before reaching a crisis situation, he wanted to know. His question was pointing toward possibly advising the Secretary about a model of the best predictors that identifies when there will be a

critical situation unless some intervention takes place. Dr. Hannemann questioned whether such thinking has taken place in obstetrics; it has in pediatrics, at least at local areas, where people are able to predict that a loss of providers in 3 to 10 counties will result in a crisis situation in the State. He does not know whether those models are being applied nationally at the Academy or at ACOG.

- Dr. Strunk explained that the experience at ACOG is similar to that of the pediatricians, and ACOG has not been able to obtain national data to model the national impact of, for example, the liability insurance factors, which vary widely. And curiously, some States with the highest liability premiums also have the highest physician densities. So in those States, the loss of significant numbers of physicians has not yet resulted in the public health impact that might otherwise be expected. Conversely, there are any number of States in which liability premiums continue to be fairly reasonable and are not forcing doctors out of business. The areas with the most impact are rural areas and other underserved populations, urban or rural, with possibly only one or two providers and the loss of one provider has a dramatic impact on access. But this variegated pattern has made it difficult to formulate a model that helps predict the impact of this crisis nationwide. And it has also made it difficult to galvanize legislatures and, in particular, the U.S. Senate, to look at this problem as a nationwide issue.
- Dr. Tu complimented Dr. Scroggs for two powerful slides that would impress upon anybody the impossibility for a practitioner to deliver 600 babies a year without eroding the quality of service. It is blatantly apparent that even the best obstetrics and gynecology program cannot be filled and these programs are accepting medical students of comparatively lower quality than in dermatology or in plastic surgery, including non-U.S. graduates. She stressed that the erosion of and barriers to access of care, which impacts public health, is coming. How fast is not an issue; it will be in this lifetime.
- Dr. Collins expanded Dr. Tu's observation by pointing out how many doctors leave practice earlier because they have reached their personal limit of dealing with these frustrations and decided they are not going to practice obstetrics but will practice gynecology in their particular locality. With fewer new providers coming out of training, the long-term impact will not be positive.

### **Remarks by Charles Schulte, III, M.D., FAAP**

Dr. Schulte was substituting for a colleague who is now the American Academy of Pediatrics' (AAP's) representative to the AMA CPT Editorial Panel. Dr. Schulte also served on this panel in the past and continues to be involved with the Academy and its activities not only in teaching physicians about coding, which is an essential problem, but also in the entire reimbursement process.

Dr. Schulte indicated that his comments about what the Academy does and how it functions would be similar to the systems described earlier by his ACOG colleagues. AAP is also represented on the RUC, PERC, and AMA CPT Editorial Panel as they are constantly involved

in surveying for practice expense and similar activities.

Dr. Schulte began with some history, noting that in his last year as a resident, a physician who lived on the shores of the Chesapeake Bay invited him for dinner. The physician was really looking for help with his practice so he could spend time with his son and family. The physician had two small examining rooms built onto his kitchen and a tiny office area in between with a student desk. The physician had a drawer for his patients to take out a few dollars or put a few dollars in it; some would pay with fish, oysters, or crabs because that was their livelihood. The physician said that these are his people, and he did not charge them: he took care of them from birth to death, he explained, and they took care of him. Dr. Schulte accepted the offer.

Dr. Schulte showed a complex schematic of a medical encounter. His country physician's payment plan was at the top of the schematic where the patient pays the physician and that was the system. The country physician also had a box of 5 by 7-inch file cards; each card contained the entire medical history of a family.

Times have changed, but medical record documentation remains in the middle of a high-tech schematic graphic of a modern medical encounter. It is a major area of concern. Dr. Schulte referred to the 1995 and 1997 guidelines when he was the Advisor to the Editorial Panel that wrote the new format guidelines designed to solve documentation issues. The Academy recognized that those documentation guidelines were inappropriate for pregnant women and children. The Academy then wrote children's guidelines, but realized that they were inappropriate for infants. So the Academy then wrote another set of documentation guidelines for infants, which were peer reviewed by the AMA and subspecialty groups and then sent to Secretary Donna Shalala. The guidelines were never seen again. CMS told the Academy there would be guidelines for the year 2000 that a contract firm in Rockville, Maryland, was going to develop. He became involved and asked that the new guidelines be appropriate for children and pregnant women, and was assured that they would be. But the contractor had not included considerations for children and pregnant women because, the contractor said, Medicare only covers 1 million children so there were not enough data for guidelines for children.

Dr. Schulte emphasized the need for documentation guidelines to bring third-party payers and providers together to debate what services would be rendered. The other interesting point for pediatrics that was alluded to for pregnant women is that this discussion is about preventive health care. Medicare is not about preventive health care. There have been some recent changes for colonoscopy, mammography, and the Pap smear, but most of the system is not focused on preventive health care. Nowhere in the documentation guidelines is there any mention of preventive health care and well-child checkups. The Government (and now with the AAP) has a few programs, such as Bright Futures, that contain some guidelines, but these guidelines are not officially accepted. And if the third-party payers do not want to cover preventive care, they do not see a reason to do so.

Once there is documentation, it needs to serve a purpose. Two code sets—the CPT code and the *International Classification of Diseases 9<sup>th</sup> Revision* (ICD9) code—summarize the medical record. The CPT code is owned, operated, and managed by the AMA. ICD9 is the diagnosis

code that explains why the service was rendered. ICD9 is from the World Health Organization, but the clinical modification is maintained by the NCHS. The Academy also has a representative in that group.

Another process issue Dr. Schulte raised is whether every procedure is necessary. The CPT says that a procedure must meet the medical necessity test. There is a debate about each procedure that is available and whether insurers want to pay for each one. According to Dr. Schulte the next area of concern in the system is the absence of standards for medical necessity. Dr. Schulte explained that the two codes used to be sent out on paper, on a HCFA 1500 form. Now with HIPAA the information is sent electronically. He then described another area of concern. HIPAA insists that providers use ICD9 and CPT as code tables, but does not say how. There are no standards for how to use these code tables, which leads to a constant struggle among stakeholders. He referred to Dr. Scroggs' use of the term bundling. Payers want to bundle services together and the providers, particularly if they are having trouble paying their bills (which is what Dr. Hannemann alluded to), want to unbundle services. There is a need for some standards that instruct providers on how to use the code tables.

Having submitted the claim to the payer, the payer enters it into the computer to generate a report. However, the reports are only as good as the data, and if the data have not been submitted correctly according to certain standards, both the reports and decisions will be flawed. Services are paid to the physician's office, called a reimbursement check, and the patient makes some co-pay. The payment is determined by RBRVS, but not everyone follows it. So another concern results from some CPT codes for screening and preventative health care that do not have a RUC value or an RVU. They are published in the *Federal Register* in October or November. But CMS decides not to include them because they are not payable by Medicare.

Dr. Schulte went on to discuss how physicians are reimbursed using a schematic prepared by Joel Bradley, M.D., FAAP, of AAP's Committee on Coding and Nomenclature. Another major issue for this group is that Medicaid, in general, pays less than Medicare. In 2001, the Academy published a survey of all State Medicaid programs, CPT code by CPT code, and determined what the value was compared with the Medicare rate and with other States. It is rather shocking, he said, because reimbursements are 40 to 60 percent of Medicare. So although children are not little adults, the payments are little, although the Academy participated in the entire RUC process and the entire PEAC process of determining what the value should be. But payers discount those values for children. This is a crisis.

Dr. Schulte discussed gender as a controversial topic. When he entered pediatrics, there were only men. Today, there is hardly a male in the residency programs. Women are competent pediatricians too, maybe better than men. In Dr. Schulte's personal practice in northern Virginia and universities with which he is associated, women finish residency training and look for work. It is very difficult to hire them, because more often than not they only want to work 3 days a week, they do not want to take night calls, and they want to be mothers. Men do not want to go into the practice because it no longer pays enough. They can make a better living in cardiology. So in the end, the workforce is shrinking tremendously. There is already a shortage of practitioners for an expanding number of children.

Benefits are another issue. Employers have to be brought into this discussion because they frequently determine the benefits package. It is not at all a one-way street, because after that check arrives, the data are entered into the office computer. Reports from the electronic data can now profile the payer to determine whether the payer is following the terms of the contract and how much the payer is actually paying per CPT code. So it is a two-way street if the data are good.

Fraud and abuse is another part of the system. Where the codes are applied to the system, and entered into the billing contract, it is fraudulent if services are submitted that are not medically necessary or that misrepresent the codes or that do not include the codes. On the other hand, reports can pick up outliers who do not follow the rules, and thus present a problem.

Another concern, according to Dr. Schulte, is when payers frequently instruct providers to misrepresent the services rendered in the codes. He illustrated an example in northern Virginia where there are four different Medicaid programs. If one service is performed, such as a measles, mumps, and rubella shot, Virginia Medicaid indicates to use a product code. Modifier SL will work because that is in the book, but there is no code for administering the service. However, it is permissible to charge the administration fee. That means the administration fee is charged on the product code, which is bundling and that is wrong. The Virginia Department of Medical Assistance Services either receives State Children's Health Insurance Program (SCHIP) support or is eligible for a SCHIP-supported vaccine. But again, there is no vaccine administration code, so the instructions indicate to bundle the administration fee with the product code. The database is now incorrect on both plans. For Unicare, it is the same problem. So there are four different methods for applying the data to the claim, three of which are wrong and are going to provide false reports on the other end. Payers say they do it this way because it will not fit their software. Under HIPAA, payers were supposed to implement a code set at the start of this year, but it did not happen. The code set is not used correctly, partly because HIPAA provides incorrect instructions. Yet when providers do not exactly follow the method of those four plans for that patient, they will not be paid.

Another problem is that in northern Virginia, patients have the opportunity to switch plans every month. In practice, providers have to call every month to determine whether or not to send in which kind of fraudulent claim. The more deficits the practice has, the more incentive there is for the provider to misrepresent services. Dr. Schulte has been in offices where it is flagrant. His solution is HIPAA II, a single process system of medical payments with codes that are used correctly, which both payers and providers are not doing.

Because of these concerns Dr. Schulte sees the need for a guardian within CMS, the CPT process, the RUC process, and the PERC to protect the interests of pregnant women and children and to ensure that the coding system is appropriate. The system is inappropriate for those populations in many areas.

Dr. Schulte referred to the different guidelines, which he first started to work on in the early 1990s as an advisor to the AMA CPT Editorial Panel. It is hard to believe that these learned

people, who have been working on these guidelines for 10 years, cannot decide how to write in a chart that a child has a disease, and they cannot agree on criteria for a well-child checkup. They need documentation guidelines. Dr. Schulte recalled that Secretary Tommy Thompson testified that these documentation guidelines do not work, never did work, and never will work. Dr. Schulte thinks the guidelines were referred to a committee, and he does not know what happened after that.

The current President has talked about electronic medical records, but it is not possible to have electronic records without documentation guidelines for pencil and paper. Appropriate standards for meeting the test of medical necessity must be developed first. Dr. Schulte asked if providers cannot decide how to write down a record for otitis, how are they going to decide whether they need that surgical procedure and then have everybody agree to it? Certainly, specialty societies must play a role in developing these guidelines. Dr. Schulte mentioned developing appropriate standards for the use of code sets to dissuade payers from instructing providers to send in fraudulent claims.

The *CPT Assistant* is a newsletter published by the AMA that attempts to suggest how the CPT codes should be used. Most providers tend to follow those suggestions and those who have been involved with CPT and the process embrace the *CPT Assistant*. But that does not mean that the payers will accept it, because they are not required to.

In the end, particularly for this group, the most important issue is payments for services discounted to Medicare. Dr. Schulte asked if this issue can be taken to the Secretary. This Committee has to do everything it can to make Medicare a floor and not a ceiling for Medicaid services for children. Medicaid children are the most difficult cases to care for, and they require the most time. And the process of just completing the coding for a vaccine shot adds extra work that takes even more time.

There are many discussions about access to care in a medical home, but providers cannot afford to do that. Some physicians are taking money out of their savings and investments to pay their bills and continue to treat these children.

## **Discussion**

- Dr. Hayes asked for a set of Dr. Schulte's slides.
- Dr. Yvonne Bronner, Sc.D., R.D., L.D., commented that she now understands why clients say they are so confused.

## **ETHICAL DILEMMAS AND DECISION MAKING IN NEONATAL INTENSIVE CARE UNITS**

*John Lantos, M.D., Professor of Pediatrics, Associate Director, MacClean Center for Clinical Medical Ethics, University of Chicago*

As a pediatrician, Dr. Lantos first became interested in medical ethics as a resident at Children's National Medical Center in the early 1980s—the Baby Doe years. He wanted a better understanding of how people make life and death decisions, such as withholding and withdrawing life-sustaining treatments. He developed an interest in innovative therapies in general, including neonatal intensive care units (NICUs), cancer treatment, extracorporeal membrane oxygenation, and transplants. He then chose general pediatrics, and does most of his clinical work in a specialty hospital for children with chronic diseases. He has also worked extensively in Chicago with his colleague William Meadow, M.D., a neonatologist. Dr. Lantos said they have tried to integrate insights from philosophy with insights from epidemiology to examine the NICU environment in the context of decisions to initiate or stop treatment and conversations between doctors and parents, nurses and parents, and other professionals and parents as they make these decisions.

Dr. Lantos discussed what he found when he studied these issues. He described three large categories of infants most likely to be admitted to the NICU. The first group consists of full-term infants with acute illnesses such as infections, hypoglycemia, or meconium aspiration with pulmonary problems.

Infants with congenital anomalies comprise the second group. These anomalies include myelomeningocele or chromosomal problems such as trisomies, trisomy 21 or Down syndrome, or trisomy 13 and 18. Or they may be infants with congenital heart diseases, particularly ones that lead to cardiorespiratory instability and require emergent surgery.

The final group is premature babies. Their disease is their prematurity; they often do not have one of the other diseases listed above. They usually have a set of physiologic problems associated with the prematurity that are not necessarily diseases.

For infants with acute illnesses (category 1), there are really no ethical dilemmas about initiating treatment. These illnesses are similar to acute illness in any other population. Treatment is generally initiated and parents are almost universally supportive. Ethical issues arise when the treatments do not clearly succeed or fail but are partially successful. Despite the physician's best efforts, the treatment does not really work and the results are infants with meningitis who survive, for example, and have severe brain damage; or in meconium aspiration, infants survive but have chronic lung disease and become ventilator dependent. To the extent that this happens, the ethical issues start to resemble those that arise with infants with congenital anomalies, which means that they become issues of either quality of life or the burdens of treatment.

Dr. Lantos described how technology has changed the concept that a fatal congenital anomaly is incompatible with life. Some doctors at his center stated in a *Hastings Center Report* paper a few years ago that nothing is incompatible with life anymore. A tertiary care ICU noticeably reflects this shift: physicians can at least prolong life and maybe prolong it for a long time in

virtually every situation. Dr. Lantos referred to a famous textbook, *Smith's Recognizable Patterns of Human Malformation*, that is a compendium of all congenital anomalies in the world. Until the 1988 edition, many anomalies were characterized as incompatible with life. The more recent editions no longer include that description for any condition.

Basically nothing is incompatible with life anymore, and issues that arise in congenital anomalies are global quality-of-life issues. Therefore, trisomy 13 or 18 infants are severely mentally retarded, often with some organ system involved, so what drives decisions and what makes people assert that it is sometimes appropriate not to provide life-sustaining medical treatment is the perception of a very low quality of life for the infant. Anencephaly is probably the most extreme example. Those infants are born without any cerebral cortex but with an intact brain stem, so they basically have no consciousness or awareness. They do have normal newborn reflexes such as sucking and swallowing, so they can be fed by mouth, and they normally do not require ventilators for support. So there is the question of the implications for a quality of life that is low and the consensus that has developed around such issues.

A separate set of issues relates to the burden of the treatments that are necessary to sustain life. For example, the only necessary treatment for many infants with trisomy 13 and 18 is to feed them by mouth. So the burden of treatment is low but so is the quality of life, some could argue. With Werdnig-Hoffmann, a progressive neurological disease that leads to paralysis and ventilator dependence, life can only be sustained with lifelong ventilator dependence and that is a burden-of-treatment issue. The infants are cognitively intact but have no motor functions.

Hypoplastic left heart syndrome, however, is a constant controversy, which is unusual among syndromes in newborns. For most syndromes in newborns that are ethically controversial, the controversy is resolved within 10 or 15 years. A consensus usually emerges as to whether treatment is appropriate or inappropriate. Looking at different centers throughout the country, ethical issues surrounding hypoplastic left heart syndrome seem to be unresolved. Some doctors adamantly believe that treatment is ethically obligatory, while others adamantly believe the parents should have the right to decide whether to attempt to repair this condition or let their infant die. Dr. Lantos thinks that the burdens of treatment—multiple open-heart surgeries—fuel the controversy. The children are in the hospital for long periods of time in the pediatric ICU, and each round of heart surgery has its own mortality rate associated with it. Some people think that the cost of survival in relation to the burdens of treatment is just too high.

There is, in this country at least, a rough consensus on the quality of life that is below the threshold of quality of life that permits parents to decide not to provide treatment. In the United States today, it is not permissible to stop treatment if the disease is similar to trisomy 21 (Down syndrome), which is what the Baby Doe debate was about, and withholding treatment became medical neglect. It is permissible if it is similar to trisomy 18. It is the characteristics of these diseases that drive these decisions, and the simplest way is in the context of IQ or ultimate cognitive ability. The average IQ in Down syndrome is probably between 65 and 80. With trisomy 13, the average is around 30 to 50. But those IQ numbers leave a gray zone in between, such as an IQ of 60. In that gray zone, decisions are currently left to the parents.

The outcomes of extremely premature infants again reflect decisions that are driven by this attempt to put infants into categories above which treatment is obligatory. There is a lower limit below which infants are not considered to have any chance of survival. In between these two categories is the gray zone where the ethical controversy exists. This zone of uncertainty is currently fairly narrow in the United States. Surveys of doctors or studies of actual practices reveal that treatment is generally considered obligatory for infants 25 weeks or older. Calculations can be by birth weight or gestational age. Gestational age is probably better for determining the ultimate prognosis, but it is somewhat more uncertain in its assessment. This is because it is much easier to weigh an infant and arrive at an exact birth weight, whereas a range of uncertainty always exists with gestational age.

Treatment is generally considered futile for infants younger than 22 weeks of gestational age. So the zone of uncertainty, where 95 percent of the ethical dilemmas associated with prematurity arise, is between 22 and 25 weeks of gestation or roughly between a birth weight of 450 to 650 grams.

Dr. Lantos showed a table from the January 2005 issues of the *New England Journal of Medicine* that summarized outcomes of extremely premature children who were followed until age 6 years, stratified by 22, 23, 24, and 25 weeks of gestation. The most interesting line on the table, he pointed out, is the percentage of live-born infants who survived without severe or moderate disability. The basic percentages are 0.7 percent of infants born at 22 weeks, 3 percent of those born at 23 weeks, 9 percent at 24 weeks, and 20 percent at 25 weeks. So 20 percent is the percentage of live births, and 24 percent is the percentage of admissions to the NICU. Of the infants who did not survive without severe or moderate disabilities, most of those at the lower birth weight died. At the higher birth weights, there were more survivors with disability. The ethical controversies arise at this measure of illness severity represented by gestational age. That is almost all the information that is needed.

These outcome data are unique because, in the past, outcome data were examined and stratified by different birth weights. But there was always a sense that neonatology was progressing and improving so rapidly that 5-year outcome data were obsolete by the time they were available and were not considered reliable enough as a basis for decisions.

What has happened recently that has made ethical decisionmaking possible in the NICU is that progress has basically stopped in neonatology during the past 10 years. That means birth-weight-specific survival rates, especially for the lower birth weight infants, have leveled off with relatively little change.

A line graph with two different data sets of mortality rates for infants weighing less than 1,500 grams (501 to 1,500 grams) who were born between 1991 and 1999 was shown. One data set included 362 Vermont-Oxford network hospitals and the other was from 39 hospitals; both lines looked basically the same. The graph showed that mortality steadily declined until 1994 and 1995. For extremely low birth weight infants, mortality remained relatively unchanged to 1999; the most recent data from 2002 are similar.

Dr. Guyer commented that 500 to 1,500 grams is a wide range, and wondered whether the distribution with that range remained the same at the beginning and at the end. Dr. Lantos said yes, the National Institute of Child Health and Human Development (NICHD) has published a paper from the 2002 data that were broken down into 250-gram increments and 500 to 750 grams and 750 to 1,000 grams are relatively the same. That is to say that infants weighing 600 grams are doing about the same in terms of survival to discharge in 2002 as they were in 1995.

Dr. Guyer stated that his was a slightly different question. Looking at such a broad range, it could be true that in any small stratum the probability of survival does not change very much, but this curve changes because there are significantly more babies at the lower end who weigh closer to 500 grams at the end than there were at the beginning. It may be that the distribution of those weights is important as opposed to the survival at any particular weight. He raised the point because he has been working with neonatologists in Delaware. In this small State with only one NICU, more and more infants are born at the lower end, so certainly there has been a cutoff under 500 grams with a bunching up among 600 grams birth weight. There is a shift in the distribution that partly accounts for why this curve is now flat and is going back up.

Dr. Lantos agreed that average survival along the distribution has remained about the same, as illustrated in data for infants weighing 500 to 750 grams and 750 to 1,000 grams within the NICHD data categories (the curves look just like this as well). And there is a good reason for it, Dr. Lantos said. The last major advances in neonatology that seemed to have had a measurable impact on survival were surfactants, which came into widespread use around 1989 to 1991; antenatal steroids for women in premature labor, which increases the development of the fetal lung; and screening mothers for group B strep, which also came into widespread use as the standard care in the early 1990s. If mothers are treated for Group B strep, infants do not get sepsis, pneumonia, or meningitis with Group B strep. Those were the last three major population-based innovations that seem to have had a significant effect on lowering birth-weight-specific mortality.

It appears that for the first time since initiating ventilation for premature infants, the 5-year survival data are actually relevant for infants born today. And it appears that, also for the first time, doctors and parents can both know with fairly good accuracy the chances for survival and also long-term morbidity assessments.

This degree of accuracy has led to a fairly widespread consensus on treatment decisions. At least four sets of guidelines from various perinatal organizations follow the schema presented earlier, with some variation among infants born at 23 and 24 weeks, a point at which treatment is considered obligatory. (The guidelines are from Canadian Pediatric Society [CPS], 1994; AAP/American Heart Association Neonatal Resuscitation Program, 2000; Thames Regional Perinatal Group, 2000; and Colorado Collective for Medical Decisions, 2000). However, infants born at less than 22 weeks receive compassionate care only; at 23 and 24 weeks, an assessment is made in the delivery room; from 25 to 27 weeks there is full resuscitation; and noninitiation at less than 23 weeks. The CPS provides more room for parental autonomy at 22 weeks only at the request of fully informed parents. At 23 to 24 weeks, the CPS permits parental wishes to drive

the decision, and at 25 weeks, resuscitation is mandatory. Colorado's assessment is similar on a State basis.

Dr. Lantos' center conducted a 2003 survey of actual physician practices. Five hundred surveys were randomly sent to U.S. neonatologists with four delivery room scenarios by birth weights roughly correlated to gestational ages:

- Less than 500 grams, gestational age 23 weeks
- 500 to 600 grams, gestational age 24 weeks
- 601 to 750 grams, gestational age 25 weeks
- 751 to 1,000 grams, gestational age 26 weeks

The results were:

- At 23 weeks, 92 percent of physicians preferred comfort care.
- At 24 weeks, 81 percent preferred resuscitation and 30 percent deferred to parental wishes.
- At 25 or more weeks, an overwhelming majority preferred full resuscitation; few deferred to the parents, leaving no role for parental wishes—treatment was obligatory because it was in the infant's interest.

These findings raise the question of what the parents want. One way of thinking about the problem in neonatal bioethics, which was widely prevalent in the 1970s and is still accepted by many people today, is that neonatologists are driven by a technological imperative. They consider death a failure. But parents do not want aggressive treatment if their infants are going to grow up with any disabilities. Many of the early statements about ethics written by physicians and philosophers permit parents the right to reject treatment. The idea that physicians were not empowering parents to refuse unwanted treatment was seen as a moral failing within the field of neonatology. The sentiment was similar to bioethics related to adults and the whole movement toward living wills and patient autonomy that doctors were imposing on people. If people were given the authority with information through an informed consent process, living wills, or the Patient Self-Determination Act, they would refuse treatment. Dr. Lantos provided data indicating that no study has ever been conducted showing that this is what is happening in neonatal intensive care.

Some of the best studies are by Saroj Saigal, M.D., a neonatologist at McMaster University in Canada. He has conducted many studies with parental interviews relating to specific scenarios that were also shown to health professionals. A total of 742 participants were interviewed between 1993 and 1995: 100 hospital neonatologists; 103 NICU nurses; 264 adolescents (aged 12 to 16 years), including 140 who had been extremely low birth weight infants themselves; and 275 parents of the recruited teenagers. Preferences or utilities for four or five hypothetical health states of children were presented to participants as vignettes, ranging from very minor impairments or disabilities to more major ones. Examples include the following:

1. Jaimie can see, hear, and talk normally; can walk, bend, lift, jump, and run normally; is happy and not worried most of the time; learns and completes schoolwork more slowly than others in the class; can eat, bathe, dress, and use the toilet normally; and is not in pain.
2. Chris can see, hear, and talk normally; needs equipment and assistance from another person to walk; is sometimes angry, worried, or sad; can learn and complete schoolwork without special help; can eat, bathe, dress, and use the toilet normally; is not in pain.
3. Sandy has problems seeing, hearing, or talking, even with glasses and a hearing aid; needs equipment to walk; is sometimes angry, worried, or sad; learns schoolwork very slowly and needs special help; needs special equipment to eat, bathe, dress, or use the toilet; is sometimes in pain that is relieved by Tylenol.
4. Pat is blind, deaf, unable to talk, and needs equipment to walk; is happy and not worried most of the time; learns schoolwork very slowly and needs special help; needs help from another person to eat, bathe, dress, or use the toilet; is sometimes in pain that is relieved by Tylenol.

Dr. Lantos showed a chart of the average ratings designated by the parents and the health professionals. First, there is a general trend. It is not that people are ignoring the disabilities. The utility scores seem to track expected responses in that children with more severe impairments had lower utility scores. For the two children with minor impairments, the parents and the health professionals responded almost the same. For the two children with major impairments (Sandy and Pat), the health professionals' ratings were much lower and even crossed the zero line (death). The parents' ratings were not that low and were systematically higher than those of the health professionals. It turns out that physicians and nurses seem to rate quality of life lower or are unduly pessimistic. The data can be framed differently; there are other studies that are similar.

One question people ask about the study is the possible difference in responses between these adolescents and people who are actually facing these decisions. Dr. Saigal's group went back and interviewed pregnant women with high-risk pregnancies who were recruited at 24 weeks of gestation. The researchers also included 75 mothers of very low birth weight infants who were recruited within 1 week of delivery. The participants were given the same four scenarios plus one more, and the mothers were interviewed at an antenatal visit, a postnatal visit, and at a 12-month chronological age visit.

Once again the trend declined but with little change over time for high-risk mothers facing the possibility of delivering a child with impairments. Assessments right after the delivery and a year later do not seem to be dispassionate or disinterested. It appears that parents really have different values about treatment choices.

The conclusion of these attitude surveys is that, compared with parents, health professionals are more likely to rate some outcomes as worse than death. No survey, however, looks at the worst-

case scenario, which neonatologists think is analogous to anencephaly: children with a massive intracranial hemorrhage who are not going to be able to relate to their environment in any way. These scenarios were not included in the survey, although they are exceptionally rare and difficult to predict.

These surveys also do not consider prognostic uncertainty. It is rare in the delivery room or in the NICU to have certainty that a child is going to turn out like Sandy or Pat. Data show that 20 percent will have one kind of problem and 30 percent will have another kind of problem, and in every situation there will always be a small percentage who will have very few problems. And how parents deal with probabilistic information was not really factored in, although most studies of the decisionmaking process show that the less certainty there is about a possibly adverse outcome, the more likely parents are to request treatment; if there is any hope. Parents tend to overvalue even small amounts of hope.

An important factor in decisionmaking is how prognostic uncertainty plays a role in what has become the standard of care for decisions about children at high risk for adverse outcomes. Prognostic uncertainty is difficult to predict in most cases in which infants are going to die, although it is relatively easy within a birth weight category to predict that 80 percent of the infants will die.

It is not as difficult to predict which infants will either die or have significant neurologic morbidity. But accurate predictions in these scenarios take time, and cannot be determined accurately in the delivery room. Information learned in the first few days or sometimes in a week enables a prognosis to be refined, and neonatologists prefer to assert that infants declare themselves—they reveal their outcomes. Dr. Lantos showed a bar chart of data by birth weights that his center published in 1996. There is the familiar survival curve depicting the survival rate at the moment of birth. Infants weighing 525 or 650 grams have much lower survival rates than infants weighing 800 grams.

The second bar is the same graph broken down in birth weight increments of infants who had survived for 3 days. Looking at all the infants in a NICU who are 4 days old and parsing it out by birth weight, the predictive power of birth weight by itself disappears. Of the infants who are 4 days old, those weighing 500 grams have almost the same survival rate as those weighing 1,000 grams—about 80 percent for all of them. So in a sense, those first 3 days are when the infants declare themselves, a trial of diagnostic and therapeutic interventions—there are many different ways to describe it.

Part of the reason for these patterns is that most infants who die, die quickly. Another graph showed the percentage of infants who died stratified by the day of life on which they died. Of the infants who were going to die, 30 percent died in the first 24 hours. Another 15 to 16 percent died in the next 24 hours; and another 7 or 8 percent on the third day. Within 72 hours, about two-thirds of those who were going to die had died, in spite of intensive care. The result is that the survival rate of the surviving infants will be much higher.

Data showing the accuracy of predicting which infants will fall into that group are the most complicated. A study referred to as the Crystal Ball Study compared objective illness severity scores with clinical intuitions. In SNAP, the score for neonatal acute physiology, the “P” denotes a measure of physiological derangement or how sick the infants are. The researchers examine that component on days 1, 3, 4, 5, 7, 10, 14, and 21.

Clinical intuitions were collected during rounds using a simple one-question survey asking physicians (including residents and neonatal fellows) and nurses whether they thought a particular infant would live to go home to the family or die before hospital discharge. The higher the SNAP score, the sicker the infant. The nonsurvivors had higher SNAP scores on all days (from day 1 to 21), which could imply that this approach could separate out the two groups. But the two groups overlapped. Another graph shows that on any day of life there were infants who would survive despite very high SNAP scores and infants with very low SNAP scores who died. So the SNAP scores are a better epidemiological tool than a clinical tool, and are very useful when comparing and assessing two different NICUs, for example, how sick the infants are at Northwestern University compared with those at the University of Chicago. But to make a blanket statement that because an infant has a SNAP score of 28, treatment should be stopped because it is futile would not be an appropriate use of this tool. It is useless in that decisionmaking scenario because of the overlap.

Clinical intuitions represented different patterns of prognostication by day of life. From the ethical point of view, the most challenging issues came to light during rounds where out of five experienced experts who had taken care of many of these infants, three expressed one opinion and two disagreed. On different days, these experts changed their opinions about the outcomes for the same infants, raising questions about the ethical implications for parents in terms of what messages the team should communicate about outcomes and stopping treatment, and whether to communicate intraprofessional disagreements and uncertainties.

In the various nonsurvival scenarios from the Crystal Ball Study, the experts were wrong 60 percent, 49 percent, 31 percent, and 18 percent of the time, respectively. Neonatologists can make incorrect nonsurvival predictions 30 percent of the time. These statistics point out the crucial relationship between epidemiology and ethics. All recommendations depend entirely on outcome statistics because the decision is driven by the ethical principle that physicians should do what is in the infant’s best interest. Outcome statistics can be interpreted in many different ways, so there are important questions about how certain and accurate they are.

The current consensus to initiate treatment for most infants (and then wait to see how they respond) depends on the time it takes for infants to declare themselves. One of the interesting future directions for research in this area is potentially troubling in terms of whether advances in therapy (and there have been incremental advances in therapy during the past 10 years that do not seem to have had any significant impact on birth-weight-specific survival) have had an impact on the time it takes for infants to declare themselves—essentially the time it takes for infants to die who are going to die.

The graph showing that two-thirds of infants who will die do so in the first 3 days is probably the most out-of-date information in this presentation, although it appears that no one has upgraded that graph. Time has been stretching out more and more as partially effective therapies become available, and infants who used to die in 2 days now die in 5 days. Those who used to die in 3 days may now die in 10 days, but their overall survival rate has not improved very much. One major effect is to increase the pain and suffering of the infants and the emotional stress on the parents. The other effect is an increase in cost without any offsetting benefits. So another question to think about is the use of treatments that prevent infants from declaring themselves in the context of whether the decisionmaking process can be improved. These questions reflect important research that needs to be conducted, at least to examine possibilities for improvement.

What is not well known is the degree of consistency or differences in the information neonatologists actually provide to parents. Parents generally do not choose their neonatologist; usually they are referred to a tertiary care center and the physician who is on service that month will take their case. Different physicians clearly have different approaches to these decisions, as shown in surveys in various studies. When talking to parents, neonatologists may cite different survival statistics, may describe morbidity differently, may use institution-specific data that vary significantly among institutions, may use national data that may not be exactly relevant or appropriate for a particular institution, and may or may not use international data.

Many of the best studies come from Europe where there is significantly better tracking for long-term followup data. In addition to superior tracking, Europeans may have better interventions as well. But there are questions as to whether the data are relevant for counseling, what should be told, and how much consistency there should be.

Other questions include whether the studies adjust for race and gender. Very good studies have shown significant differences in birth-weight-specific survival rates by both race and gender. Black infants do better than white infants, and girls do better than boys. There also are numbers on how a 600-gram infant fairs. Dr. Lantos then referred to John Tyson's paper, which found being a Black girl is equivalent to adding 150 grams to her birth weight in terms of her ultimate outcome compared with that of a white boy.

Issues to be considered to improve the decisionmaking process include the facts that neonatologists provide; their communication styles and whether they are directive and collaborative, believe in a shared decisionmaking process, or are more paternalistic; whether they listen, seek to empower parents, or simply impose an agenda; whether they are tolerant of different approaches within families and how tolerant they should be; if there is a gray zone between 22 and 25 weeks when parents should be allowed to make decisions; and what neonatologists do to facilitate that process—some doctors are more adept than others. What these physicians do has not been well studied.

Finally, to the extent that these differences exist (which Saigal and others have shown), it is not known whether parents and neonatologists differ because their values are different or because they have different information and understanding. Studies might look at communication using retrospective assessments of satisfaction with the process to determine whether parents believe

they received all the information they needed, whether they think they would have done something differently, and whether any parents regret the decisions that they made (either discontinuing or continuing treatment) and the reasons for any regrets.

## **Discussion**

- David Baines, M.D., asked about the study at McMaster University of the adolescents who had been very low birth weight infants and whether the researchers had pooled the parents' data with the adolescents' data. Dr. Lantos said the data were pooled and they looked similar to those of the parents. Many similar studies in the disability studies literature show that people with disabilities and people with disabled family members all rate their own quality of life or that of their family members higher than professionals do. This has been a source of tension between the disability community and the health professionals.
- Dr. Hayes asked about the ethnic and racial diversity of the parents in the survey. Dr. Lantos thought they were Canadian, and compared with an American population, Blacks and Hispanics were probably underrepresented but there were more Asians and Eastern Europeans. Dr. Lantos thought another good topic for future research would be to look for any differences among these groups. Studies comparing African Americans and White Americans in the context of do-not-resuscitate (DNR) orders and end-of-life care in the adult setting show that African Americans have fewer DNR orders, are less likely to be referred to hospice care, and seem to choose and prefer it that way. It does not appear to be an issue of denial of access to these services. Dr. Hayes questioned that assumption based on the inconsistent information obtained from the caring provider. She has seen many examples of that, including a recent Unequal Treatment Examination by the Institute of Medicine (IOM) of the extreme bias that exists about what providers say to minority populations.
- Dr. Lantos responded that concern falls into a general question he has as to whether people make certain decisions because they are not given information or because their values are different. He agreed that these issues have not been well studied.
- Dr. Collins agreed with Dr. Hayes' concern. For African American families, the decision cannot be made in isolation within that family, but with all of the community members, including a community leader or minister, extended family members, etc. And once whomever is deemed the leader in that community approves the decision, then the family approves. But for some reason, that link is not made early, and the family may not reveal who that contact person is. Dr. Collins also agreed with Dr. Lantos about how individually specific the neonatologist is, depending on who presents the scenario and how well the information is received. Dr. Collins noted he basically learned from people who were above him professionally; he tried to select the good methods and not emulate the bad ones. He asked Dr. Lantos whether neonatologists receive formal training in ethics. Dr. Collins received no training in ethics.

- Dr. Lantos did not know any neonatologist-specific data, although medical schools now offer a growing number of courses on ethics. He thought it unlikely that those courses focused on NICU decisions because the other end of the life spectrum usually receives a great deal of attention.
- Ann Miller, Ph.D., expressed gratitude for the presentation as well as the comments on the styles of communications of various neonatologists. In an unscientific way, when she does presentations on ethics and the language of physicians when speaking to families in crisis, she can tell that the ones who are very good sit in the front row. Physicians most in need of this assistance do not attend. The people who are good know the value of and seek additional education in that arena. She referred to Dr. Lantos' point about patriarchal physicians, but at the other end of the spectrum, some physicians who are either risk adverse or try hard to be respectful of families abdicate their authority in the situation. As in any other profession, families have come to the neonatologist for expertise. Guidance is a very important part of being a good physician, which is different from violating a person's rights. But people deserve the best professional opinion, and too many physicians today are not willing to provide that.
- Dr. Lantos said that it is a fine line to walk especially in the context of the Saigal data showing that health professionals in general devalue the quality of life in infants with impairments. To the extent that physicians are supposed to give a professional opinion, they should also be aware that professional opinions are outliers compared with the opinions of the population. Dr. Miller added that some physicians do not even mention the possibility of stopping treatment; they wait for a family member to bring it up, which is at the other end of the spectrum. But families do not want to be seen as terrible parents for even mentioning that possibility. The neonatologist should express to the family that it is a reasonable decision to stop or limit aggressive care at this point, or to continue treatment if that is their choice, and any decision they make would be supported.
- Characterizing infants who weigh less than 500 grams as being on the border of viability, Dr. Guyer noted that a major concern in Delaware centers on reclassifying what would have been fetal deaths to live births. The resulting increases in birth-weight-specific mortality rates reflect poorly on neonatologists when it is really a delivery problem in many ways. Women are being brought to delivery either by induction, sometimes spontaneously, and sometimes with a cesarean section, and the infant is right on that borderline. As the data show, these infants die in the first 3 days. Questions about ethical issues surround the decisionmaking of women presumably in preterm labor or having some complication of pregnancy whose deliveries result in a live birth at a weight and maturity that are not really viable. This phenomenon is not entirely responsible for the rise in infant mortality, but it is certainly a contributing factor.
- Dr. Lantos described these circumstances as a significant ethical issue. Part of the reason that these situations do not attract attention is because they concern inadequate communication between obstetricians and neonatologists. Parents often do not receive adequate counseling, especially in the NICU, and prenatal counseling is even worse.

Neonatologists often do not have an opportunity to talk, sometimes because it is an emergent delivery, but usually because the teams are not working smoothly together. And neonatologists will often tell their obstetric colleagues that if they are called to the delivery room, they will resuscitate. So obstetricians who do not want resuscitation will not call neonatologists to make decisions in the delivery room. Neonatologists intubate in the delivery room and make decisions later, which leads to exactly the phenomenon Dr. Guyer just described. Improved, focused analyses are needed on the 450- to 550-gram range to determine whether those infants still declare themselves in the first 2 or 3 days. If they do, it is not a large problem to initiate treatment for these infants who are going to live. For infants who are going to die and do so within 3 days, it may be bad for the outcome statistics. However, the neonatologist must analyze and explain the data to others.

There is another phenomenon that all clinicians know exists, and philosophers and lawyers deny. Philosophers and lawyers indicate there is no moral or legal difference between withholding a treatment and withdrawing a treatment and there is no difference between no resuscitating in the delivery room or waiting 2 days and then stopping. Physicians, nurses, and parents all know that there is a huge difference emotionally. If the infant dies in the delivery room because he or she was not viable, that is sad, but it does not have the same sense of guilt and culpability that deciding to stop a ventilator has. So a neonatologist can initiate treatment and see what happens, but making the decision to stop after 2 days becomes much harder. It almost forces people to make decisions with less than perfect prognostic information rather than waiting for better information.

- Dr. Collins referred to the vital statistics handout in the packets (*National Vital Statistics Reports, 54(12): 1–23*, “Explaining the 2001–02 Infant Mortality Increase: Data From the Linked Birth/Infant Death Data Set”) that explains the increase in mortality rates. He pointed out the increase in the 2001 and 2002 percentages of infants weighing less than 500 grams at birth. Associated with that increase is an increase in fetal mortality, suggesting that it is not, by itself, a classification problem. Dr. Guyer said the report does not include State-by-State variation data, which is prevalent around the country. There does not appear to be a good analysis of variability in what has happened during this time period, and it is worth studying.
- Dr. Hannemann commented that for a long time he has advocated for and trained pediatric psychologists. He emphasized the need to assign a pediatric psychologist to every NICU to provide counseling to families with these low birth weight infants under discussion as well as to families of all infants admitted to NICUs because the risk is very high that, even if they survive, there will be long-term psychological, learning, and other difficulties about which the parents should be informed. The only reason these counseling services are not there has to do with the reimbursement issue; those services are not reimbursed, they are neglected. It is something that was generated from the successes of the neonatologists but has been largely ignored over the years and is somewhat related to the reimbursement discussion this morning. Dr. Lantos agreed, and pointed out significant differences between the United States and many countries in

Western Europe (France and Holland) and in Scandinavia, where psychologists are core members of NICU teams.

- Dr. Ryan commented on how the discussion naturally focused on the neonatal perspective, but all of these deliveries are a continuum that begins with obstetrical decisionmaking and then becomes neonatal decisionmaking. And there is not always good communication between the two specialties. Discussions about the differences in weights of 450, 500, and 550 grams can wait until after the infant has been weighed. But it is difficult to do so antenatally with an ultrasound or other available technology. Obstetricians are making decisions about what kind of therapy they will use and whether or not they will intervene with a cesarean section, and they are dealing with less information than the neonatologist has when the infant can be physically examined. But many of those decisions have significant implications if the neonatologist enters the delivery area. Many obstetricians generally know less than neonatologists or pediatricians about the realistic (especially the institution-specific) outcomes that are based on approximate gestational age or birth weight.
- Dr. Collins noted that a number of studies were conducted in the 1980s, but he has not seen any recent ones. Obstetricians and general pediatricians do not know much about these issues either. Neonatologists are more accurate, but even they tend to be pessimistic compared with the real outcome. There is some lag time, but that could change now that progress has stopped. The fact that outcomes have remained about the same for 10 years could have decreased that lag time between personal assessments and the data.
- Speaking as an obstetrician who grew up in Los Angeles County, Dr. Tu remembered that when she was trained, the county had the highest delivery numbers in volume, and 1,250 grams and higher was the threshold for survival and now it is 500 grams and higher. The key issue is access to appropriate care; usually, an infant in the mother fairs better than the infant who has been delivered, unless the inside environment is much worse. And as for communicating with a neonatologist, the mother's physician should be brought in when there is concern about her having a preterm delivery. It is typical in Dr. Tu's community to communicate daily with neonatologists so they know what to anticipate; generally, neonatologists know before they walk into the delivery room whether or not they are going to resuscitate as part of appropriate care. Obstetricians do not have that kind of communication or backup. So it is appropriate care, not just care alone. The little ones need the specialty care.
- Dr. Collins asked what legal considerations neonatologists take into account when they make decisions on counseling parents about withdrawing support. Dr. Lantos said it is difficult to know. When asked, they all say they are not thinking about legalities; the survey included a question on that. There have been a few high-profile cases. In a recent Texas case that was discussed in the *New England Journal of Medicine* and many other places, parents had requested nontreatment and the physicians treated the infant. The lower court awarded the parents \$60 million in restitution; the higher court overturned it.

The extent to which legal issues enter into a decision is difficult to determine because the most risk-averse route is based on that confusing precedent. Overall, it appears that the law has been pro-life, and physicians are seldom punished. It is difficult to think of a case—and the Texas case is a good one because it was overturned—where physicians continued to treat to keep the infant alive even if the parents protested because the infants were harmed by the treatment. So to some extent, legal considerations drive these decisions about economic concerns and physicians' decisions. Economics are probably a much stronger factor. NICUs have become the economic engine of pediatrics, and neonatologists recognize that keeping the NICU beds full keeps the hospital administrators happy and supports the rest of the department. So there is an enormous economic benefit to continuing treatment.

Risk-averse decisions direct physicians to continue treatment. Making money is an impetus to continuing treatment. And listening to parents compels physicians to continue treatment. So it takes a very principled decision to stop treatment and be subjected to the emotional turmoil of both personal and psychological costs, as well as real financial costs, to indicate that the treatment is futile.

#### KEY ISSUES DISCUSSIONS—SMALL WORKGROUPS

*James W. Collins, Jr., M.D., M.P.H.*

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

Dr. Collins reminded members to move forward with determining the subcommittee work. The goal of each workgroup is to agree on three specific topical areas. When examining a topic, he asked members to determine what aspect of the topic to highlight. He also encouraged participants to identify any topic that appears to be critically important. Each group has a designated group leader. That person should assign a member to report back to the full Committee. When it comes time to choose key topics, each workgroup member will vote three times, and the workgroup will select the top three choices, which will be reported to the full Committee. We will hear the reports, discuss them, and then vote again on the final three choices for the subcommittees.

#### COMMITTEE BUSINESS: SACIM PRIORITY ISSUES—DISCUSSION AND SELECTION

*James W. Collins, Jr., M.D., M.P.H.*

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

Initially, each of the small workgroups reported on the three issues they proposed for concentrated SACIM effort.

#### **Workgroup 1**

Dr. Bronner summarized the top three issues that members of Workgroup 1 selected: funding, adverse infant outcomes, and racial disparities.

The workgroup wants funding to be linked to outcomes, and characterized the issue as the epidemiology of funding and its relationship to maternal and infant outcome. For example, the

workgroup wants to know whether there are disparities, which persons and conditions are covered, and the implications of any disparities.

The discussion of adverse infant outcomes focused on the report of low birth weight infants, preterm births, and SIDS that a past committee is about to publish. The workgroup is interested in monitoring the outcome of that report. Agreeing that infant mortality takes place within a system, the workgroup proposed funding a system that would model public health problems with existing ongoing applications that utilize engineering modeling principles. The workgroup suggested examining a continuum of variables for a predictive model: weight gain, weight change, preterm birth, low birth weight, and SIDS. The results should be made publicly available.

The workgroup then discussed the issue of racial disparity in relation to maternal and infant outcomes, and agreed on the need for an in-depth analysis of pregnancy and infant outcome problems in the African American community. The analysis should subset the data to singularly address the African American experience and to look within that experience to identify predictors of the various outcomes. Subsets should include looking within geographic locations for the economic impact of racial disparity and disparity in the predictors. Dr. Bronner noted that it is commonly known that disparities in areas such as education, income, and housing are underlying issues in and predictors of infant mortality, and the analysis should include predictive values to shed more light on these disparities in an environmental and contextual framework. The analysis should also address a continuum of prejudice, racism, and stress within disparities. Qualitative measures of prejudice are now available, as in research conducted at Harvard University, that would make it possible to look at this continuum in the context of a case study of infant mortality in a location with a specific history of infant mortality, such as Detroit, Michigan. The workgroup could then invite anthropologists and others to conduct a qualitative analysis of the findings to help inform the group's decisionmaking.

Dr. Collins suggested the following labels for these issues to simplify the voting that would take place later in the day:

1. Funding
2. Low Birth Weight Subcommittee
3. Racial disparities

## **Workgroup 2**

Dr. Sapien summarized the three priorities that members of Workgroup 2 selected: improving the data, reducing disparities, and financing a continuum of maternal care beyond the postpartum period.

Improving the data must include disseminating information in a timely manner, applying the findings to policymaking, and establishing a level of accountability for how Federal agencies and the Secretary respond to and utilize the findings. Data from fetal and infant mortality review teams and child fatality review teams should be included.

Disparities that interfere with access to appropriate health care are societal issues. There needs to be a comprehensive and systemic approach to identify and reduce racial and socioeconomic status disparities. Subgroup topics that should be studied include post-neonatal mortality, what happens to the infant between the ages of 2 months and 12 months, and intentional and unintentional injuries from domestic violence.

The group's third issue is a focus on funding. Most often the mother loses health care coverage when her infant reaches 1 month of age. Children usually retain health care coverage. The workgroup discussed ongoing health care for the mother from preconception through the child's first year. Just as a learning environment at home usually translates to better learners in school (an issue that this society values), a healthy mother can take better care of her children and can lead to healthier children.

Dr. Sapien summarized the workgroup's concerns: improving the data, postnatal mortality, racial disparity, and combining funding and financing.

Dr. Collins agreed with the following priorities listed by the group:

1. Improving data
2. Postnatal mortality and racial disparities
3. Funding/financing the expansion of maternal health care coverage

### **Workgroup 3**

Dr. Tu summarized the top three priorities Workgroup 3 members selected: policy, practice, and training and education. The workgroup developed a narrative organized around goals, strategies, and tools or vehicles for each topic.

The policy goal is to impact the effectiveness and efficiency of maternal and child health care services administered by Medicaid, which in turn determine the outcomes. Vehicles or tools include assessing eligibility, reimbursement, and range-of-service criteria as they relate to effective and efficient services and effective outcomes.

Practice issues include opportunities to improve preconception and prenatal care. The vehicles or tools are the data collected, for instance identifying women who have premature births and the variables that characterize these high-risk groups. There should be clear data to support and guide improvements in a continuous quality of care system with no disparities. The workgroup would also like to look into progesterone use, and to establish or start to work on, if possible, new codes for services not currently provided—lifestyle changes such as smoking cessation, diet, and nutrition.

This group identified training and education as a means to eliminate disparities. The tools to do so include identifying and supporting strength-based and community-based assets that in turn support and strengthen minority families. Identifying the resources of these assets helps to strengthen the family unit and establishes the resources as key contacts to reach out to and help

the family, thus positively impacting prenatal and infant mortality outcomes.

### **Summary of Workgroup Issues**

Dr. Collins consolidated the priorities and offered seven issues:

1. Funding/financing/policy
2. Continuation of the Low Birth Weight Subcommittee
3. Racial disparities and maternal and infant outcomes
4. Improving vital records data collection and timeliness
5. Post-neonatal mortality
6. Clinical practice as it relates to preconception and prenatal care
7. Education and training specifically aimed at eliminating racial disparities

After a round of thought-provoking discussion, Dr. Collins combined issues numbered 3 and 7, reducing the total number of issues to six.

### **Discussion**

- Dr. Hayes raised the issue of the quality of data because all three workgroups identified data as an important topic. She wants the topic to be part of the overall strategy for improving quality. Why do we want data, she asked? To accomplish something, such as improving conception or preconception care; data by itself should not be an issue.
- Dr. Sapien added that Workgroup 2 discussed accountability, such as expecting a response to the data.
- Dr. Ryan said his workgroup viewed data as an important component for improving the quality of clinical care. He agreed that data should be thought of more broadly in the context of an entire system, noting that the two overlap.
- Dr. Baines explained that the issue is using vital record data that are already 3 years old. Dr. Sapien added that expecting responses to the data is important and just generating numbers is not enough.
- With agreement from Ronald A. Finch, Ed.D., and Dr. Ryan, Deborah L. Frazier, B.A., R.N., summarized that the issue of data is an overarching issue—no area of concern can be addressed without accurate and timely data, and it is not just having data for the sake of having data.
- Dr. Ryan pointed out that each workgroup mentioned racial disparities in one way or another, and financing and funding in different ways. He noted that his workgroup expressed a strong interest in numerous ways to improve the quality of clinical care, which included data collection, a topic of concern to Dr. Tu's workgroup as well. Dr. Ryan said that it would be difficult not to vote for all of those issues as well as for

concerns about data. He would not want to vote against addressing racial disparities, and he also recognized the importance of financing and funding policies. Settling on only three issues would therefore be difficult; the overarching issue of data versus improving clinical practice is not an easy choice.

- Dr. Hayes commented that while serving on the Committee, she has been impressed by how much the experts know and how so little of that knowledge has been integrated into and applied in practice. She noted in particular the issue of progesterone and women having low birth weight infants are most likely to repeat those outcomes. The system needs to find ways to target these women—it is not always doing so. She said no further research could be expected if the Committee is to make practical recommendations that can be used in practice within the next year.
- Dr. Collins suggested combining the two issues of clinical and public health practice into one issue. Public health practice indirectly relates to the need for timely data. Dr. Baines was concerned that the infant mortality rates for 2003 and 2004 are not yet available. Dr. Sapien added that his group talked about health disparities in general, not only among minority populations. He presented urban versus rural disparities as an example, and requested a broader discussion on this topic.
- Dr. Collins then read the revised list:
  1. Funding/financing/policy
  2. Low Birth Weight Subcommittee
  3. Eliminating health disparities/post-neonatal mortality (Dr. Collins asked Dr. Sapien whether post-neonatal mortality could be combined with disparities. Dr. Sapien responded that in a discussion of intentional and unintentional injuries, domestic violence, and homicide, among infants aged 2 to 12 months, his group included these events as disparities. Dr. Collins suggested calling disparities maternal, infant, and early childhood, which would be the third priority, in place of post-neonatal mortality.)
  4. Improving clinical and public health practice (improving vital record data)
- Dr. Miller expressed concern that the topics were now too broad to remain practical. Dr. Collins responded that the ultimate goal is to make practical recommendations that can be relatively easy to implement. Dr. Ryan said that it is essential that the recommendations be practical, and those that are more doable can be selected from a broader scope of categories. Dr. Hayes agreed, saying that the titles are just umbrellas that have to be narrowed and made practical. As an example, she asked how clinical and public health practice could be improved without improving the timeliness of the data. She also wanted to ensure that providers are using progesterone when appropriate, and that they are targeting women who have had low birth weight infants because those women are more likely to repeat that outcome. If members are comfortable with this approach, making the issues broad offers the opportunity to narrow down strategies and make recommendations based on what is doable in a shorter amount of time and without

additional research.

- Dr. Hannemann said it might be worthwhile to look at the work of previous subcommittees that were designed specifically to address individual problems. One focused on Healthy Start, another on early hospital discharge of mothers and infants, and the last on low birth weight/preterm births. SIDS was included in response to information that the incidence of low birth weight rates and preterm births was up and that infant mortality was related. Dr. Hannemann said that SIDS was included as a research topic, and all of these categories were to be addressed as the problems emerged during the time that the subcommittee was in existence. He added that there may have been a subcommittee on children or mothers with special needs, but in any case that was part of an issue. All subcommittees issued reports and recommendations; we presented the Healthy Start and low birth weight reports to the Secretary in the same meeting.
- Dr. Koontz asked about the number of issues on the list, and Dr. Collins confirmed that there were four.
- Dr. Collins indicated that committee members could vote three times to select the priority issues for SACIM concentration. There were hand votes on each of the four topics: financing, Low Birth Weight Subcommittee, disparities, and clinical/public health practice (including improving data). The members selected the following topics for Subcommittee work:
  1. Disparities
  2. Financing
  3. Clinical/public health practice (including improving data)
- Dr. Koontz introduced Madelyn Renteria from the Division of Healthy Start and Perinatal Services, who was also assisting with the meeting.
- Dr. Collins asked members to indicate their preferred committee interests, in order of preference, from one to three.
- Renee T. Barnes, M.S., R.N., asked whether it is possible to adopt all four issues and whether listing low birth weight means that it is an extension of the subcommittee's previous recommendation. Dr. Hannemann stated two purposes that continuation of the Low Birth Weight Subcommittee would serve: to continue monitoring the existing recommendations that will be presented to the Secretary, and to continue addressing the issue of low birth weight in preterm births as noted in the vital statistics report he had referred to earlier in the day, which makes it a key issue. Very preterm and very low birth weight infants should be the focus of efforts to further lower the U.S. infant mortality rate, which he characterized as an overarching response that a subcommittee should be doing on a routine basis anyway. He suggested that perhaps reports from Dr. van Dyck would cover those particular areas, but felt that it would be remiss on the part of SACIM not to do what is within its purview to carry out recommendations from the Centers for

Disease Control and Prevention (CDC) and similar entities that directly address preterm and very preterm issues. The CDC infant mortality statistics indicate how directly these issues are related, which is why it is important to continue in that direction, whether it is with a report at each meeting, through a subcommittee, or some other way, Dr. Hannemann continued.

- Dr. Collins agreed that the Committee should not abandon the low birth weight issue, noting that it is the most important predictor of neonatal, post-neonatal, and infant outcomes, and felt there should be frequent reports communicated to this Committee at every meeting or every other meeting. He added the reports will also help Committee members, most of whom are new to the process, to understand how the work proceeds beyond this Committee, which can add momentum and enthusiasm to move forward with the subcommittees. Due to funding reasons of staffing, there is a limit of three subcommittees.
- Dr. Hayes said that the recommendations from the Low Birth Weight Subcommittee are already being used by SACIM, including the incorporation of some of the findings. Under clinical and public health practice, for example, one recommendation was to examine several research agendas for preventing low birth weight, and progesterone was even included in that. Another example, she said, was the issue of who should be assessed for these risks in terms of who is likely to give birth to low birth weight infants. SACIM is already trying to implement some of the recommendations from systems and policy perspectives. She also encouraged the Committee to look for opportunities to inform the IOM about those and to share any recommendations so the IOM Low Birth Weight Committee does not duplicate efforts. At the same time, SACIM could use that opportunity to get some visibility for itself. When an IOM committee completes its work, there is usually some visibility for what is published. Dr. Hayes wants to see a connection between SACIM and when IOM decides to disseminate its findings. SACIM should be out there visibly disseminating the work and thoughtful deliberations of this group.
- Dr. Hannemann supported publicly disseminating this information. He asked Dr. van Dyck whether a report presented by this Committee to the Secretary could then be sent to IOM as a special message from either this group or from the Secretary. Dr. van Dyck responded that the document would be cleared first. Dr. Hayes added that the IOM report is due 18 months from the beginning of deliberations, and the IOM has already selected its committee. Dr. Hannemann noted that he preferred to see SACIM send the information to IOM rather than have SACIM be the recipient of IOM information. Dr. Sapien added that IOM is currently compiling a health disparities report, and the committee is in its selection stage.
- Ms. Barnes noted that SACIM is limiting the discussion to three priorities but will not drop the low birth weight issue. Ms. Frazier agreed that the low birth weight issue as well as the work of that earlier committee are very important and should not be lost. She noted that it is apparent by just looking at financing, that these issues need as many voices

supporting them as possible and SACIM should be part of that effort. She suspected that the low birth weight issue will also resonate within each of the three topics chosen today, so it will not be lost but will be built upon.

Dr. Collins reminded the members to complete their forms on Committee priorities, and adjourned the meeting for the day.

## WEDNESDAY, MARCH 2, 2005

Dr. Collins said the speakers for this morning would follow up on activities within NCHS.

### **IMPROVING PERINATAL DATA**

*Isabelle Horon, Dr.P.H., Director, Vital Statistics Administration, Maryland Department of Health and Mental Hygiene*

*Charles J. Rothwell, M.S., M.B.A., Director, Division of Vital Statistics, National Center for Health Statistics, CDC*

### **Remarks by Isabelle Horon, Dr.P.H.**

Dr. Horon discussed four broad areas: what vital statistics are, what is right with vital statistics, what is wrong with vital statistics, and what needs to change. Dr. Horon included Maryland data in her presentation but also indicated she was speaking on behalf of the National Association for Public Health Statistics and Information Systems (NAPHSIS). This organization represents State vital records and public health statistics offices in all 50 States, the District of Columbia, New York City, and in the five U.S. territories. Many of the vital records offices also handle a variety of additional data sets, including population data, Pregnancy Risk Assessment Monitoring System data, cancer data, and newborn screening data.

Vital statistics are data relating to births, deaths, marriages, and divorces. Professionals think of vital statistics as three systems:

1. Civil registration system. (When a person is born, dies, is married, or is divorced, that event is registered with the Vital Statistics Office.)
2. Records management system. (Many States have vital events data dating practically back to the beginning of time.)
3. Public health data set. (Some of the information collected on vital records is used for administrative purposes, and other information is used solely for public health purposes.)

How are vital records collected? Collection is a State function; it is the responsibility of the jurisdiction in which each event occurs. Mr. Rothwell's group from NCHS (the next speaker) has to take the information that 57 jurisdictions are collecting, each with its own statutes and policies, and consolidate the information into a national data system that everyone can use.

States have contracts with and supply data to a number of Federal agencies, including the Social Security Administration (SSA), the Consumer Product Safety Commission, and the National Institute for Occupational Safety and Health. But NCHS is the main partner in this collaborative effort where everyone shares the same goals of collecting timely, complete, and accurate data, and preparing standard certificates.

What is right with vital statistics? They are a critical source of public health data. There is almost complete reporting because it is required for legal purposes. All States have laws that require the reporting of births and deaths, and the data among jurisdictions are mostly consistent.

What is wrong with vital statistics data? The problems fall into four areas:

1. Data quality: Problems exist with timeliness, completeness, and accuracy; and with poor reporting of certain events.
2. There is no standard national data set.
3. The data are underutilized.
4. Most of the States are working with antiquated data systems.

Dr. Horon described the Maryland experience as an example of what is taking place in many States. Under Maryland law, birth certificates must be filed within 72 hours of delivery. Until the late 1990s, this law was not enforced and the average length of filing time was 20 days. To use these data for public health and legal purposes, it is important that the data be filed, edited, and available immediately.

In December 1997, compliance was less than 1 percent of all certificates filed. About that time, there were changes in the Health Department, and Vital Statistics became a separate administration. Vital Statistics had been part of General Services, which included parts of the Health Department that ran the parking garage and provided other services not related to public health. The director of General Services was completely uninformed as to what vital statistics were and why they were important.

Then a new health director was appointed who had a strong interest in public health and vital statistics data. He elevated Vital Statistics to a separate administration and wanted to know what the problems were. He wrote a letter to the hospitals informing them, probably not in the nicest way possible, that birth certificates needed to be filed within 72 hours of delivery and those hospitals that did not comply would be penalized. Hospitals were furious and started complaining; the hospital association called and complained. But the letter worked. In less than a year, compliance had increased to 80 percent and is now well over 90 percent. It was simple. It just took one letter—well, it really took two letters. The director had to write a letter of apology for the first letter.

Maryland also lacked complete data, which resulted in erroneous conclusions about what was going on in the State. At the top of a two-line graph, which Dr. Horon displayed, is the percentage of births to women who received late or no prenatal care through the 1990s, and the rate appears to be declining nicely. But at the bottom of the graph, the percentage of birth certificates with incomplete prenatal care information was increasing at the same time. Looking at the per hospital data, it was apparent that the hospitals most likely to have the poorest outcomes were those that were not providing the prenatal care data. So the health officer wrote another letter to the hospitals informing them that certificates with incomplete data would be sent back. The hospitals ignored the letter at first. But a rejected certificate forced a hospital to pull all of the medical records for that patient. So it only took one rejected certificate to correct the problem.

The completeness of the data started to improve quickly and the percentage of certificates with incomplete prenatal care information started to decline, and the percentage of women with late or

no prenatal care increased. The incomplete data were clearly not distributed randomly and incorrectly indicated that problems were getting better when they really were not.

It was relatively easily to solve the problems of the timeliness and completeness of the data. But the quality of the data was a more difficult problem. Relatively complete hospital data did not necessarily mean that they were good data. It is easy to fill in a blank with just anything to avoid having a certificate rejected.

So a monthly hospital report card was created and disseminated that only identified each hospital's data to that particular hospital. Everything else was coded to avoid any embarrassment (they all managed to figure it out anyway). The report card showed a hospital the timeliness and completeness of the data compared with other hospitals, and hospitals started asking for help so they could improve their performance. It was a very successful strategy and is still in use today. Medical record audits were also initiated. A nurse was hired to visit; she prepared a list ahead of time of the medical records she wanted to see. She then compared the information on the medical records with the information on the birth certificates, and wrote a very detailed report for the hospital that identified strong areas as well as weak areas and included recommendations for improving the data. Hospitals that were below the threshold for good quality data were contacted a few months later to assess improvements. These efforts are still in effect. They have been very successful and have made a significant difference in the quality of the data. At the same time, more workers were hired to monitor fetal and infant death certificates.

Maryland was also having problems in the 1990s with poor reporting of certain events—mainly fetal deaths and early infant deaths. Professionals know that fetal mortality data are very poorly collected and reported in many jurisdictions. When one person was hired in Maryland just to concentrate on the fetal and the infant mortality data, it made an enormous difference. This worker now reviews every fetal and infant death certificate that is submitted and if there is missing or inconsistent information, she goes back to the hospitals. Before she started, most fetal deaths were reported with almost no information, barely a name and birth weight.

The State also revised the fetal death certificate. They expanded the short form to include all of the information on the birth certificate that was relevant to a fetal death as well as the death information, resulting in a much richer data set. There was also an effort to collect information on fetal deaths from other jurisdictions. All States exchange data on births and deaths that occur among their residents in other States. But the fetal death information was not being shared as extensively, so an effort was initiated to obtain complete data. The Maryland fetal data set is now quite complete and has revealed that there are actually more fetal deaths than infant deaths in Maryland, and the fetal deaths are responsible for a substantial proportion of reproductive loss. There was so much attention on infant mortality data when significantly more of the reproductive loss was occurring during the fetal period. To basically ignore that reality because of flawed data was a very serious problem.

The data set also showed the misclassification of many fetal and early infant deaths, which has since been corrected. The trends were also found to be quite different for fetal deaths than for infant deaths. For example, infant mortality rates by maternal age in Maryland reveal an

insignificant difference in infant mortality by maternal age among Blacks in Maryland. But the fetal death rates reveal a relationship that is quite different. There is definitely a dramatic increase in the fetal mortality rate among older Black women. Trends by maternal education among Blacks in Maryland again show that the trend for infant deaths is very different from that for fetal deaths, with some decline with an increase in maternal age for infant deaths, but a more substantial decline for fetal deaths. So one cannot assume that the trends for reproductive loss are the same for fetal and infant deaths, which makes it even more important to collect better fetal mortality data.

There is very poor reporting of infant deaths at early gestations in some jurisdictions. The contract that all of the States have with NCHS says that the States need to link every infant death record with a corresponding birth record, and States do a reasonable job of that. But the contract also says that the States need to follow up on all live-born infants weighing less than 750 grams. Maryland actually goes up to 1,000 grams, and follows up on every infant under that birth weight for whom there is not a death certificate by calling the hospital to find out what happened to that infant. If the infant was transferred to another hospital, that hospital is called. The infant is tracked until it can be confirmed that the infant either was discharged to his or her home or died.

A problem in a number of jurisdictions is that a death certificate might be filed but a birth certificate had not been filed, or the converse. Dr. Horon showed a slide of a bar graph with infant mortality rates by birth weight in Maryland. Under 500 grams, almost every infant dies. Then the mortality rates start declining. The graph shows mortality rates for a neighboring jurisdiction in which many Maryland infant deaths occur. Those rates are completely out of line with what is in Maryland on the lower bar. There are many infants born who weigh 100, 200, and 300 grams in that jurisdiction who supposedly survive, which is impossible. What is happening is that birth certificates are being filed but death certificates are not, and the infant mortality rates appear lower than they really are. In Maryland, if a birth certificate is submitted for an infant who could not possibly have survived based on birth weight, gestational age, and the APGAR scores, dummy death certificates are created to make the data as accurate as possible. NCHS cannot really do that. So Dr. Horon assumes that the infant mortality rate for the Nation is actually higher, although it is not known how much higher. But if all infant deaths were reported, the infant mortality rate would be higher than what is currently being reported nationally. It is a significant problem, and not easy to address because there are States that do not understand the importance of this information and do not understand that they should not be following up on these infants just because NCHS is asking them to do it. They need to do it for their own purposes.

The problem in a number of vital records offices is that the people running the office are administrators rather than public health personnel and, in many cases, they do not necessarily understand the importance of the data. It is unlikely that Maryland would have improved the data so significantly without professionals (such as Dr. Horon and her colleagues) with a maternal and child health background and an interest in the data.

Another problem is the absence of a standard national data set. (Dr. Horon referred again to Mr. Rothwell as one who is dealing with that problem.) The standard certificates that all States use

are periodically revised. Planning for the last revision began in the 1990s. Originally, all States were supposed to adopt a revised birth and death certificate in 2003. In the 1990s, when resources were more readily available, the assumption was that NCHS would receive funding to help States transition to the new certificates. Those funds did not materialize, which has caused an enormous problem for Mr. Rothwell. Dr. Horon added that it has also caused an enormous problem for them because many changes that were recommended could not be implemented by the States. And many important variables will not have data because States do not have adequate resources to adopt the new certificate. New items on the revised certificate include fertility therapy; Women, Infants, and Children (WIC) support during pregnancy; infections during pregnancy; maternal morbidity; breastfeeding; and source of payment for the delivery. All of this information is clearly needed, but it is not available now and it will not be available, at least on a national basis, until every State is able to implement the new certificate. There are also new items on the fetal death certificate that are critical but unavailable until the States have that new certificate.

Another problem is the underutilization of data. Data were traditionally collected for statistical reports. The States and NCHS each prepared their reports. There was some sharing of the data; however, these were static data sets. It is now important to expand those functions. In addition to the three systems that comprise vital statistic systems, there is a need for a fourth system. Vital statistics should also be expanded to include a public health surveillance system to monitor trends as data are collected and not 2 years later. Problems would be identified, and additional perinatal data would be collected. This also would enable States to routinely link data to other data sets. This expansion needs to take place at the State level. The data are needed nationally, but the process has to be implemented at the State level because the States are collecting the data from the source. Only States have the identifiers that are necessary for linking the data, and only States have access to other data sets.

The problem underlying all of the other problems is that the States, for the most part, are working with antiquated data systems. These systems limit efforts to improve the quality of the data, and they create difficulties for the States in transitioning to the revised certificate. These antiquated systems also limit efforts to expand the uses of the data. States have known for a long time that they needed to update their systems.

States started reengineering when they were able to, but many of the early attempts were not successful. The States realized quite early that the approach of every State trying to work alone was flawed. The reasons for the failures were repetitive costs in terms of dollars, human resources, and time. States lacked technical resources. Each State was assuming a high risk individually, and individual States were not building on the collective expertise of the States.

The States then developed a reengineering strategy for a national model that integrated the collaborative efforts of the States, NCHS, and SSA. There was a major effort for quite a long time using project teams from the States and from NCHS. The goal was to develop State-specific systems that use the same standards to record the same information in the same manner by adhering to the same business rules. The goal was to create standardized systems that would meet at least 85 percent of the reengineering needs of any jurisdiction.

This strategy offered a number of benefits:

- Greater probability of success from using the shared expertise and best practices of the States.
- Faster implementation.
- Significantly lower costs by working together as a group rather than individually.

What would reengineering systems allow professionals to do?

- Collect better quality data that are more timely, more complete, and more accurate. The plan was to have Web-based systems that would allow for the immediate collection of the data and that would check for incomplete data (and not permit hospitals to submit incomplete records). There would be consistency checks to ensure that hospitals were not making mistakes. For example, if a gestational age of 27 weeks was entered along with a birth weight of 3,400 grams, that error could be corrected at the source before it reached the States. States may detect that error, but by the time the hospitals are recontacted to check their medical records and then respond, a lot of time has been wasted.
- Uniformly employ national standards.
- Implement revised certificates (the reengineering would be based on the revised certificates).
- Enhance the role of vital statistics as a surveillance system.

There have been some success stories with reengineered systems, although not necessarily with the national model, which is fairly new. The process does work, as it has in South Dakota, where there is a new Web-based system that collects vital records data, metabolic screening data, hearing screening data, and hospital immunization data for infants. The results of this system are the following:

- Improved timeliness, completeness, and accuracy of the data.
- Automatic linkage of the birth data with metabolic screening, hearing screening, and immunization data.
- Immediate identification of unscreened infants. The information is disseminated in real time before the infant leaves the hospital. As a result, there has been a substantial increase in the percentage of infants who are screened.

What progress has been made nationally? There are functional requirements for birth and death registration that NCHS and NAPHSIS have worked together to develop, and a national model is now being implemented in selected States. New York City is working on deaths and Georgia is working on births. But there is a shortage of funds to complete the process, and current funds will only implement the system in a few States.

What is the vision for the States?

- Timely, complete, and accurate data.
- Reengineered, Web-based systems that immediately transfer records from the source to

State agencies and offices for immediate access.

- An immediate transfer of the data to other State agencies that need the data for perinatal purposes: immunization registries, hearing screening offices, or birth defect offices.
- A rapid transfer of data to partners in other States so they have a full accounting of what is occurring with their residents.
- Shared data in a timely manner (the day after data are collected, instead of many months later) with Federal partners, particularly NCHS.
- An immediate linkage between birth and infant death data and the States, which would provide a richer data source to assess reproductive loss (rather than simply an infant death file).
- A linkage between States and other perinatal data sets.
- An evolution from a vital registration system to a surveillance system.

What is needed to achieve this vision?

- Funding for reengineered systems in every State based on the national model.
- Funding to implement revised certificates in every State.
- Funding to improve the quality of the data.
- A national training coordinating center. NCHS does offer several courses per year to the States to help train vital records staff. But more is needed. There is a real need to educate the hospital workers who are collecting the data. Collecting birth data for vital registration offices is not the top priority for most hospitals. The clerical staff who collect the data are really at the lowest occupation level in the hospitals and they do not receive a lot of training. They receive whatever the States are able to provide, which is often not very much; there is also an enormous turnover. Yet the data that they collect are the State and national data that are used to look at trends and make decisions, and the data are just not good enough.
- There is a need for a national training coordinating center to ensure that everyone concerned has the best understanding of how to collect and analyze the data and what to do with the data. Technical assistance would also be useful to the States to improve their collection and analyses of perinatal data.
- Maryland's data have improved largely because of Dr. Horon's personal interest in that area. But most vital records offices do not have people with doctorates in maternal and child health running the office, and their priorities are different. All State offices are understaffed and overwhelmed and do what they can do. But they also set priorities within their offices. If perinatal health is not an area of interest to the director, it will not receive many resources. So providing technical assistance to vital records offices could improve the quality of the data.

Dr. Horon summarized the NAPHSIS wish list:

- Continue the reengineering effort.
- Develop a national training coordinating center.
- Provide technical assistance to States to improve the quality of the data.

Dr. Horon said that for further information on NAPHSIS or on the reengineering effort, contact Jan Markowitz, Ph.D., who is the Acting Director of NAPHSIS as of Mar 15, 2005, at 801 Roeder Road, Suite 650, Silver Spring, Maryland 20910. Telephone: 301-563-6001; E-mail: [jmarkowitz@naphsis.org](mailto:jmarkowitz@naphsis.org).

## **Discussion**

- Dr. Collins asked for an estimated percentage of records from Maryland that required the creation of dummy variables. Dr. Horon said 10 to 15 percent; it varies from year to year. Dr. Collins commented that the estimate was not trivial. Dr. Horon added, with absolute certainty, that those were the infants who died, and a number of infants are in a gray area. If there is any question at all, their survival is assumed, but many more die that are not counted.
- Dr. Hayes complimented Dr. Horon for an excellent presentation, and was struck by how the new director of the Maryland Health Department was able to convince the hospitals to improve their reporting in 1 year. Dr. Hayes wondered what would happen if officials at another level could use the same approach with the States. She asked whether NAPHSIS has ever considered issuing report cards for the States so they could have some sense of how well or how poorly they were doing in relation to their peers. Perhaps that approach could motivate health departments whose leadership does not recognize the importance of timely and accurate information. She was impressed by South Dakota, a small State with a successful Web-based system that contains all maternal and child health information. It seems apparent, Dr. Hayes continued, that some of the major users are maternal and child health people. So there has to be a very strong correlation between the users of the data and the people who analyze the data that have been collected. Without someone to create a demand, it is not going to happen. She was also very curious about the role of maternal and child health as both the user of the data and the impetus for trying to improve the system. If the people using the data are not the ones asking for that information and are underutilizing it, Dr. Hayes wondered how the message would be heard that somebody cares about the data. And they certainly belong together.
- Dr. Horon commented that success depends on how interested the health officer in a State is in the data. The health officer who helped them was very interested in the data. Every time he had to present a talk, he contacted her office to seek input or ways to use the data. The current health officer has different priorities, and it is not certain that he will lend the same kind of support; it varies from State to State. Dr. Hayes asked what would happen if the health officer received an unfavorable report card for some aspect of his health department, such as his vital records department; would anyone be responsive to that? Dr. Horon said that NCHS does put some of that information in a report that assesses the completeness of data, although she is not certain how many are aware that it exists.
- Mr. Rothwell added that NCHS does everything possible not to characterize a single State or a person representing a State in a disparaging context. Even in slide presentations showing State data, the names of the States are omitted. It is part of the NCHS culture.

- Dr. Guyer followed up on Dr. Hayes' comments with a suggestion for improving State data by highlighting how the States are using the data better, rather than Dr. Hayes' idea that would punish people for not having a good system. The other way is to identify the benefits of a good system. Dr. Guyer was unaware of the South Dakota successes and wanted to know what has improved there. He recalled a presentation at a previous SACIM meeting from Illinois about linking data sets across State systems that had impacted areas related to finances and reporting. So additional analyses of information plus other benefits should be promoted. He wanted to know the estimated costs for reengineering the systems at different levels for different accomplishments.
- Dr. Horon said reengineering costs a few million dollars per State. Dr. Guyer suggested that to advocate for additional funds and to be taken seriously, there should be a business plan for specific accomplishments with different levels of investments at the Federal and State levels. With that information, a committee such as SACIM could consider endorsing, commenting on, or promoting the effort. Dr. Horon said that the information could be prepared for Dr. Guyer.
- Ms. Ryan told Dr. Horon not to omit the partners and the health care systems and hospitals that provide most of the information. Ms. Ryan knows how much time is spent with the clerical associates and full-time equivalents when they turn in a 14-page birth certificate and what an improvement it will be when there is a Web-based system, which will also save money. Do not be afraid to look at partners for this, she added, especially if an objective is to reduce costs. She also had a question about the differences and difficulties among States as to how information is reported. For example, there has always been somewhat of a black hole with inductions or terminations for multiple congenital anomalies where different States list them as a birth and then as a death. She wanted to know how those differences influence fetal or infant mortality rates. Dr. Horon responded that said she does not see many live births that occur as a result of termination. Ms. Ryan said that is because the State does not classify them that way, which is very confusing.
- Dr. Horon explained that in Maryland, if the infant is born alive after a termination and then dies, a birth certificate and an infant death certificate would have to be filed. Most terminations in Maryland are fetal deaths. The information is only collected if the fetus is being transported for burial, because that requires a burial transit permit and is part of the death certificate. But it is not included in fetal death statistics. Ms. Ryan raised that question because it is sometimes a State-by-State classification issue that is misleading unless there is a medical record review. There could be additional fetal deaths in the statistics that were actually induced labors for serious multiple anomalies and the families wanted the respective pregnancies terminated.
- Dr. Bronner also complimented the presentation. She pointed out the degree to which prescriptive questions can lead to answers and subset analyses, such as the examples in the presentation of the African American population that reveal different trends and approach the question from a different perspective. So what she has been trying to

advocate relative to the data is the quality of the questions that the data permit.

**Remarks by Charles Rothwell, M.S., M.B.A.**

Mr. Rothwell agreed with most of Dr. Horon's presentation, especially the importance of the background and an interest in the data by the person who is the head of vital registration. It makes the most significant difference for that State. And having a maternal and child health director who has an interest in the vital statistics data, even if the registrar does not, can also make a significant difference. Obviously, if the State health officer is interested in objectives and how that State is doing and how it compares nationally, then the vital statistics will be used and can have an impact. But if the registrar is interested only in registration, that is, registering events, which is important, the interests will only be in the registration process. And that person will do the best job possible in that area, which is what he or she is being paid to do. And the money that is charged for the certificates is intended to provide a responsive registration system, not necessarily to create the data sets that have been the focus of this discussion.

Another issue is that in small States these are rare events, because there may not be enough data to say anything definitively. Those States may have to gather the data over several years. And conditions can change during those same years, raising questions as to the comparability of the events that have been grouped together. However, if NCHS is slow to disseminate that information, the impact for that particular State is diminished. And in fact, NCHS is very slow. So these spinning wheels are not taking these efforts anywhere. In this context, Mr. Rothwell stated that where his presentation reflects accurate information, others deserve the credit. Any information that is incorrect is strictly his error.

In relation to what Dr. Horon said, live births and deaths are counted in the millions; there are over 6 million events. Fortunately, fetal and infant deaths are in the tens of thousands, and the magnitude of the differences is enormous. So the implication is that a system that says something about 6 million events may have problems with rare events, especially those that relate to a fetal event, which is a paper form that people may not be able to find or may not even be aware of when to file it.

Mr. Rothwell referred to definitions of a small infant or fetus and whether a death is really a fetal death. (His slide defined live birth, fetal death [more than 20 weeks], and infant death.) He then discussed reporting issues that might affect infant mortality rates. For example, if States improved their reporting of deaths of infants weighing less than 500 grams, those changes could have a major impact on infant mortality rates. Changes in the reporting of deliveries on borderline viability, that is to say, determining whether it is a fetal or an infant death, will also impact the infant mortality rate.

Mr. Rothwell placed a special emphasis on the data in a line graph containing infant mortality rates by birth weight in the United States in 2002. He focused on the tail end, which represented the low birth weight events. Even though infants weighing from 750 grams to less than 500 grams are all at a higher risk, the magnitude of the differential in outcome between those two groups is huge, so any shift in this area as far as the number of events that take place will have a

significant impact on infant mortality. It does not take many events in either one of these low birth weight groups to change the overall infant mortality rate. So in the context of a vital records system, a vital statistics system of more than 6 million events, very few events in this area can affect more than national rates. So any reporting problems or any shift for whatever reason can have a significant national difference.

Also keep in mind that these rates (of higher weights) would have looked very different when Mr. Rothwell and Dr. van Dyck began working in public health years ago. Unfortunately, this change has nothing to do with public health but everything to do with improvements in infant mortality at those weights as a result of advances in neonatal care in the hospital.

The trends in low birth weight or preterm rates do not reflect favorably on public health; there has been little or no improvement. Possible causes include older mothers and multiple deliveries. But even after teasing out a variety of possibilities, issues of prematurity or low birth weight have not really been impacted. The distribution reveals that there has been a fairly obvious shift. Looking at completed weeks of gestation data on a two-line graph depicting the distribution of births by gestational age in the United States (1990 and 2002), does it make a difference at the height of the bell when this distribution shifts? Remember that the high-risk events will also shift, and those events are critical.

Comparing 1990 and 2002 data for births of infants weighing less than 500 and 750 grams, there was a very small growth in the percentage of those births that are less than 500 grams and in the total. And even though the amount of growth appears to be very small, any change in that type of distribution will have an impact on infant mortality.

Multiple births also affect issues of low birth weight and very low birth weight. Data on singletons only also document very little impact on outcome.

There are all sorts of reporting on fetal deaths. The Model Law recommends reporting fetal deaths at 350 grams or 20 weeks. But some States report all birth results regardless of the weight or number of weeks. Most States follow the standard itself. Each State receives an average of \$1,600 per year from the Federal Government for fetal death reporting. To improve infant mortality rates, each State receives an average of \$3,600 Federal dollars. So each State receives about \$5,200 a year from the Federal Government for perinatal reporting. Mr. Rothwell indicated that this amount of money is inadequate for the task.

Although reengineering is important and should therefore be funded, there is an opportunity to target dollars and efforts to perinatal reporting that could make a significant difference. This improvement could be achieved even if overall reporting of vital events in general remains unchanged.

During the past 12 years, the trends in reporting both late fetal deaths (28 or more weeks of gestation), and early fetal deaths (20 to 27 weeks) show that late fetal death rates declined and then somewhat leveled off. Trends of fetal deaths are similar to those of live births of less than 500 and 750 grams, and it becomes apparent that both groups have experienced a growing

percentage of less than 500 grams reporting and 500 to 749 grams reporting. So when there was an upturn in the 2002 infant mortality rate, one immediate thought was that some events in one category had shifted to another category. But the increases were in both categories during that time, which is not to say that within individual States one category did not move into another. But in the overall national trend, that was not the issue.

Mr. Rothwell then returned to a question Dr. Guyer had posed earlier about the possible impact on reporting from variations in definition among the States. Looking at a percentage of all fetal deaths of 20 or more weeks that occur at 20 through 27 weeks, these are the all-period States. Compared with all the rest, there is a greater percentage of reporting of those events for early fetal deaths. Those data indicate, as Dr. Horon pointed out, that many events are unreported, which is not to say that these States are receiving what they should be. What Maryland is accomplishing is taking place in few (if any) other States to that extent. NCHS is not allocating funds for States to conduct these followups, which results in a basic acceptance of what there is. And professionals know what that means.

Returning to the upturn in infant mortality, Mr. Rothwell said that Dr. Horon is probably correct when she maintains that the infant mortality rate is not as low as professionals say it is. But even if those low rates are accurate, that reporting problem has always existed, and it is probably not any worse. So the trend line may be up here, but it is still following the same line that reflects a dramatic improvement. With that improvement, there was a 3-percent increase in 2002. And such an improvement magnifies any events that take place in low birth weight areas because the rates are then affected. Referring to the graph again, Mr. Rothwell pointed out that the rate that had increased from 6.8 to 7.0 was really in the early neonatal period, and noted that the group of perinatal events of less than 750 grams (including fetal deaths and births) had experienced an increase in the reporting of these low birth weight events.

Mr. Rothwell then referred to a graph with infant mortality rates by State to show how extensive the problems are with the data. So the example discussed earlier, where the decrease in infant mortality shifted slightly upward, really reflected some of this reporting. And fairly large States that are part of this group would have affected the overall national reporting.

It is very important to actively follow up on births of infants weighing less than 750 grams. maternal and child health activities at the State level with State registrars can be the impetus for this followup, which would not require an enormous amount of money or effort. More money does need to be allocated for fetal death reporting, but it is not necessary for NCHS to do that. A variety of areas can provide the support; maternal and child health could assist in bringing about change in selected States. Professionals who work in these areas would be surprised by the differences that are possible with a small amount of money. In addition, State laws need to be modified uniformly across the country. And all birth gestational ages should be reported without eliminating some categories.

Reengineering is important for many of the reasons already articulated by Dr. Horon: it would automate the linkage and improve the surveillance of borderline events. Without active surveillance at the time that these events are reported, it is really too late in the process to

intervene effectively. Active surveillance means knowing immediately what changes are taking place. At a meeting with the U.S. Surgeon General at the time that infant mortality rates had increased, data for events from 2 years before were presented as explanations for the cause of the increase, because data for the previous year were not yet available. The provisional infant mortality rate for 2003 is 6.9, which is not statistically different from 6.8 but it at least plateaued at that point. The final 2003 rate and the provisional rate for 2004 are not yet available.

The fetal event is rare, and it is hard to capture with a seldom-used paper report. Maybe there should be a different tool. Even if it is not possible to immediately implement a Web-based system for all mortality reporting, there should be a mechanism to make fetal reporting easier and to let people know how critically important it is. There is also a need to report infant deaths differently. These are not areas where NCHS performs well; the inclination is to provide the same data for all events—for all births and deaths. But certain events are more critical than others, such as issues relevant to perinatal outcomes. People need to know that these rare events—fetal or early neonatal events—make a significant difference.

## Discussion

- Dr. Finch wanted to know who uses NCHS data.
- Mr. Rothwell said just about every part of the Department, whether it is MCHB or CMS. Within the Healthy People objectives that the Department and States use, vital statistics is a major component. Researchers also use the data. Mr. Rothwell believes that maternal and child health directors may not use the data—not using the data is not the issue. Unfortunately, people accept what NCHS distributes despite problems with timeliness (the data are old) and problems with quality that were noted in today’s presentations. And therein lies the dilemma. NCHS data should not be accepted with these problems, nor should NCHS accept flawed data. But until NCHS receives a disparaging report card, there will be no improvements.
- Dr. Hayes agreed, and pointed out that using report cards does not necessarily send a message that is personally critical of the workers. She was very encouraged when she read *Crossing the Quality Chasm*, which discusses issues related to quality that will not change as long as problems are ignored. People need to know. She then wanted to know what the Surgeon General’s reaction was to the problems with the timeliness of the infant mortality data.
- Mr. Rothwell responded that the Surgeon General was interested, but was about to visit some hospitals and needed to be prepared to respond to questions from reporters about those troubling 2002 statistics. He needed to appear informed about the issues, and he achieved that very effectively, Mr. Rothwell added.
- Dr. Guyer shared the concerns that Committee members have expressed about the data. Dr. Guyer indicated that he had also spoken to others at NCHS about the problems, and added that these data will never improve unless there is a constituency for their use. That constituency has to extend beyond State health officers and maternal and child health

directors, and as Ms. Ryan pointed out, hospitals and payers are also affected. Dr. Guyer then referred to an annual article written for the journal *Pediatrics* that has support from a pediatric constituency. If the article does not appear, people write letters to the editor wondering why the Government is withholding information. If the article does not include country-by-country comparisons of infant mortality, Jerold Lucey, editor of *Pediatrics*, will receive 25 letters asking for the information. This Committee needs to learn how to build that constituency and serve all of the users of the data by reinterpreting the data so they are useful.

- In the context of Dr. Horon's presentation, Dr. Guyer said that he had chaired the Infant Mortality Commission in Maryland when the electronic birth certificate was being implemented. He had insisted that the State analyze the data by hospital at birth. The hospitals reacted quickly and became interested in the vital statistics data. The results were never publicly reported and the hospitals were never identified, which was a major issue because other States have released that data to the public. The strategy created an immediate constituency among hospitals for the quality of vital statistics reporting. This Committee needs to innovate similar strategies to effectively make a difference. Otherwise, the struggles within and among bureaucracies for the limited resources will continue.
- Mr. Rothwell acknowledged how important Dr. Guyer has been in the publication of NCHS information in *Pediatrics*. Mr. Rothwell added that this is the first year there has been a delay in that reporting. The problem reflects Dr. Horon's comments about the variety of standard forms that States are using for the data they send to NCHS. And NCHS then has the task of consolidating these data sets so they make sense and are useful. And not only new items, but changing existing items at the national level. Within all of the NCHS data systems, whether the surveys or the registration systems, those in the surveys are becoming more responsive; only vital registration is becoming less responsive. There are better reports and better staff; they just are not getting out the data.
- Ms. Ryan commented that this is an era of public reporting and the empowered consumer. CMS has public reporting definitions and requirements for providers in terms of adult deaths, regardless of whether they are associated with acute myocardial infarctions, pneumonia, or sepsis. She wondered how it was possible to pay so little attention to maternal and child issues associated with infant mortality and then publish a document characterized as a national vital statistics record when there is no national standard for State-to-State comparisons. It is just as important for CMS to do better in that area as it is for the Government to improve public reporting, which will now be linked to reimbursement.
- Mr. Rothwell added that there is evidence of some improvement and it has nothing to do with public health. The President signed the Intelligence Reform Act in December 2004, which addresses the registration of birth certificates. In identity issues related to fraud or terrorism, the gold standard for developing identity is through the birth certificate. Linking the death certificate to the birth certificate should prevent birth certificates from

being issued for people who have died. This legislation may fund States to improve their registration processes, which could improve the statistics. Mr. Rothwell would not refuse any money, but he finds it troublesome that a different mechanism other than public health will be responsible for gathering the data needed for public health reporting.

- Dr. Hayes shared a similar irony in the recently disputed Washington State gubernatorial election that was undecided for a long time. Vital records became very important when one of the candidates maintained that dead people had voted for the other candidate, and the Health Department had to provide and substantiate mortality statistics. So, inherent in efforts to reform voter registration is the importance of vital records. And people became very interested; there were several editorials and front-page news articles about these deceased voters.
- Adding a positive note, Mr. Rothwell described the vital registration and statistics system as one of the proudest activities that citizens of the United States have. Each person has had a part in it and has contributed information to it. All hospitals and physicians become involved. No one is paid for it; vital registration workers receive very little money. Yet this voluntary system works extraordinarily well at providing the data. The system would work better if money could be targeted to certain areas such as perinatal events.
- Dr. Collins thanked Dr. Horon and Mr. Rothwell for their leadership.

#### **PUBLIC COMMENT PERIOD**

*James W. Collins, Jr., M.D., M.P.H.*

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

Dr. Collins pointed out that the public comment period is new to the agenda. He introduced the commenter, Lori Cooper, from the National SIDS and Infant Death Project IMPACT, which is a cooperative agreement between MCHB and the Association of SIDS and Infant Mortality Programs (ASIP).

Ms. Cooper thanked SACIM for adding the public comment period. She has been an observer of SACIM for a few years and is impressed by the breadth of responsibilities that the Committee assumes and the many challenges the members face. She is here today speaking on behalf of Marie Chandick, President of ASIP.

Ms. Cooper reviewed for the Committee the four SIDS and infant death projects that MCHB supports, which are all national in scope. Project IMPACT basically builds infrastructure to enhance communication among State and local SIDS and infant death programs and between those programs and the Federal Government. There is also the Program Support Center in Baltimore, Maryland, which focuses on technical support and training for the range of professionals who work with SIDS and infant death. The National SIDS and Infant Death Resource Center, which is based in Virginia, provides referral information for the public and professionals. The National Center for Cultural Competency at Georgetown University supports these programs as well as all of the maternal and child health programs in ensuring that the

outreach and services are culturally competent.

Ms. Cooper distributed to each Committee member a copy of the 2005 ASIP Annual Report, *Helping Families, Protecting Babies*. She mentioned that the next day, ASIP will convene its annual conference here in Washington, DC, and is commemorating the passage of the SIDS Act of 1974, PL 93-270. This law funded information and counseling programs for families who lose a child to SIDS. By placing the responsibility for bereavement services with the MCHB, Congress acknowledged that comprehensive perinatal care can and must include care for families whose infants die in the first year of life. She commented that it felt strange to follow the previous discussion with a presentation that advocates for services for families of infants who have died. But 30 years ago, there were not many programs that provided these services to the families.

The legislation established the following:

- Objectives and standards that included an autopsy for all sudden and unexpected deaths of infants.
- Designation of SIDS as a cause of death when appropriate.
- Notification to parents within 24 to 48 hours of the preliminary cause of death.
- Counseling for bereaved families.
- Development of public and professional educational programs.
- Development of data collection and analysis.

There are still many challenges in these arenas. But in place of a litany of what needs to change, Ms. Cooper chose to focus on some of the highlights that reflect the progress across the Nation since the implementation of the SIDS Act.

Although autopsies are not routine in every State, many medical examiners and coroners now comply with the standards for investigating sudden and unexpected infant deaths. Some of these issues are the same as those that were described earlier in efforts to arrive at consistency between the investigations and data collection. In many places, death scene investigations have become comprehensive and routine. Those investigations include reenactments, where investigators are on the scene, in many cases with dolls. The investigators sensitively work with families to elicit information and ascertain the cause of death. In many cases, these investigators find problems such as co-sleeping and unsafe sleeping environments that have caused significantly more of these deaths than SIDS has caused. CDC, in collaboration with the SIDS, infant death, and maternal and child health communities will soon implement revised guidelines for investigating sudden, unexpected infant deaths that will assist in promoting uniform reporting and data collection. CDC refers to these guidelines as the SUIDIRF (Sudden Unexplained Infant Death Investigation Report Form).

The designation of SIDS as a cause of death has changed; it now has an ICD code. In 1991, NICHD updated the SIDS definition to include the death scene investigation. NICHD continues to fund research investigating the causes of SIDS as well as other unexpected infant deaths, such as stillbirths, on which this Committee has had presentations. Breakthroughs in genetic

screening have revealed the cause of some previously unexplained sudden infant deaths. More careful death scene investigations have actually explained the causes of many deaths that had been misdiagnosed. Some researchers have initiated a process to refine the SIDS definition, and there is a national group of researchers and practitioners, led by Henry Krous in San Diego, who have taken on that task.

There is also the issue of notification to parents. In most of the country today, parents who experience the death of an infant are contacted by trained professionals who are able to provide information, support, and referrals to local resources. Efforts are ongoing to ensure that the support is culturally and linguistically appropriate. Many Web portals are now in Spanish, and many publications are being printed in other languages. The intent is to understand the cultural beliefs that surround infant deaths to ensure that the families receive more appropriate services.

Counseling for bereaved families has been available for the past 30 years. State and local programs, in addition to other professionals, have counseled thousands of families who have lost a child to SIDS. ASIP and other similar programs have, in recent years, expanded their services to respond to parents who lose a child to other causes of sudden and unexpected death. This support has always been available from ASIP, and other programs have probably also provided this kind of support. But there has been a formal decision to provide support for the sudden, unexpected death of children. Some organizations are now providing online support and peer-group support around the country.

There are also public and professional educational campaigns. A familiar national campaign is the *Back to Sleep Campaign*, initiated in 1992. This campaign, considered instrumental in reducing the incidence of SIDS by half since its inception, has been adapted by local and State programs throughout the country. There is not a State that does not visibly display a brochure or posters or some other educational materials that inform about *Back to Sleep*. The campaign has been expanded well beyond the sleeping position issue to a safe sleeping environment that addresses infant development (e.g., tummy time and talking with people about what happens to the shape of a child's head) as well as safety issues. The campaigns and the training are currently focused on child care settings because the data show that 20 percent of deaths from SIDS occur in that setting.

In addition, ASIP has developed professional educational programs about risk reduction as well as bereavement services for physicians, nurses, social workers, first responders, law enforcement officers and detectives, medical examiners, and funeral directors. It is apparent from that list the types of challenges there are to integrate data collection and consistent services.

For data collection and analysis, SIDS and other infant deaths are routinely reported by NCHS, and ASIP has developed a model database for SIDS and infant deaths that is currently being tested at the SIDS Center in Massachusetts. The database will be available for other programs through the Internet.

Service delivery for SIDS and other infant deaths has progressed well. In addition, the field itself has matured and has returned to the heart of public health, which is prevention. The lessons

learned from programs that respond to SIDS and to other causes of infant deaths have moved professionals in the field to expand the focus from mortality to bereavement, and more recently from bereavement to risk reduction. Mortality reviews related to maternal, infant, and child issues are no longer limited to medical interpretation. Communities are using the data to develop action plans for the entire community that reduce the risk. One request on behalf of the SIDS and Infant Death Committee would be for SACIM to assist with the integration of the child death review, maternal mortality reviews, and fetal and infant mortality reviews, and the SIDS and infant death programs.

Basic struggles remain. Limited resources mean a reduction in and, in some cases, the elimination of services. When this program began in 1974, there were about 30 programs that were funded to provide counseling and support for families. There are now programs of some degree in every State; the SIDS and infant death response is handled through block grants. But in many States, the allocation pays 5 percent of one worker's time in the health department, which may or may not be appropriate to the number of SIDS deaths in that State. The purpose of the example is to enable members of SACIM to envision how the services have changed.

Strategies for the collaboration and integration of services have enabled systems to become more efficient. These efforts will continue to pursue all paths that do not erode or compromise the comprehensive and compassionate care that ASIP and others provide to bereaved families. And ASIP has recently released a publication that details core competencies for professionals in this field. Ms. Cooper commended that publication to the members of SACIM.

Disparities in deaths from SIDS haunt researchers and practitioners. Reasons for the disproportionate SIDS rates among African Americans, American Indians, and Alaska Natives compared with White populations continue to elude the professionals, although they are close to finding new ways to identify and study causative factors. In the meantime, professionals are exploring how to effectively translate the existing research into meaningful behavioral strategies for families and communities that reduce the risks.

Ms. Cooper expressed her appreciation for the leadership from the Committee in many of these same efforts. She wanted the Committee to know that President Chandick and ASIP look forward to working with SACIM, and will keep the members apprised of critical developments in professional bereavement support efforts and in related training and educational programs. She thanked the members for their time.

Dr. Collins thanked Ms. Cooper and asked for further public comments. As no other attendees requested to speak, he transitioned to the subcommittee announcements.

#### OVERVIEW OF SUBCOMMITTEE TASKS

*James W. Collins, Jr., M.D., M.P.H.*

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

Dr. Collins opened the session by announcing the appointments of members and chairpersons for each subcommittee. Members of the Finance and Funding Subcommittee are Betty Tu, M.D., M.B.A., Chairperson; Robyn Arrington, Jr., M.D.; David Ray Baines, M.D., FAAFP; Jennifer

Cernoch, Ph.D.; Ronald Finch, Ed.D.; and Joyce Roberts, C.N.M., Ph.D. Dr. Roberts and Dr. Cernoch were absent. Members of the Eliminating Health Disparities Subcommittee are Yvonne Bronner, Sc.D., R.D., L.D., Chairperson; Renee Barnes, M.S., R.N.; James Collins, Jr., M.D., M.P.H.; Deborah Frazier, B.A., R.N.; Fredric Frigoletto, Jr., M.D.; Ann Miller, Ph.D.; Robert Sapien, M.D., FAAP; and Mary Lou de Leon Siantz, Ph.D., R.N., FAAN. Drs. Frigoletto and Siantz were absent. The members of the Clinical and Public Health Practice subcommittee are Kevin Ryan, M.D., M.P.H., Chairperson; Bernard Guyer, M.D., M.P.H.; Robert Hannemann, M.D.; Maxine Hayes, M.D., M.P.H., FAAP; C. Renee Elmen Hollan, R.N., B.A.N.; Yvonne Moore, M.D.; and Christina Ryan, R.N., M.P.A., B.S.N.

Dr. Collins then described his expectations for the initial Subcommittee Meeting. Subcommittee members, under the leadership of the chairperson, were to set the agenda for their subcommittee. They were asked to define more clearly what their focus would be, what they expected to accomplish, and to generate a preliminary plan and timeline for their work. Subcommittee members were to identify any agenda items requested for the next meeting, and plan to report back to the whole committee in the afternoon session.

Dr. Guyer asked if all of the work of the subcommittees was to be done during SACIM meetings or if there would be any subcommittee work in periods between meetings. Dr. Collins indicated that much of the work could be accomplished during SACIM meetings, but arrangements could be made for conference calls and an occasional subcommittee meeting outside of the regular meeting. Dr. Guyer suggested that a full day be given to subcommittee work at the next meeting. Dr. Collins agreed and directed the members to their subcommittees.

#### COMMITTEE BUSINESS: FUTURE ACTIVITIES

Dr. Collins opened the session with the announcement of the dates for the next meeting: July 7–8, 2005. He then called for the subcommittee reports.

#### **Finance and Funding Subcommittee**

Dr. Tu summarized the subcommittee's discussion. She stated that yesterday's group initially looked at CMS. The subcommittee started by looking at how to enhance, expand, and improve or increase eligibility, reimbursement, and the range of services offered by Medicaid and Medicare.

The discussion focused on practical recommendations in the context of current political discussions that Federal funding will be reduced and each State will have to provide more money, which appears unlikely. So it is not practical, for example, to ask for an increase in reimbursements or expansion of eligibility when there is no money to pay for these additional costs.

Dr. Finch informed the subcommittee about the history of Medicaid and how it began as a service dedicated to maternal and child health care. Members who are not familiar with the origins of Medicaid would like to have a presentation or more information that could also be included in the report. Once the subcommittee has been fully informed about this dedicated

commitment, the members could work to secure funding for the full scope of that commitment, with no reductions, by redirecting resources in Medicaid to not only maintain current service levels but to ensure that Medicaid is fulfilling its original purpose. So the subcommittee is examining the range of Medicaid services. Dr. Tu underscored the subcommittee's request for a speaker to review the original mission of Medicaid and the circumstances that framed its inception.

The discussion then switched to Medicare. The 2004 Medicare Modernization Act included prescription medications and preventive care. Preventive maternal and child health care services are not adequate in Medicaid or Medicare. The subcommittee wants more information about how the 2004 modernization act is providing for or developing evidence-based preventive services for mothers and children. Members also want information on the work of the U.S. Preventive Services Task Force, such as the preventive services that are under discussion and development, and want to include that information in recommendations to expand preventive services in both Medicaid and Medicare. To avoid duplicating efforts, subcommittee members want to know what resources already exist or are being developed so this information can be included in their recommendations.

Discussing service indicators and preventive services and care, members contemplated whether they could identify an indicator for preventive care, which could reveal the impact of a service or intervention on the outcome. Dr. Tu said that members want their recommendations to be practical and to impact the outcome. The discussion included the Health Plan Employer Data and Information Set (HEDIS) indicators. Dr. Tu indicated the HEDIS indicators hold the health plan and the payees accountable for recording the correct data and documenting what services were performed. Dr. Tu added that there may be a maternal and child health HEDIS that this subcommittee is not aware of. She compared the usefulness of these indicators with the historic impact Pap smears have had on health outcomes. A Pap smear, in the long run, will directly and indirectly impact maternal and child outcomes, or maternal and infant outcomes, or prenatal and preconception outcomes.

The subcommittee spent the most time discussing obesity as an indicator. The members are aware that obesity impacts an outcome indirectly and directly. The Task Force has gathered a wealth of information on obesity in the context of preventive measures, and how it impacts outcomes, health care costs, and disparities in services. The subcommittee again suggested having speakers on the subject so there would be evidence supporting the facts that would form the basis of any recommendations.

The subcommittee also suggested that upcoming SACIM meetings should include speakers who can clarify the role of the U.S. Preventive Services Task Force and talk about the obesity guidelines. Suggestions for speakers included Bill Dietz, Ph.D., from the CDC; Helen Darling from the National Business Group on Health; Peggy O'Kane from the National Committee for Quality Assurance; Helen Burstin, M.D., M.P.H., from AHRQ/U.S. Preventive Services Task Force; Toby Merlin, M.D., of CDC; and Brian Smedley, Ph.D., from the IOM report.

Dr. Tu added that the subcommittee plans to spend more time discussing information provided

by Dr. Finch about how costs relate to disparity and about the IOM report.

In summary, the subcommittee would like to focus on Medicaid, particularly maternal and child health services for services from preconception and prenatal care to 12 months after delivery. Another focus is determining which HEDIS measurement impacts the maternal and child health outcomes—members do not know which measurement provides that information. The subcommittee would also like to focus on the U.S. Preventive Services Task Force guidelines, starting with obesity.

Members agreed on three goals. The first goal is to secure and protect current maternal and child health services from any reduction. Members may not be able to ask for any expansion, but they would like to remind the Secretary of the reasons why Medicaid was created. The second goal is the possibility of expanding Medicare evidence-based preventive services to mother and infant care, which members view as very deficient. The third goal is to look for an index or indicator that has enough evidence-based data to impact outcomes, similar to the use of obesity as a preventive service indicator.

Dr. Tu also said the group has a “bigger goal” that Dr. Finch proposed: to develop a recommendations model drawing on lessons taken from the Secretary’s accomplishments in Utah. Biographical sketches of the Secretary characterize him as a “health innovator” for his efforts to restructure health care services in Utah. Subcommittee members want to tailor their recommendations to the Secretary’s experiences and successes. They requested a speaker for another meeting who could help them understand what the Secretary did in Utah.

### **Eliminating Health Disparities Subcommittee**

Dr. Sapien reported for the subcommittee. The subcommittee opened with a brainstorming session on specific areas of disparities, including the cause of death and related issues (which may be cultural or geographical, such as border health or urban versus rural).

The subcommittee then discussed programs relevant to the disparities. Subsequently the members decided to focus on four topics: extremely low birth weight, SIDS, intentional and unintentional injuries. Dr. Sapien explained a matrix (or box chart) that was illustrated on a flip chart; and how the subcommittee intends to complete one matrix for each topic. The four matrices are works in progress and are based on the Haddon Injury Prevention Matrix. Categories of input (working from the left vertical axis) are pre-event, event, and post-event, where the event is the actual death of the child. The input categories are correlated with the categories of actual infant or host; community (the household, the physical community around the household such as the extended family); systems; and recommendations (along the top horizontal axis). There will be recommendations for all pre-events, events, and post-events, as well as for the infant, the infant’s community, and the system as a whole.

The subcommittee selected SIDS as an example, and Dr. Sapien filled in the matrix with the following partial information:

**Table 1 SIDS Matrix**

SIDS	Infant or host	Community	Systems	Recommendations
Pre-event	Sleep position Recent vaccinations Viral illnesses	CPR training Tobacco use in the home as a risk factor Co-sleeping Health education	CBOs Back to Sleep Program WIC Fatherhood Initiatives Healthy Start Definition differences	
Event	SIDS Death	Available CPR		
Post-event	Autopsy Organ donation	Counseling for SIDS families Conducting the autopsy	Data collection/statistics Business community	
Recommendations				

Dr. Sapien mentioned that there is often no consistency between reports from the pathologist and reports from the coroner as to what is SIDS; the definitions are different for the investigation versus the autopsy. He then stated that each member of the subcommittee has selected one of the boxes to work on.

The members also worked on a matrix for extremely low birth weight infants that reflects their approach and their progress.

Dr. Guyer said that he lost the intended link to disparities as he listened to the report. Dr. Sapien said the subcommittee members also lost that link initially. But as they began their deliberations with the specific areas where there are disparities—intentional and unintentional injuries, SIDS, and low birth weight—a theme emerged that the four categories share disparities at all levels.

Dr. Bronner explained that the goal is to investigate the issues contributing to the disparity in SIDS, which will then provide insights into the many factors and programs that could comprise solutions and recommendations. Dr. Guyer requested further clarification about the data in the matrix, and provided as an example, information in the pre-event box that would not necessarily be all of the risk factors for SIDS, but only risk factors for certain disparities. Dr. Sapien illustrated his response with sleep position data, which could reflect cultural or generational beliefs. Inserting those variables in the “Systems” column of the matrix could include educating individuals and populations in a culturally sensitive context. Dr. Hayes observed that the presentation is a means of identifying practical ideas that can be implemented within a year; Dr. Sapien agreed with that intention. Once the background has been identified, even if there is only one recommendation in each box, the task has been narrowed.

Dr. Collins pointed out that the assigned timeframe for recommendations of 1 year or 1 year plus 6 months is flexible, not rigid, and the members should think about that.

Dr. Collins added that the Disparities Subcommittee also recommends bringing in experts on SIDS (there already is a list of suggested speakers).

## Clinical and Public Health Practice Subcommittee

Dr. Ryan reported for the subcommittee. Members decided to aim for two products in the context of their responsibility to provide viable recommendations to the Secretary, and to adhere to past SACIM practices of including the recommendations in formulated reports. The subcommittee agreed to the following reports:

1. Quality improvement opportunities in clinical and public health practice
2. Using data to improve birth outcomes

In the discussion on quality improvements in clinical care, most of the time was spent identifying opportunities. Many options were then narrowed to what was practical and possible within a year (or some other reasonable timeframe, although some may still be eliminated):

- More effective family planning.
- More effective integration of smoking cessation into prenatal care. (Dr. Ryan noted that where recommendations are related to reimbursement issues, the Financing/Funding Subcommittee would probably need to be consulted. For example, smoking cessation is often intended to be part of the general prenatal package with no specific reimbursement as a service, and may therefore not be adequately addressed. The members know that evidence-based smoking cessation services are available, and women who stop smoking during pregnancy have a very important impact on birth outcomes—of any other specific intervention, it is probably the single, most important factor influencing birth outcomes.)
- More effective preconception care by integrating it into routine services for women and men of childbearing age.
- Risk-appropriate prenatal care so women with chronic medical diseases are ensured access to appropriate treatments.
- Risk-appropriate intrapartum care. (Commonly cited as a mechanism for improving birth outcomes. Delivering very low birth weight babies at tertiary centers is considered appropriate and has been observed and followed for some time. There are challenges to those practices, especially around managed care.)
- Clinical continuous quality improvement initiatives. (At the recent AMCHP meeting, there was a good discussion by Jeff Gould, M.D., M.P.H., about activities in California that relate primarily to neonatal practice but can be adapted more generally to perinatal practices. These are instances where there is a significant amount of work invested in a well-designed data system, effective risk adjustment tools, effective strategies that engage partners, and mechanisms for sharing outcome data with neonatologists and hospitals in general, all of which have improved clinical practice. Using data to bring issues to light leads to effective improvements in clinical quality, and the subcommittee sees opportunities in these approaches that are worth exploring.)
- Improving the Medicaid package. (The subcommittee agrees with the importance of Medicaid and would like to collaborate with the Financing/Funding Subcommittee to develop a cogent discussion on how Medicaid should support reproductive health services to improve birth outcomes and reduce expenditures. A variety of services should comprise a Medicaid package. Dr. Ryan said his group agrees with the

Financing/Funding Subcommittee about the need to defend and retain those services amidst the current cost-cutting environment.)

Concurring with Dr. Tu's group, this subcommittee also thinks that a presentation on Medicaid would be beneficial. The members are very interested in Medicaid's Pay-for-Performance Initiative. The subcommittee tried to identify improvement opportunities that are consonant with the philosophy of the current administration, which is interested in the Pay-for-Performance Initiative. If the subcommittee could learn more about that initiative, it might be possible to add some recommendations to it that would improve maternal and child health services.

The discussion moved from the clinical side of the provider/client relationship to a broader ecological perspective of public health. Dr. Ryan explained that the most important goal is to optimize the health of persons of reproductive age, starting well before that age. Both the private and public sectors have a role in addressing the social determinants of health. The members discussed a number of issues, such as reproductive health education, general nutrition and fitness, and smoking. The subcommittee recognizes the challenge in bringing about these types of social changes, and would like a motivational speaker to address the Committee on how to motivate change. One possible speaker is Bill Novelli, who has been working with smoking cessation efforts. Dr. Ryan said the members want a perspective on the types of efforts and interests that need to coalesce to create broad social change. He added that the members must restrict themselves to what can be accomplished in a limited timeframe, but agreed on the need for a broad ecological perspective, which is the life cycle approach.

The discussion then moved to data, with a realization that topics such as clinical quality improvement initiatives had also included some data issues. The subcommittee agreed with some of the opportunities to improve data that were presented to all of the participants that day:

- Standardize definitions
- Improve timeliness
- Increase accuracy

The members agreed that data can be used to promote change and improve quality. They want to use better data more effectively and increase competency among those who generate, analyze, and utilize the data to translate a better understanding of the data into better program decisions.

There was an extensive discussion about accountability issues. When done well, report cards can motivate people to change. The subcommittee expressed a need to use data in continuous quality improvement initiatives that are, according to Dr. Saunders, dependent on the timely availability of the data. These were the main issues of the subcommittee.

The subcommittee decided that two additional presentations might be of value. Dr. Ryan noted that spokespersons for the March of Dimes have made presentations to SACIM in the past, and the organization is currently conducting a campaign to reduce prematurity. It might be wise to ask a representative to return to SACIM to address the group. The IOM also has a new study committee examining premature birth, and staff working on that initiative could also be invited

to address SACIM at an appropriate time.

Ms. Ryan suggested combining Dr. Ryan's report with Dr. Tu's comments on CMS and maternal and child health indicators for public reporting. Ms. Ryan again alluded to the report card theory, but then pointed out the possible timeliness for more immediate opportunities while the government is paying more attention to public reporting and requirements for providers (i.e., physicians or institutions). She indicated that it might be opportune for SACIM to assist with the development of indicators that could then be translated into the clinical initiatives the group may ultimately want to achieve.

Dr. Ryan expressed his gratitude to Ms. Ryan for those remarks.

Dr. Collins asked that the chairpersons prepare a 1-page summary of their presentations, which should be sent to Dr. Koontz.

Dr. Tu asked, and Dr. Collins concurred, that the chairpersons include in their summaries the requests for speakers and relevant information to carry out those suggestions.

Dr. Collins asked for input on additional issues. There were no responses. He thanked the members for a very productive meeting, and indicated that he is looking forward to more progress on their efforts in July. He wished the members safe travel.

In response to a question about subcommittee operation from Dr. Bronner, Dr. Collins said that the next meeting will include concentrated time for Committee work. Members will, in the meantime, receive individual mailings of any relevant information that may arise.

Dr. Sapien reminded Dr. Collins about the request for Internet access. Dr. Collins clarified that each subcommittee, particularly the Disparity Subcommittee, had requested access to the Internet during the meeting, and he would try to make that available.

Dr. Collins adjourned the meeting at 2:08 p.m.

## PARTICIPANT LIST

### **Advisory Committee Members**

James W. Collins, Jr., M.D., M.P.H., Chair  
Robyn J. Arrington, Jr., M.D.  
David Ray Baines, M.D.  
Renee T. Barnes, M.S., R.N.  
Yvonne Bronner, Sc.D., R.D., L.D.  
Ronald A. Finch, Ed.D.  
Deborah L. Frazier, B.A., R.N.  
Bernard Guyer, M.D., M.P.H.  
Robert E. Hannemann, M.D.  
Maxine Hayes, M.D., M.P.H., FAAP  
C. Renee Elmen Hollan, R.N., B.A.N.  
Ann Miller, Ph.D.  
Christina M. Ryan, R.N., M.P.A., B.S.N.  
Kevin J. Ryan, M.D., M.P.H.  
Robert E. Sapien, M.D.  
Betty K. Tu, M.D., M.B.A.

### **Advisory Committee Staff**

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

Ann M. Koontz, C.N.M., Dr.P.H.  
Associate Director for Perinatal Policy  
Division of Healthy Start and Perinatal Services, MCHB, HRSA

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

### **Presenters**

James W. Collins, Jr., M.D., M.P.H.  
Associate Professor of Pediatrics  
Northwestern University Medical School  
Chairperson, SACIM

Edith Hambrick, M.D., J.D.  
Medical Officer  
Center for Medicare Management  
Centers for Medicare and Medicaid Services

Isabelle Horon, Dr.P.H.  
Director, Vital Statistics Administration  
Maryland Department of Health and Mental Hygiene

John Lantos, M.D.  
Professor of Pediatrics  
Associate Director, MacClearn Center for Clinical Medical Ethics  
University of Chicago

Charles J. Rothwell, M.S., M.B.A.  
Director, Division of Vital Statistics  
National Center for Health Statistics  
Centers for Disease Control and Prevention

Charles J. A. Schulte, III, M.D., FAAP  
Former Chairperson, AAP Committee on Coding and Nomenclature  
Private Pediatric Group Practice

James A. Scroggs, M.H.A.  
Director, Department of Health Economics  
American College of Obstetricians and Gynecologists

Linda A. Tavener  
Team Leader, Non-Institutional Payment Team  
Division of Reimbursement and State Financing  
Center for Medicaid and State Operations  
Center for Medicare and Medicaid Services

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

**Public Commenters**

Lori Cooper  
ASIP Project IMPACT

**Other Attendees**

Maribeth Badura  
MCHB, HRSA

Sharron Cozle  
Association of Maternal and Child Health Programs

Ada Determan  
HRSA

Ellen Hutchins  
HRSA

Michael Kogan  
MCHB, HRSA

Monique La Rocque  
Office of Minority Health, DHHS

Marian MacDorman  
NCHS, CDC

Jan Markowitz  
NAPHSIS

Susan Meikle, M.D., M.S.P.H.  
Agency for Healthcare Research and Quality

Julie Moreno  
Office of Minority Health, DHHS

Deborah Outlaw  
Pediatrix Medical Group

Lauren Ratner  
HRSA

Madelyn Renteria  
HRSA

Maria Rios  
HAB, HRSA

Phillip Smith  
IHS

Peter Sybinsky  
Association of Maternal and Child Health Programs

Stephanie Ventura  
NCHS, CDC

# **Addendum**

**Public Comments to SACIM  
March 2, 2005**

## **Public Comment before the Secretary's Advisory Committee on Infant Mortality**

March 2, 2005 Sheraton National Hotel, Washington, DC

Marie Chandick, President, Association of SIDS and Infant Mortality Programs (ASIP)  
(Lori Cooper, Executive Director, ASIP Project IMPACT speaking on behalf of Ms.Chandick)

Good morning, Dr. Collins and Committee Members:

Thank you for the opportunity to speak with you this morning, and to share with you the 2005 ASIP Annual Report, *Helping Families, Protecting Babies*. Tomorrow, the Association of SIDS and Infant Mortality Programs will convene its annual conference here in Washington, DC. This year, we are commemorating passage of the SIDS ACT OF 1974, PL 93-270. This law authorized funding for information and counseling programs for families who lost a child to SIDS. By placing the responsibility for bereavement services for SIDS with the Maternal and Child Health Bureau, Congress acknowledged that comprehensive perinatal care can and must include care for families whose infants die in the first year of life.

The legislation established objectives and standards that included the performance of post-mortem examinations, including autopsies for all cases of sudden and unexpected deaths of infants; the use of SIDS as a cause of death when appropriate; notification of the preliminary cause of death to parents within 24-48 hours; provision of counseling for bereaved families; development of public and professional education programs; and data collection and analysis.

We still face many challenges in these arenas today, but I would like to share with you some highlights of our progress as a nation since implementation of the SIDS ACT:

(1) Post-mortem examinations: Although autopsies are not routine in every state, many medical examiners and coroners comply with the standards for investigation of sudden and unexpected infant death. Death scene investigations have become comprehensive, and in many jurisdictions, are routine. The CDC, in collaboration with the SIDS/ID and MCH communities, will soon implement revised guidelines for investigating sudden unexpected infant deaths that will help to promote uniform reporting and data collection.

(2) The use of SIDS as a cause of death: In 1991, NICHD updated the SIDS definition to include death scene investigation, and NICHD continues to fund research investigating the causes of SIDS and other unexpected infant deaths. Breakthroughs in genetic screening have revealed the cause of some previously unexplained sudden infant deaths, and more careful death scene investigations have actually explained the cause of many deaths which in the past may have been misdiagnosed. Some researchers have begun a process to refine the SIDS definition, and there is a national group of researchers and practitioners who have taken on that task.

(3) Notification to parents: Today, in most of the country, parents who experience the death of an infant are contacted by trained professionals who provide information, support and referral to local resources. We are working to ensure that the support that is offered is culturally and linguistically appropriate.

(4) Provision of counseling for bereaved families: In the past thirty years, state and local programs, along with other professionals, have counseled thousands of families who have experienced the loss of a child to SIDS. In recent years, ASIP along with many of these programs, has expanded our services to respond to parents who lose a child to other sudden unexpected death.

(5) Development of public and professional education campaigns: Most of you are familiar with the national *Back-to-Sleep* Campaign, initiated in 1992. This campaign, considered instrumental in halving the number of SIDS cases since its launch, has been adapted by local and state programs throughout the country. It has been expanded well beyond sleep position to a safe sleep environment, the components of which address infant development (e.g. tummy time) as well as safety.

Professional education programs about risk reduction as well as bereavement service have been developed by ASIP and others for physicians, nurses, social workers, first responders, law enforcement officers and detectives, medical examiners, and funeral directors.

(6) Data collection and analysis: SIDS and other infant deaths are routinely reported by the National Center for Health Statistics. And ASIP has developed a model database for SIDS/ID, currently being tested in Massachusetts, that will be made available for other programs through the internet.

Service delivery has come a long way. In addition, the field has matured and returned to the heart of public health, which is risk reduction. The lessons learned from programs responding to SIDS and other causes of infant death pushed those professionals in the field to expand the focus from mortality to bereavement, and more recently, from bereavement to risk reduction. Mortality reviews—maternal, infant and child—are no longer limited to medical interpretation. Communities are using the data to forge action plans that reduce risk for the entire community.

Some of our basic struggles remain. Limited resources mean reduction, and in some cases, elimination of services. Strategies of collaboration and integration of services have helped to make systems more efficient, and we will continue to pursue all paths that will not erode or compromise the comprehensive and compassionate care that ASIP and others provide to bereaved families.

Disparities in SIDS deaths haunt researchers and practitioners. Reasons for the disproportionate rate of African American and American Indian/Alaska Native SIDS deaths compared to white deaths continue to elude us, although we are closing in on new ways to identify and study causative factors. In the meantime, we are exploring how to best translate the research that we do have into meaningful, risk-reducing behavioral strategies for families and communities.

I appreciate that the Committee is leading the way for us in many of the same efforts. On behalf of ASIP, we look forward to working with you, and to keeping you apprised of critical developments in professional bereavement support and related training and educational programs.