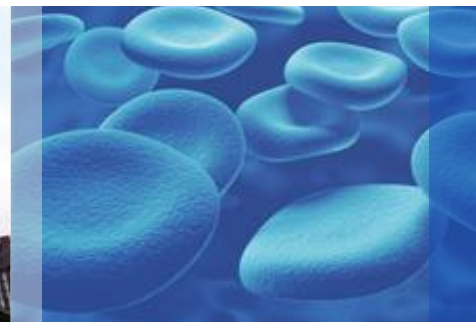


History of the Other Work of the SACHDNC

Alex R. Kemper, MD, MPH, MS

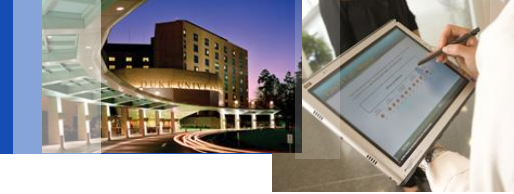
September 22, 2011





Background

- The SACHDNC has addressed broad issues related to improving health outcomes through newborn screening
- Many active subcommittees
 - *Surveys*
 - *White papers*
 - *Recommendations to the SACHDNC*
- Focus: Recommendations made to the Secretary, HHS, from the SACHDNC



Chartered in 2003

“SEC. 1111. ADVISORY COMMITTEE ON HERITABLE DISORDERS IN NEWBORNS AND CHILDREN.

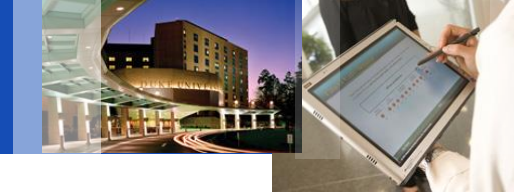
“(a) ESTABLISHMENT.—The Secretary shall establish an advisory committee to be known as the ‘Advisory Committee on Heritable Disorders in Newborns and Children’ (referred to in this section as the ‘Advisory Committee’).

“(b) DUTIES.—The Advisory Committee shall—

“(1) provide advice and recommendations to the Secretary concerning grants and projects awarded or funded under section 1109;

“(2) provide technical information to the Secretary for the development of policies and priorities for the administration of grants under section 1109; and

“(3) provide such recommendations, advice or information as may be necessary to enhance, expand or improve the ability of the Secretary to reduce the mortality or morbidity from heritable disorders.



Newborn Screening Saves Lives Act

One Hundred Tenth Congress of the United States of America

AT THE SECOND SESSION

*Begun and held at the City of Washington on Thursday,
the third day of January, two thousand and eight*

An Act

To amend the Public Health Service Act to establish grant programs to provide for education and outreach on newborn screening and coordinated followup care once newborn screening has been conducted, to reauthorize programs under part A of title XI of such Act, and for other purposes.

*Be it enacted by the Senate and House of Representatives of
the United States of America in Congress assembled,*

SECTION 1. SHORT TITLE.

This Act may be cited as the “Newborn Screening Saves Lives Act of 2007”.



SACHDNC Activities:

Newborn Screening Saves Lives Act

- Make systematic evidence-based and peer-reviewed recommendations
- Develop a model decision-matrix for newborn screening expansion, including an evaluation of the public health impact of expansion
- Consider ways to ensure that all states attain the capacity for screening, short and long-term follow-up
- Standardize language and terminology used by state newborn screening programs
- Quality assurance, oversight, and evaluation
- Education
- Assessment of costs and effectiveness
- Coordination of surveillance activities



Summary of Activities

- Topics to discuss today
 - *Health Reform, including Coverage for Medical Foods*
 - *Education*
 - *Long-Term Follow-Up*
 - *National Contingency Plan*
 - *Sickle Cell Disease*



Health Reform:

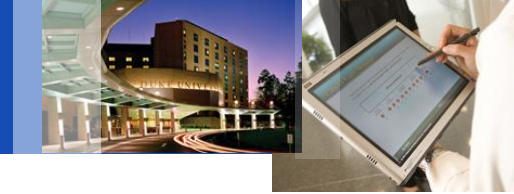
Letter to the Secretary, HHS, May 19, 2009

- The committee desires
 - *A more uniform approach toward coverage by health care payers of medical foods and foods for those conditions recommended by the Committee*
 - *Specific amendments to Medicaid legislation to ensure more uniform coverage by State Medicaid Programs*



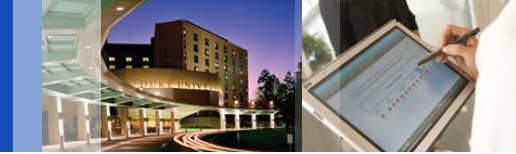
Health Reform: Letter to the SACHDNC, October 2, 2009

It is understood that the Committee feels that policies are needed to address gaps in coverage for items that are a vital component of medical management but are not typically included as “medical” services for the disorders identified through newborn screening. I recognize that medical foods and other foods modified to be low protein are important treatments for inborn errors of metabolism, and the Department will be further exploring these proposals. However, the Committee’s recommendations to enact legislation are beyond the Department’s authority. Therefore, I am neither adopting nor rejecting the Committee’s recommendations.



Health Reform: Letter to the Secretary, HHS, March 23, 2010

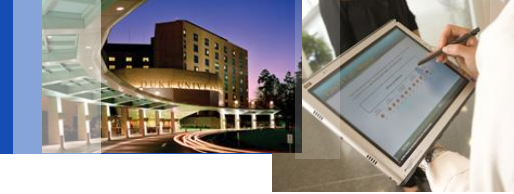
1. Encourage the Centers for Medicare and Medicaid Services to convene an expert panel to examine coding changes to streamline the billing process for newborn screening services and to put forth recommendations that enhance the standardization of health care transactions.
2. Encourage the Centers for Medicare and Medicaid Services to develop and pilot a payment method for an integrated system of care coordination through the medical home framework for children diagnosed with heritable and congenital disorders as a result of screening.
3. Encourage the adoption and further definition of the Newborn Screening Use Case within the Department's health information exchange endeavors, specifically encouraging the Centers for Medicare and Medicaid Services to make use of the Newborn Screening Use Case when defining "meaningful use" of Electronic Health Records and the Office of the National Coordinator for Health Information Technology to further facilitate the adoption of the Newborn Screening Use Case.
4. Support, as allowable, the closure of gaps in insurance coverage for medical foods and foods modified to be low in protein, as recommended by the Committee in April, 2009.



Health Reform:

Response from the Secretary, HHS, September 23, 2010

- The first 3 recommendations were accepted
 - *The lack of coding and billing is an administrative burden*
 - *Medical home models were specifically highlighted*
 - *The benefit of electronic exchange of data was seen as a way to improve care coordination*
 - *But, what about medical foods?*

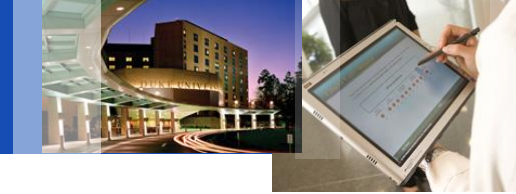


Health Reform:

Response from the Secretary, HHS, September 23, 2010

SACHDNC's Recommendation 4: Support, as allowable, the closure of gaps in insurance coverage for medical foods and foods modified to be low in protein, as recommended by the Committee in April, 2009.

Recommendation respectfully not accepted at this time. HHS recognizes that there is a need for policy to address gaps in coverage for medical foods and foods modified to be low in protein that are essential treatments for certain heritable disorders identified in newborn screening but are not typically considered "medical services." We are currently reviewing SACHDNC's June 14, 2010 letter in which many of these same concerns are raised in the context of enactment of the Affordable Care Act. My forthcoming response to the June 14 letter will address this issue further. I will also ask CMS to review State Medicaid programs to determine if there is opportunity to improve federal guidance to the states regarding existing coverage for medical foods and foods modified to be low in protein.



Health Reform:

Response from the SACHDNC, June 14, 2010

The Committee believes that our nation has a special responsibility to assure evidence-based treatments for individuals identified with these disorders. This responsibility does not end with identification of these disorders, rather it extends to ensuring medically necessary coverage for these life saving treatments. Your appropriate policy decisions will have an immediate and substantial impact for thousands of affected individuals and their families.



Health Reform:

Response from the Secretary, HHS, December 14, 2010

The information you have provided will help inform our ultimate decision about essential health benefits. However, until I have the results of the Department of Labor survey and the Institute of Medicine recommendations, I am not in a position to make determinations about particular benefits. Please be assured that when I am able to make these decisions, I will give serious consideration to the issues you raise.



Health Reform

- RCs
 - *Have conducted a survey of barriers to the receipt of medical foods*
 - *Will address these barriers at a local level, with lessons learned summarized in partnership with the NCC*



Health Reform

- Illustrates how the SACHDNC works with subcommittees
 - *Defining LTFU (care coordination through a medical home, evidence-based treatment, QI, new knowledge discovery)*
 - *Facilitating assessment in partnership with the RCs and the NCCs*



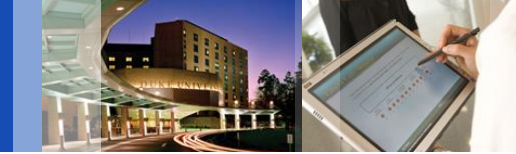


Education

- The early work of the SACHDNC anticipated the Newborn Screening Saves Lives Act

On December 19, 2006, the Advisory Committee on Heritable Disorders and Genetic Diseases in Newborns and Children (Committee) met in Washington, D.C. The Committee reviewed the work of its Subcommittee on Education and Training and made the following recommendation with a unanimous vote:

- the Secretary, HHS shall *"develop and fund a mechanism to study the distribution of existing newborn screening educational materials and acquisition of knowledge about newborn screening by expectant parents in the context of the healthcare provider-patient relationship."*



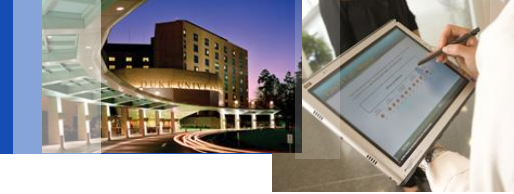
Education

- Education Subcommittee developed a report describing the need for primary care education that was endorsed by the SACHDNC
- Led to the funding, through HRSA, of a Genetics in Primary Care Training Institute
- Illustrates
 - *Active role of subcommittees*
 - *Action through funding*



National Contingency Plan

- Presented to the Secretary on August 6, 2010
- Each state to have a newborn screening contingency plan
- CDC, with support from HRSA, will lead efforts to coordinate implementation with the Assistant Secretary for Preparedness and Response
- RCs have taken an active role in disaster planning

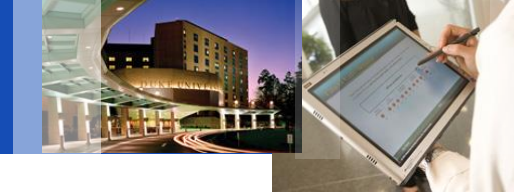


Sickle Cell Trait:

Response from the Secretary, HHS, June 27, 2011

I am pleased to support your first three recommendations:

- All individuals should have the opportunity to find out their risk for various medical disorders, including their carrier status for genetic conditions such as sickle cell disease;
- Evaluation and testing for sickle cell disease and other genetic conditions should take place within the individual's medical home. That evaluation should include counseling regarding the implications of the information for the individual and assurance of the privacy of genetic information. Genetic testing should not be a pre-requisite for participation in sports, unless deemed medically necessary; and
- As part of the individual's annual medical evaluation for participation in sports, all potential athletes should receive education on safe practices for prevention of exercise and heat related illnesses.



Sickle Cell Trait:

Response from the Secretary, HHS, June 27, 2011

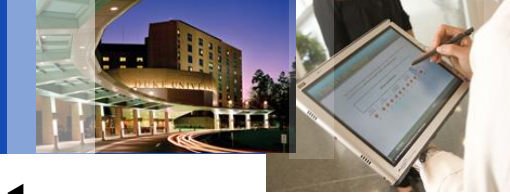
At this time, the Committee's remaining two recommendations are not ready for adoption:

- The Secretary, HHS, instruct SACHDNC to work with the Sickle Cell Disease Association of America, relevant federal HHS agencies, athletic associations, community-based and health care professional organizations to develop guidelines and educational resources about screening for sickle cell trait in all persons, including athletes; and
- The National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC) conduct research to ascertain if some athletes with sickle cell trait are at increased risk of exercise-related sudden death.



Dried Blood Spots

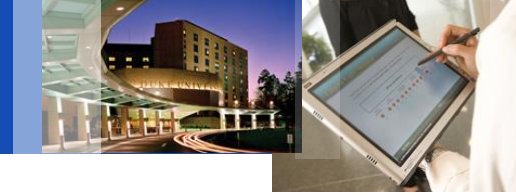
- States develop policies related to
 - *Access*
 - *Disposition*
 - *Education of health care professionals*
 - *Education of families*
 - *Documentation of parents' wishes*
- Facilitate a national dialogue
- Explore the utility and feasibility of a voluntary national repository



Dried Blood Spots:

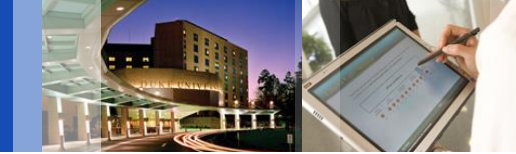
Response from the Secretary, HHS, April 13, 2011

At this time, the Committee recommendations are not ready for adoption. Therefore, I am referring the Committee's report, *Considerations and Recommendations for a National Policy Regarding the Retention and Use of Dried Blood Spot Specimens After Newborn Screening*, to the Interagency Coordinating Committee on Newborn and Child Screening (ICC) for its review and input regarding possible future implementation of the recommendations. The use of the ICC allows a more formal engagement of the Office for Human Research Protections and Office for Civil Rights, along with the federal agencies assigned to the ICC by its authorizing legislation. I will encourage the ICC to submit a report with recommendations for appropriate Departmental action by June 1, 2012.



Dried Blood Spots

- Area of intense work by
 - *RCs*
 - *NCC*
 - *NNSTRN*
 - *Subcommittees of the SACHDNC*
 - *Projects funded by HHS*



Summary

- SACHDNC and its subcommittees are active and productive
- Work has led to improvement in the care that children and their families receive
- There are many important areas to address
- Model of Success:
 - *Under guidance from the SACHDNC, the subcommittees develop reports*
 - *If approved by the SACHDNC, these reports are used to*
 - Inform recommendations to the Secretary, HHS
 - The implementation activities of the RCs and NCC