Report to Congress:

Federal Activities Related to Stillbirth, Sudden Unexpected Infant Death, and Sudden Unexplained Death in Childhood

A Report Required by the Sudden Unexpected Death Data Enhancement and Awareness Act of 2014

United States Department of Health and Human Services
Washington, D.C.

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INTRODUCTION

Public Law 113-236 the Sudden Unexpected Death Data Enhancement and Awareness Act:

REPORT TO CONGRESS.—Not later than 2 years after the date of enactment of this Act, the Secretary of Health and Human Services shall submit to Congress a report that includes a description of any activities that are being carried out by agencies within the Department of Health and Human Services, including the Centers for Disease Control and Prevention and the National Institutes of Health, related to stillbirth, sudden unexpected infant death, and sudden unexplained death in childhood, including those activities identified under subsection (a).

The following report has been prepared by the Department of Health and Human Services (HHS) in response to this request.

BACKGROUND

Stillbirth
A stillbirth is the death or loss of a baby before being born. Both miscarriage and stillbirth describe pregnancy loss, but they differ according to when the loss occurs. In the U.S., a miscarriage is usually defined as loss of a baby before the 20th week of pregnancy, and a stillbirth is loss of a baby at 20 weeks and greater of pregnancy.

Stillbirth effects about 1 percent of all pregnancies, and in 2015 about 24,000 babies were stillborn in the U.S.

Sudden Unexpected Infant Death and Sudden Unexplained Death In Childhood
In 2015, there were about 3,700 sudden unexpected infant deaths in the U.S. Sudden unexpected infant death (SUID) is the death of an infant less than 1 year of age that occurs suddenly and unexpectedly, and whose cause of death is not immediately obvious before investigation. Most SUIDs are reported as one of three types.

1. Sudden infant death syndrome (SIDS) - The sudden death of an infant less than 1 year of age that cannot be explained after a thorough investigation is conducted, including a complete autopsy, examination of the death scene, and a review of the clinical history. In the U.S., about 1,600 infants died of SIDS in 2015. SIDS is the leading cause of death among infants 1 to 12 months old.

2. Unknown cause - The sudden death of an infant less than 1 year old that remains undetermined because one or more parts of the investigation were not completed.

3. Accidental suffocation and strangulation in bed-The sudden death of an infant less than 1 year of age that can happen because of
   o Suffocation by soft bedding—for example, when a pillow or waterbed covers an infant’s nose and mouth.
   o Overlay—when another person rolls on top of or against the infant while sleeping obstructing the infant’s nose and mouth.
- Wedging or entrapment—when an infant is wedged between two objects such as a mattress and wall, bed frame, or furniture obstructing the infant’s airway.
- Strangulation—for example, when an infant’s head and neck become caught between crib railings.

Nationally, SUID deaths have declined considerably following the release of the American Academy of Pediatrics safe sleep recommendations in 1992 and the initiation of the Back to Sleep campaign in 1994. After the release of the Sudden Unexplained Infant Death Investigation Reporting Form (SUIDIRF) in 1996, trends in SUID by type shifted, potentially reflecting changes in cause of death categorizations. Differences by race and ethnicity in SUID exist, with rates for American Indian/Alaska Native and non-Hispanic black infants more than twice those of non-Hispanic white infants.

Sudden death in the young (SDY) is a broader category and includes infants, as well as children and young adults ≤ 19 years old, who die suddenly and unexpectedly (see Figure 1). This differs from sudden unexplained death in childhood (SUDC), which excludes infants, and is the sudden and unexpected death of a child 12 months and older which remains unexplained after a thorough case investigation is conducted. A SUDC diagnosis is made only if other causes of death are not identified after a thorough evaluation. About three quarters of SDY deaths are among infants aged 12 months or younger.

Figure 1: Categorization of SDY, SUID, and SUDC.
ADMINISTRATION FOR CHILDREN AND FAMILIES ACTIVITIES

The Administration for Children and Families (ACF) is a division of the Department of Health & Human Services. ACF promotes the economic and social well-being of children, families, individuals and communities with leadership and resources for compassionate, effective delivery of human services.

ACF Activities to Address Stillbirth, SUID, and SUDC

Child Care and Development Fund (CCDF)
The Office of Childcare administers the CCDF, which is the primary federal funding source for child care subsidies to help eligible low-income working families access child care and to improve the quality of child care for all children. The program is authorized by the Child Care and Development Block Grant Act, which was updated in 2014. A regulation based on the law was published in 2016. The updated Act and regulation require States to establish health and safety standards for child care providers who serve children receiving CCDF subsidies. In addition, the caregivers, teachers, and directors who work for these CCDF providers must receive pre-service/orientation and ongoing health and safety training. Both the standards and the training must address specified topics, including the prevention of sudden infant death syndrome and promotion of safe sleep practices. ACF’s Office of Child Care is providing oversight and technical assistance to ensure that States meet these requirements.

Standards for Safety Training and Safety Practices
The Office of Head Start (OHS) manages grant funding and oversees local agencies providing Head Start services. Head Start promotes school readiness of children under 5 from low-income families through education, health, social and other services. In order to prevent stillbirth, sudden unexpected infant death, and sudden unexplained death in childhood, OHS set standards for safety training and safety practices for Head Start workforce and for providing family support services for health, nutrition, and mental health. The standards indicate that Head Start centers must collaborate with parents to promote children’s health and well-being as well as collaborating to learn about preventive medical and oral health care, emergency first aid, environmental hazards, and health and safety practices for the home including health and developmental consequences of tobacco products use and exposure to lead, and safe sleep.

OHS also provides training through its Early Childhood Learning and Knowledge Center (ECLKC). The Center trains grantees through webinars, tip sheets, and developmental safety guides.

CENTERS FOR DISEASE CONTROL AND PREVENTION ACTIVITIES

The Centers for Disease Control and Prevention (CDC) works to improve outcomes for mothers and babies by compiling data to monitor health, supporting research to better understand leading causes of death and illness, and building capacity to implement prevention strategies. Through partnerships with national, state and local organizations and health agencies, CDC works to address stillbirths and Sudden Unexpected Infant Death by monitoring outcomes and identifying opportunities for prevention.
CDC Activities to Address Stillbirth

Estimating the Occurrence of Stillbirth in the U.S.

Most states report fetal deaths of 20 weeks of gestation or more and/or 350 grams birthweight. However, a few states report fetal deaths for all periods of gestation. States share their data with the National Vital Statistics System (NVSS) at CDC through the Vital Statistics Cooperative Program (VSCP) contract. Under this contract, CDC collects annual national statistical data on fetal deaths of 20 or greater weeks of pregnancy (or stillbirths) occurring in the U.S. (all 50 states, District of Columbia, New York City and five U.S. territories). These data are released in annual reports and as individual-record data files.

Stillbirth Surveillance Project, 2005 – 2015

From 2005 – 2015, CDC supported the expansion of two birth defects registries to include all stillbirths, including those with and without birth defects. Birth defect registries aim to identify all babies with birth defects in their study areas by having staff continually review medical records at multiple healthcare facilities. Although more time- and resource-intensive than systems relying on passive case finding, these methods more accurately identify babies with birth defects. For this project, birth defects registries in metropolitan Atlanta, Georgia, and the state of Iowa were expanded to identify all pregnancies resulting in a stillbirth. Both programs:

- Evaluated if their expanded birth defects tracking systems effectively captured all stillbirths, both those with and without birth defects, among residents in their tracking areas;
- Reported on the occurrence of stillbirth among the population in their tracking areas;
- Provided data for studies on factors associated with stillbirth; and
- Served as a resource for education and evaluation of strategies to prevent stillbirths.

Notable outcomes from these projects include:

- Expanding existing birth defects surveillance programs to include active ascertainment of stillbirth, which is likely a valuable approach to help address our current knowledge gaps about the incidence and risk factors for stillbirths;
- Using combined data from both active surveillance of stillbirths and fetal death certificates resulted in a 30 percent increase in the estimated number of stillbirths, over using fetal death certificates alone;
- Development of abstractor training modules for use by states to implement stillbirth surveillance; and
- Development of educational module for hospital staff in Iowa to enhance accurate case classification and reporting.

Stillbirth Risk Factor Pilot Project, 2016– present

CDC has recently funded a new project with Arkansas and Massachusetts to better understand factors that might increase the risk for stillbirth. These states’ birth defects registries have been expanded to identify all pregnancies resulting in stillbirth, incorporating lessons learned from previous stillbirth surveillance, as well as implementing innovative surveillance and analytical methods.
Improving Reporting on Fetal Cause of Death

The National Center for Health Statistics (NCHS) recently launched the new e-learning training, “Applying Best Practices for Reporting Medical and Health Information on Birth Certificates.” The training is designed for both clinical and non-clinical hospital staff and includes guidance on accurate reporting of fetal cause of death. NCHS also recently released the first national vital statistics report on fetal cause of death, “Cause of Fetal Death: Data from the Fetal Death Report, 2014.” This report presents data on cause of fetal death by maternal (age, race and Hispanic origin), and infant characteristics (sex, gestational age and birthweight).

Pregnancy Risk Monitoring System Stillbirth Pilot

CDC’s Pregnancy Risk Assessment Monitoring System (PRAMS) is used to describe the experience of women before, during, and after pregnancy, typically among women with a recent live birth. In 2016, CDC funded the Utah Department of health to expand its PRAMS methods and sampling to include women who experienced a stillbirth. Including stillbirths will provide valuable information by identifying groups of women who are at high risk for stillbirth and identifying areas for prevention.

CDC Activities to Address SUID and SUDC

Even after a thorough investigation, it can be hard to tell types of SUIDs apart from each other. Investigators may report cause of death in different ways and may not include enough information about the circumstances of the event from the death scene. CDC’s activities center around improving the accuracy and completeness of data collected for SUID and SDY to inform prevention strategies to reduce these untimely deaths.

Sudden Unexpected Infant Death Surveillance (SUID Case Registry)

The SUID Case Registry is a surveillance system made possible through a cooperative agreement with participating jurisdictions (states and large metropolitan areas), referred to as “grantees,” that builds on existing state-based child death review programs that follow the protocols developed by the National Center for Fatality Review and Prevention (NCFRP) (formerly known as the National Center for Child Death Review). Reviews of these deaths are conducted by multidisciplinary Child Death Review (CDR) teams, including medical examiners, coroners, law enforcement, personnel, public health officials, pediatric subspecialists, and social services staff. Teams meet to share and discuss case information on deaths to understand how and why children die so that they can take action to prevent other deaths. Every state and the District of Columbia has a CDR system. As of 2017, forty-five states and their local teams participate in the National CDR Case Reporting System upon which CDC’s SUID and SDY Case Registries are based.

The SUID Case Registry grantees improve the completeness and quality of SUID data by compiling information on all unexpected infant deaths from the various data sources available, including medical examiner and coroner, law enforcement, and social services reports, as well as medical records. Grantees convene multidisciplinary CDR teams to review SUID cases and enter data into the NCFRP’s Child Death Review Case Reporting System. The SUID Case Registry provides comprehensive information about the circumstances associated with an infant death, as well as information about whether a case investigation (scene investigation and autopsy) was conducted and, if so, the components of that investigation. CDC grantees receive direct technical
assistance related to data collection, case review, data entry, data analysis, quality assurance and evaluation. In turn, feedback about the submitted data can help improve the investigative process.

CDC and state grantees use the SUID Case Registry surveillance data to:

- Monitor SUID trends and characteristics;
- Encourage consistent medicolegal investigation and reporting practices; and
- Develop prevention strategies targeted to their population based on their data, such as safe sleep education and promotion.

Grantees also use SUID Case Registry data for program planning, medicolegal evaluation and training; and Title V Maternal Child Health Performance Objective reporting to document cases of sleep-related SUID per 100,000 live births. The Title V Maternal and Child Health Services Block Grant Program, funded by the Health Resources and Services Administration, addresses the health services needs of mothers, infants and children, including children with special health care needs and their families.

Select SUID Case Registry Grantee Success Stories

Michigan: Changing Policies and Practice

The Michigan Public Health Institute (MPHI) analyzed their SUID Case Registry data and found an increase in infant deaths among those within child protective services. To address this issue, MPHI worked with the Michigan Department of Health and Human Services to develop an infant safe sleep training and a policy that requires all child protection workers (e.g., foster care, child protective services) to receive this training. Additionally, Michigan passed the Infant Safe Sleep Act in 2014, requiring all birthing hospitals in the state to provide information and educational materials on infant safe sleep practices to new parents after the birth of their child.

Louisiana: Developing Partnerships

The Louisiana Department of Health, Office of Public Health, Bureau of Family Health’s SUID Case Registry provided case reviews of infant deaths in 2013 which led to recommending improved safe sleep education in hospitals. New partnerships to promote safe sleep throughout the state, such as the Collaborative Improvement and Innovation Network (CoIIN) Safe Sleep Champion Hospitals initiative, were implemented. Louisiana’s maternal and child health regional coordinators visited all the birthing hospitals in their state, shared data from the SUID Case Registry, and distributed information about the CoIIN initiative with maternal and child health administrators. As a result, all 52 birthing hospitals in Louisiana have been recognized as Safe Sleep Champion Hospitals, signing on to carry out at least one new action related to policy change, staff education, patient education, or community outreach to promote the safe sleep recommendations issued by the American Academy of Pediatrics.

Sudden Death in the Young Case Registry

The Sudden Death in the Young (SDY) Case Registry builds upon the CDC’s SUID Case Registry and the activities of local and state child death review teams by extending the age limit of case reviews beyond infancy (up to children ≤ 19 years old) and includes Sudden Unexplained
Death in Childhood, or SUDC, cases (children 12 months to ≤ 19 years old). The SDY Case Registry was created to increase the understanding of the incidence, causes, and risk factors for infants, children and young adults who die suddenly and unexpectedly. Currently, 10 states or jurisdictions participate in the SDY Case Registry. The Case Registry was developed through a partnership among NIH’s National Heart, Lung, and Blood Institute (NHLBI), their National Institute of Neurological Disorders and Stroke (NINDS), and CDC, and launched in 2014. Combined, the SDY and SUID grantees now capture data on about 30 percent of all U.S. SUID cases (see Figure 2).

As part of SDY Case Registry participation, CDR teams collect comprehensive data on new cases of infants, children, and young adults up to ≤19 years of age who died suddenly and unexpectedly and enter the data into the Case Reporting System. Autopsy protocols are standardized, and a DNA sample is collected and sent to the SDY Case Registry biorepository at the University of Michigan.

Figure 2: Funded Jurisdictions for SUID and SDY Case Registry.

**Standard guidelines for investigating SUID**

In 1996, CDC created guidelines for the investigation of Sudden Unexplained Infant Deaths and an Investigation Reporting Form (known as the Sudden Unexplained Infant Death Investigation Reporting Form or SUIDIRF). The guidelines and form were developed in consultation with forensic pathologists, medical examiners, coroners, medicolegal death scene investigators, law enforcement personnel, emergency medical technicians and paramedics, and public health agency officials to standardize death scene investigations. The guidelines and reporting form guide the investigator in collecting standardized information about the medical history of the deceased infant, family medical history, the circumstances surrounding the death, the sleep position and sleep environment of the infant, and any accidental or environmental factors that may have contributed to SIDS or other sleep-related events such as suffocation. This improves classification of SIDS and other SUIDs by standardizing data collection.

The guidelines and form were revised in 2006. In addition to the guidelines and form, CDC also developed a training curriculum and materials for investigators of infant deaths and implemented...
national training to educate professionals about the guidelines and reporting recommendations. Using a regional training approach and a train-the-trainer model, CDC trained teams of five in each state to conduct local infant death investigation trainings; it was anticipated that each team would be able to train an additional 25 people or 1,250 nationally. Each team consisted of a medical examiner or coroner; a law enforcement officer; a death investigator; an instructor of medicolegal investigations; and a child advocate, often represented by a child death review team member. The National Association of Medical Examiners, the International Association of Coroners and Medical Examiners, and the National Sheriff’s association endorsed the new SUIDIRF and training. An evaluation conducted five years after the first training academy found that 270 primary and more than 23,000 secondary participants had been trained.

In 2016, CDC began exploring the need for updates to the SUIDIRF to meet the needs of end-users, including medical examiners and death scene investigators. CDC’s program staff recently participated in two CDC-sponsored activities that allowed programs with technological or logistical issues that could be improved upon to present their ideas for product development or other evidence-based improvements (I-Catalyst and the Informatics Innovation Unit Technology Challenge). Based on information gathered through these processes, CDC has begun designing revisions to the SUIDIRF, which would entail maintaining the core information currently collected, while enhancing the flow of the document. CDC is also discussing the development of additional training to help users of the revised SUIDIRF, including potential in-person and online training approaches, the extent of which will depend upon available resources.

Death Scene Investigation Training
CDC grantees may also use federal funding to train medical examiners, coroners, medicolegal death scene investigators, law enforcement personnel, emergency medical technicians, and paramedics to conduct comprehensive death scene investigations for SUID and SDY, including the use of standard death scene investigation protocols.

CDC collaborated with a number of organizations and subject matter experts to create training materials for the investigation of infant (less than 1 year old) deaths intended for investigators and instructors that have been made available online (https://www.cdc.gov/sids/trainingmaterial.htm). Sudden Unexplained Infant Death Investigation: A Systematic Training Program for the Professional Infant Death Investigation Specialist teaches death scene investigators how to conduct a comprehensive infant death scene investigation. Investigators learn how to conduct witness interviews and doll reenactment and to develop a narrative report for the forensic pathologist. This training gives investigators the necessary knowledge and skills to complete the SUIDIRF during and after the scene investigation. CDC also has a curriculum guide available to provide teaching and evaluation techniques for instructors who train investigators to conduct infant death investigations.

Professional medicolegal organizations and federal workgroups continue to adopt and endorse the training materials, CDC’s SUID Investigation forms, and the Guidelines for the Scene Investigator. The American Academy of Pediatrics, in its 2016 updated guidance on infant safe sleep, recommended that the standardized protocols for death scene investigation developed by CDC continue to be implemented (http://pediatrics.aappublications.org/content/138/5/e20162938). Many of these efforts have been
institutionalized in academic settings. For example, Saint Louis University School of Medicine, which conducts a 5-day training program annually for investigators, law enforcement officers, forensic scientists, and physicians incorporates the CDC SUID investigation training into its curriculum. The National Institute of Justice has also sponsored live virtual training courses on SUID Investigation. Infant death investigations are included in the curriculum for national death scene investigator certification by the American Board of Medicolegal Death Investigators, a voluntary national, not-for-profit, independent professional certification board established to promote standards of practice for medicolegal death investigators.

**Efforts to Improve Data Quality**

Each quarter, CDC prepares and releases Data Quality Summaries to each SUID and SDY Case Registry grantee, tracking data timeliness, completeness, and case counts. For example, grantees are asked to identify a case within 30 days of an infant’s or child’s death and aim for zero missing responses and fewer than 10 percent unknown responses for key variables. CDC works closely with grantees to identify strategies to improve data completeness and timeliness.

**Autopsy Guidelines**

In 2014, as part of the SDY Case Registry development, CDC and NIH developed the SDY Autopsy Protocol by consulting with experts in a wide range of disciplines including forensic pathologists, medical examiners, coroners, pediatric pathologists, pediatric cardiologists, pediatric neuropathologists, geneticists, infectious disease specialists, and SDY parent advocacy organizations. The Protocol for Standard SDY Autopsy was implemented by SDY Case Registry grantees’ forensic pathology offices beginning in 2015.

**Maternal and Child Health Epidemiology Program**

CDC also supports the Maternal and Child Health Epidemiology Program (MCHEP). MCHEP assigns epidemiologists and fellows to state, local, and tribal public health agencies. This promotes and improves the health and well-being of women, children, and families by building capacity to use and apply sound epidemiologic research and scientific information to maternal and child health programs and policies. A major focus of MCHEP is addressing fetal and infant mortality (including SUIDs), through improved access to and use of robust data. This includes efforts to:

- Assess existing information and surveillance to improve reporting or use of infant mortality data;
- Develop and disseminate communication products that inform infant mortality reduction; and
- Address data and/or surveillance gaps in areas crosscutting clinical care and public health.

**Key Information Dissemination**

Manuscripts related to SUID statistics and investigation practices have been published in the peer-reviewed literature for dissemination to researchers, public health professionals, the medical community, and program planners:

Examined trends in SUID rates and disparities by race/ethnicity since the Back-to-Sleep campaign

   Described variation in cause-of-death certification of sudden unexpected infant deaths (SUIDs) among US medical examiners and coroners

   Described and compared sudden unexpected infant death (SUID) investigations among states participating in the SUID Case Registry from 2010 through 2012

   Provided neonatologists and pediatricians current and updated US definitions and reporting requirements for live births, fetal deaths, and infant deaths.

   Evaluated the SUIDI Training Academies by determining professional characteristics of participants, assessing the level of confidence in infant death investigation components, enumerating the number of secondary trainings, and discussing recommendations for future trainings

   Described the SUID Registry’s cause of death classification system, including its definitions and decision-making algorithm, and applies the system to 436 US SUID cases that occurred in 2011 and were reported to the registry

   Identified maternal and infant characteristics associated with accidental suffocation and strangulation in bed (ASSB) in US infants

HEALTH RESOURCES & SERVICES ADMINISTRATION ACTIVITIES

The Health Resources and Services Administration’s (HRSA) mission is to improve health and achieve health equity through access to quality services, a skilled health workforce, and innovative programs. HRSA’s programs work to improve health care to people who are geographically isolated, and economically or medically vulnerable, including pregnant women and mothers. Given this authority and expertise, prevention of child and infant deaths, including deaths from stillbirth, sudden unexpected infant death syndrome (SIDS), and sudden unexplained death in childhood (SUDC) is a valuable part of HRSA’s portfolio. HRSA invests in several programs that use data and evidence to prevent infant and child deaths, including through improving safe sleep outcomes and promoting safe sleep behaviors. HRSA plays a significant role in supporting the public health infrastructure of the nation, and as such, efforts around reducing infant mortality and improving early childhood health and development are key priorities.
HRSA Activities to Address Stillbirth, SUID, and SUDC

Title V State Maternal and Child Health Block Grant Program

The Title V State Maternal and Child Health (MCH) Block Grant Program awards formula grants to 59 states and jurisdictions to address the health needs of mothers, infants, and children, as well as children with special health care needs. Fifteen National Performance Measures (NPMs), including one on safe sleep, were established for the Title V MCH Services Block Grant Program. Based on their identified priority needs, states select eight of the 15 NPMs for programmatic focus. For each of these selected NPMs, states implement evidence-based or –informed strategies and develop at least one related Evidence-based or –informed Strategy Measure to assess and demonstrate the impact of its strategies on the NPM.

As of 2017, 33 states have chosen to focus efforts on improving safe sleep. Strategies for improving safe sleep practice have focused on promoting review of SUID deaths, safe sleep hospital certification, adoption of safe sleep toolkits, training professionals on model safe sleep environments, and assuring hospitals have safe sleep policies in place.

Maternal, Infant, and Early Childhood Home Visiting Program

The Maternal, Infant, and Early Childhood Home Visiting Program (MIECHV Program) supports voluntary, evidence-based home visiting services for at-risk pregnant women and parents with young children up to kindergarten entry. Home visitors evaluate families’ needs and provide services tailored to those needs, such as education on topics including breastfeeding, safe sleep practices, and injury prevention. State, territory, and tribal MIECHV awardees implement activities to increase the percentage of infants sleeping in safe environments. In Guam, for example, cultural and economic factors favor co-sleeping. Guam developed safe sleep resources for families, trainings and resources for home visitors, and classroom materials on safe sleep for use in high school classes on maternal and child health. State and territory awardees submitted data on the percent of infants enrolled in home visiting who are always placed to sleep on their backs, without bed-sharing or soft bedding in the fall of 2017. The data is being analyzed and is expected to be available in the spring of 2018.

Healthy Start

The Healthy Start program provides 100 competitive grants that reach 127 counties in 37 states and the District of Columbia to reduce disparities in infant mortality and improve perinatal outcomes for women and children in high-risk communities. Healthy Start aims to reduce these disparities by empowering high-risk women and their families to identify and access needed services to improve the health of mothers and children before, during, and after pregnancy. Programs also provide educational support to participants and families through skill building and information sharing. Because SIDS is one of the five leading causes of infant deaths in the U.S., Healthy Start includes a focus on quality safe sleep education. Examples of safe sleep efforts by Healthy Start grantees include:

1. The Healthy Start Rochester program and their parent agency, Healthy Baby Network, are members of the Baby Safe Sleep Coalition (BSSC) in Rochester, NY. Activities include partnering with area hospitals to provide infant safe sleep kits for every baby born in their four city hospitals and hosting an Infant Sleep Training Workshop for staff and community partners.
2. Camden Healthy Start encouraged its participants to use the Safe Sleep Sweep app, a mobile app designed to raise awareness about safe sleep best practices.

**Collaborative Improvement and Innovation Network to Reduce Infant Mortality**

The Collaborative Improvement and Innovation Network to Reduce Infant Mortality (IM CoIIN) is a national initiative to accelerate reductions in infant mortality and improve birth outcomes within 18-24 months. It accomplishes these objectives by providing a platform for multi-disciplinary and multi-sector teams from all states and jurisdictions to engage in collaborative learning, apply quality improvement methods, and spread policy and program innovation.

A Safe Sleep Learning Network developed out of the IM CoIIN, focusing on reducing infant sleep-related deaths by improving safe sleep practices. Forty states participated in this Learning Network and received technical assistance from the CoIIN, including: monthly calls that include expert coaching, written monthly assessments from improvement advisors, and ad-hoc emails and calls. Several states worked with pilot sites to test and implement innovative preventative strategies. Examples include:

- **Massachusetts** worked to improve safe sleep practices in Neonatal Intensive Care Units (NICUs) across the state. Through the development of an algorithm that identifies medically stable infants ready for safe sleep and crib card reminders, and by modelling safe sleep for parents, hospitals were able to increase:
  - the percentage of infants in the NICU placed on their back by 6 percent, from 90 percent to 96 percent; and
  - the percentage of infants in the NICU in a safe crib environment (e.g. free of dolls, blankets) by 13 percent, from 75 percent to 85 percent.

- **New York** worked with 81 of its 124 birthing hospitals to provide and document safe sleep education, as well as model safe sleep practices. New York also worked with community-based organizations to provide follow-up care for babies after leaving the hospital. Through this work, New York was able to increase:
  - the percentage of infants in hospitals without medical contraindication who are sleeping on their backs and in a crib or bassinet without extra bedding from 79 percent to 91 percent, an improvement of 15 percent; and
  - the percentage of safe sleep recommendations that families report being provided by 6 percent, from 79 percent to 84 percent.

Over the course of the IM CoIIN, states and jurisdictions implemented numerous programs, products and policies to help sustain safe sleep-related improvements. Examples from selected states and jurisdictions include:

- **Policy and Payment Changes:**
  1. Illinois enacted several policy changes including: requiring birthing hospitals to provide written and verbal infant safe sleep education prior to discharge of newborn; requiring licensed childcare providers to have safe sleep/SIDS risk

1 All percentage changes are calculated using the formula \((Y2-Y1)/Y1\)
reduction education every three years in order to obtain and maintain licensure; and passing an ordinance that bans the sale and purchase of crib bumpers within Chicago’s city limits.

2. Mississippi Child Care Licensure updated regulations to reflect best practices to promote safe sleep.

3. Georgia published an interagency Memorandum of Understanding in order to provide bassinets and gowns to Medicaid mothers with newborn infants to reduce SUID mortality.

- Educational and Training Resources:
  1. Tennessee developed an educational e-module on safe sleep and breastfeeding for WIC participants, and evaluates whether the training changes parents’ intent to practice safe sleep.
  2. California developed and implemented a safe sleep intervention protocol within the Black Infant Health Program to addresses the disparity in white and black SUID rates.
  3. Iowa developed a Child Care Train-the-Trainer module to educate childcare providers on safe sleep practices.

- Tools and Processes:
  1. Maine developed and tested a safe sleep assessment checklist that Department of Health and Human Services’ caseworkers can use with families of drug-affected babies.
  2. Nebraska developed a Safe Sleep Environment Checklist for use with families in the Nebraska-Maternal, Infant, and Early Childhood Home Visiting Program.

National Center for Fatality Review and Prevention

HRSA supports the National Center for Fatality Review and Prevention (the Center), which is currently housed at the Michigan Public Health Institute, to train and provide technical support to approximately 1,350 Child Death Review (CDR) and 179 Fetal Infant Mortality Review (FIMR) programs across the country, some of which are supported by Healthy Start programs. The Center also supports a web-based Case Reporting System (CRS) that collects data from 45 states, including those participating in the CDC SUID registry.

CDR and FIMR generate valuable information regarding fetal, infant, and child deaths while also providing insight into the gaps in services, systems, and modifiable risk factors that are otherwise not available from administrative surveillance systems. The Center also provides technical support and resources for CDR teams reviewing SUID deaths. Information from these reviews can be used at the local, state, and federal levels for planning and policy development, quality improvement and health systems development, and enhancing efforts to develop and maintain risk reduction and prevention programs for healthy pregnancies, infants, children, and adolescents.

For 12 years, CRS has been collecting data on infant deaths, including those that pre-date the SUID registry. As of September 2017, information on 104,590 infant deaths has been entered into CRS, one-third (31,343) of whom died of SUID, including SIDS. In 2018, a module will
capture information from multiple FIMR programs to promote standardized data collection for these programs.

National Action Partnership to Promote Safe Sleep
HRSA supports the National Action Partnership to Promote Safe Sleep (NAPPSS) Program, which was designed to convene multi-disciplinary stakeholders including safe sleep experts, breastfeeding advocates, organizations that serve families, and advocacy groups that represent groups at higher-risk for SUID. In 2015, the NAPPSS Coalition of over 60 organizations developed a National Action Plan to Increase Safe Infant Sleep, which is a foundational framework that informs national, state, and local infant mortality reduction efforts as well as guides policy and practice changes among systems that serve families. In 2017, the NAPPSS Coalition released training materials for health care and social service providers entitled “Taking a “Conversations Approach” to Safe Infant Sleep and Breastfeeding.” This resource increases provider knowledge and capacity for supporting a family’s decision-making process in considering the adoption of safe infant sleep and breastfeeding behaviors.

In 2017, the NAPPSS cooperative agreement program entered a new phase, whose goal is to work with national, state, and local partners to make safe infant sleep and breastfeeding the national norm. The program will continue the work of the Coalition and the National Action Plan. Additionally, beginning in 2018, the program will translate evidence-based practices for safe infant sleep and breastfeeding into safety “bundles.” A “bundle” is a structured way of improving the processes of care and patient outcomes: a small, straightforward set of evidence-based practices that when performed collectively and reliably, have been shown to improve patient outcomes. The program will develop and test the effectiveness of safety “bundles,” designed to improve the likelihood that infant caregivers and families adopt safe infant sleep behaviors.

NATIONAL INSTITUTES OF HEALTH ACTIVITIES

NIH’s mission is to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability. With regard to stillbirth, sudden unexpected infant death syndrome (SIDS) and sudden unexplained death in childhood (SUDC), NIH supports basic, clinical and translational research into the causes and prevention of these tragic losses. (The term sudden unexplained infant death or SUID is also increasingly used to refer to SIDS-like infant deaths that cannot be definitively diagnosed as SIDS.) Sudden Death in the Young (SDY) is a tragic event with longstanding impact on families and communities. Fundamental gaps in knowledge about incidence, mechanisms, and risk factors for SDY limit the identification of effective prevention efforts. Estimates of the incidence of sudden cardiac death (SCD) in the young vary depending upon the age group (infants, children, adolescents) (http://pediatrics.aappublications.org/content/139/3/e20162757), and many studies are limited by small sample sizes in homogeneous populations. While many SCDs are caused by a potentially

Sudden unexpected death in epilepsy (SUDEP) is the sudden, unexpected death of an individual with epilepsy, without a structural or toxicological cause of death found at autopsy. The rate of SUDEP is as much as 24 times higher than the rate of sudden death in the general population (https://www.ncbi.nlm.nih.gov/pubmed/9818844), and this risk is particularly high in those individuals whose seizures are not well controlled.

NIH activities also seek to inform and educate the public, health care providers and other stakeholders about scientifically supported approaches to reducing risks of stillbirth, SIDS and SUDC.

NIH Current research projects and resources
NIH-supported research focuses on the incidence and prevalence of pregnancy loss (stillbirth, after 20 weeks, and miscarriage, before 20 weeks) and SIDS/SUID among different populations, the causes of these losses, and how to reduce or prevent their occurrence. Such research includes demography and epidemiology, investigations of genetic and molecular anomalies and pathways and possible environmental influences as well as animal model and clinical studies. Among research priorities on pregnancy loss and determinants of normal pregnancies are developing specific predictive algorithms that include physiological, biochemical, and genetic markers for women at risk of pregnancy loss and those whose infants may be at risk. Also prioritized are discovery of physiological and molecular mechanisms involved in normal and abnormal placentation and other early factors in establishing a healthy pregnancy. Research encompasses design and evaluation of effective communications and other initiatives to increase understanding and use of science-based risk-reduction practices. Examples of current research projects and resources include the following:

PregSource™

PregSource™ is an innovative project using crowdsourcing to collect a wide range of data from pregnant women, which is expected to significantly expand understanding of the determinants and course of healthy pregnancies. Such baseline information, not currently well developed, is essential to understanding how a pregnancy can go off track, including the occurrence of pregnancy loss. https://clinicaltrials.gov/ct2/show/NCT02577536

Placenta-derived Extracellular Circulating RNA as a Tool for Monitoring Placental Function
This project leverages new technologies that are expected to enable researchers to conduct non-invasive monitoring of the placental transcriptome – the sum of all the “messenger” RNA molecules that play various roles in the expression of genes. This monitoring capacity is expected to enable ongoing placental monitoring in real time to gain insights into the origins of pregnancy-related disorders and early warning signs of such disorders. Abnormalities in placental structure and function underlie complications associated with pregnancy, including miscarriage and stillbirth as well as other disorders. https://projectreporter.nih.gov/project_info_description.cfm?aid=9145747&icde=35458344&ddparam=&ddvalue=&ddsub=&cr=1&csb=default&cs=ASC&pball=
**Yoga Online: Interconception Care to Prevent PTSD Symptoms after Stillbirth**

Yoga Online will build on established scientific evidence of the safety, efficacy and cost-effectiveness of improving mental health in a variety of populations, including pregnant and postpartum women. In this project, researchers will test and adapt a 12-week, home-based, online-streamed yoga intervention for bereaved mothers who have experienced stillbirth, with a goal of improving post-traumatic stress symptoms.


**Community Based Participatory Research (CBPR) Initiative in Reducing Infant Mortality in American Indian Communities**

This project will build on existing relationships with American Indian communities, which were established in activities to reduce infant mortality, to collect information on parental knowledge, cultural beliefs and to access resources about infant sleep environments, for use in developing and testing a group intervention program that accounts for inherent cultural beliefs in American Indian communities.

https://projectreporter.nih.gov/project_info_description.cfm?projectnumber=5R01HD080544-03

**Enhancing Safe Sleep Practices of Urban Low-Income Mothers**

This project is evaluating aspects of SIDS/SUID efforts, including the effects of such safe sleep-related preventive efforts as physician counseling, enhanced health education and distribution of cribs, and the safe sleep messages and services of the Baltimore, Maryland, “B’more for Healthy Babies” campaign.

https://projectreporter.nih.gov/project_info_description.cfm?projectnumber=4R01HD072821-04

**Cardiac Channel Mutations in SIDS**

This project will perform the first whole-genome analysis and apply other techniques to one of the world’s largest multi-ethnic group of post mortem collection of samples from 625 SIDS cases. The goal is to discover fundamental bases for the infant vulnerability that underlies SIDS, focusing on genes that regulate the heart’s electrical system, the central and autonomic nervous system, the immune system, metabolism, and other systems that seem to be implicated in SIDS.


**The Ventral Medulla and SIDS**

This project is a collaboration among three medical institutions across the country and the medical examiners system in San Diego, California, to use state-of-the-art methodologies with animal SIDS models and human tissue to understand underlying genetic factors and functional anomalies that may explain failures of critical brain processes to respond protectively to life-threatening stressors during sleep, at important developmental periods.

https://projectreporter.nih.gov/project_info_description.cfm?projectnumber=5P01HD036379-19

**Channelopathies and Cardiomyopathies among Sudden Deaths in the Young**

Research underway focuses on the potential of inherited risk factors for fatal cardiac conditions that may explain a large proportion of sudden unexplained deaths in the young. Researchers are determining the prevalence and the spectrum of genetic mutations deaths, other than those associated with epilepsy, that are included in the Sudden Death in the Young Case Registry
(SDY) and that have a high likelihood of association with cardiac problems. The researchers will also identify new SDY cases through their existing collaboration with Medical Examiner’s Offices in Chicago and surrounding counties in Illinois.
https://projectreporter.nih.gov/project_info_description.cfm?aid=9242061&icde=35441383

The SDY Registry, supported by the CDC and NIH, aims to increase understanding of the prevalence, causes, and risk factors for infants, children, and young adults who die suddenly and unexpectedly. [https://www.cdc.gov/sids/pdf/SDY-Fact-Sheet.pdf](https://www.cdc.gov/sids/pdf/SDY-Fact-Sheet.pdf) NIH’s National Heart, Lung, and Blood Institute (NHLBI), its National Institute for Neurological Disorders and Stroke (NINDS) and the CDC partnered to create a registry of SDY in individuals up to age 19 years in 10 states. The goals of the SDY Case Registry are to describe the incidence of SDY in a large population in the US using population-based surveillance, compile the data to create a resource of information and DNA samples for research, encourage standardized approaches to investigation, autopsy, and categorization of SDY cases, and develop partnerships between local, state, and federal stakeholders towards a common goal of understanding and preventing SDY. The SDY Case Registry benefits from the strengths of each collaborating agency: the CDC’s expertise in public health surveillance and the NIH’s expertise in research. The Registry is the largest known cohort to date of children who have died suddenly in the US. Data can be used to determine the incidence of sudden cardiac death in the young, as well as SUDEP, SUID, and other causes of pediatric sudden death. In addition to funding technical assistance to grantees and the data coordinating center and biorepository for the Registry, NHLBI has awarded 3 grants to investigators to use the data and DNA samples from the Registry to perform whole genome sequencing on the biospecimens from the SDY and explore the causes of sudden cardiac death in the young that may ultimately lead to successful prevention strategies. Data from the SUDEP cases will be shared with the investigators in the Center for SUDEP Research.

The rate of SUDEP is as much as 24 times higher than the rate of sudden death in the general population (https://www.ncbi.nlm.nih.gov/pubmed/9818844, and this risk is particularly high in those individuals whose seizures are not well controlled. NINDS funds the Center for SUDEP Research, a milestone-driven collaboration composed of researchers from 14 institutions across the U.S. and Europe to bring together expertise to understand SUDEP. The Center is part of the NINDS Centers Without Walls for Collaborative Research in the Epilepsies, which are multicenter, multidisciplinary consortia to solve research challenges in the epilepsies. Research at the Center for SUDEP Research is focused on understanding the mechanisms underlying autonomic, cardiac, and respiratory dysfunction that contributes to SUDEP. The Center is also working to identify biomarkers to predict those at risk of SUDEP and hone in on therapeutic targets.

**NIH Ongoing Networks**

**Maternal-Fetal Medicine Units (MFMU) Network**

Major aims of the Eunice Kennedy Shriver National Institute of Child Health and Human Development’s (NICHD’s) MFMU Network are to reduce rates of preterm birth (a significant risk factor for SIDS), maternal complications of pregnancy, fetal growth abnormalities and other maternal and fetal conditions, some of which may be implicated in stillbirth. The network focuses on clinical trials with a goal of reducing maternal complications of pregnancy as well as fetal and infant mortality and morbidity. Included in Network aims are evaluation of maternal
and fetal interventions for efficacy, safety and cost-effectiveness, and evaluation of new technologies in the promotion of maternal-child health and prevention of disease. The MFMU Network trial, “A Randomized Trial of Induction Versus Expectant Management (ARRIVE)” is studying whether elective induction of labor at 39 weeks for women in their first pregnancy decreases the rate of stillbirth, neonatal death, or severe neonatal morbidity, versus expectant management. Recruitment of 6,000 women into the trial was completed in 2017 and results will be available soon. The trial is described at: [https://www.clinicaltrials.gov/ct2/show/NCT01990612?term=A+Randomized+Trial+of+Induction+Versus+Expectant+Management+%28ARRIVE%29&rank=1](https://www.clinicaltrials.gov/ct2/show/NCT01990612?term=A+Randomized+Trial+of+Induction+Versus+Expectant+Management+%28ARRIVE%29&rank=1) Another ongoing MFMU Network trial studies the most common congenital viral infection in pregnancy, cytomegalovirus (CMV), to determine if women with primary CMV infection treated with CMV hyperimmune globulin have reduced rates of stillbirth or neonatal congenital CMV infection. This trial is described at: [https://www.clinicaltrials.gov/ct2/show/NCT01376778?term=Cytogam&rank=3](https://www.clinicaltrials.gov/ct2/show/NCT01376778?term=Cytogam&rank=3) NHLBI and NINDS also provide some support for projects within the network, which consists of 14 university-based clinical centers throughout the U.S. and a data-coordinating center. [https://mfmu.bsc.gwu.edu/](https://mfmu.bsc.gwu.edu/)

Global Network for Women’s and Children’s Health Research
The NICHD’s Global Network for Women’s and Children’s Health Research is dedicated to improving maternal and child health outcomes and building health research capacity in resource-poor settings, by testing cost-effective, sustainable interventions that provide guidance for the practice of evidence-based medicine. The Network’s Maternal Newborn Health (MNH) Registry is a prospective, population-based study of pregnancies and their outcomes in low-middle income countries (DRC, Guatemala, India, Pakistan, Zambia and Kenya). All pregnant women in participating clusters (approximately 600,000 annually) are registered and their outcomes tracked for six weeks post-delivery. The goal is to provide population-based statistics on stillbirths, neonatal (including SIDS) and maternal mortality as a basis of health care policy. The Network’s Helping Babies Breathe (HBB) study is a further development of the Network’s FIRST BREATH trial, which provided skilled birth attendants with knowledge and skills to enhance the survival of newborn infants. A network controlled clinical trial is will test whether low dose aspirin early in a pregnancy reduces the risk of preterm birth and its risks for infants. [https://globalnetwork.azurewebsites.net/](https://globalnetwork.azurewebsites.net/)

NIH Scientific Advances
Morning Sickness Linked to Lower Risk of Pregnancy Loss
Leveraging data from a large study of daily low-dose aspirin to prevent pregnancy loss in at-risk women, researchers found the strongest evidence to date that morning sickness is associated with lower risk of pregnancy loss. The cause of such nausea and vomiting early in the day, in the early months of pregnancy, is not known but researchers have proposed that it protects the fetus against toxins and disease-causing organisms in foods and beverages. Morning sickness was common among the pregnant women taking the low-dose aspirin and those reporting nausea or nausea and vomiting were 50 to 75 percent less likely to experience pregnancy loss, compared with women in the “control” arm of the study. [https://www.ncbi.nlm.nih.gov/pubmed/?term=27669539](https://www.ncbi.nlm.nih.gov/pubmed/?term=27669539)

Trying to conceive soon after a pregnancy loss may increase chances of a live birth
Many clinicians advise couples to wait at least three months after a pregnancy loss before attempting a new pregnancy. New research findings, from an NIH-supported study of more than 1,000 cases of miscarriage, found that couples who attempted to start another pregnancy within three months after a miscarriage had the same chances, if not greater, of achieving a live birth, compared with couples who waited three months or longer. While couples may need time to recover emotionally from a pregnancy loss, conventional recommendations to wait at least three months may not be warranted for couples who are ready to try again sooner. https://www.ncbi.nlm.nih.gov/pubmed/?term=26942344

**Diagnostic tests for evaluation of stillbirth**
Researchers in a multi-site, geographically, racially and ethnically diverse, population-based study of stillbirth recently reported that among the exhaustive array of tests and evaluations they used to analyze 972 stillbirths, the most informative were fetal autopsies and examination of placentas for abnormalities. Overall, these two procedures were helpful in either confirming or excluding a potential cause of stillbirth in 64.6 percent and 42.4 percent of cases, respectively. Also useful in a meaningful proportion (over 10 percent) of stillbirths were genetic testing and testing for antiphospholipid antibodies. The antibodies are a type of protein that usually defends the body against infection but in antiphospholipid antibody syndrome, an autoimmune disease, the antibodies attack and damage tissues and cells and can cause stillbirth and other pregnancy complications. Certain other tests can be informative, depending on the clinical presentation of an individual patient and available resources. Better understanding of possible causes of stillbirths can help parents and clinicians counseling them to consider possible future pregnancies and choosing the most informative tests, and is critical to advancing research that could lessen the occurrence of these losses. https://www.ncbi.nlm.nih.gov/pubmed/?term=28333795

**Exposure to fine particulate matter and stillbirth**
NIH-supported research used a geo-spatial population-based cohort study in Ohio to examine the effect of exposure to fine particulate matter air pollution and stillbirth, and found that exposure to high levels of such pollution in the third trimester of pregnancy was associated with increased stillbirth risk. https://www.ncbi.nlm.nih.gov/pubmed/25794052

**Advising moms not to share a bed with their infants does not discourage breastfeeding**
Among science-based recommendations to reduce SIDS/SUID risk are exclusive breastfeeding, for the first six months of life, and infant/parent room sharing, but without bed sharing. There have been concerns that discouraging bed sharing could also discourage breastfeeding, but a recent survey of more than 3,000 mothers has allayed those concerns. More than two thirds (66 percent) of women responding to questions about their infants’ sleep locations and breastfeeding reported room sharing without bed sharing. Exclusive breastfeeding was reported by a third of the women and of these respondents, more than half shared a room but not a bed. https://www.ncbi.nlm.nih.gov/pubmed/?term=26851615

**Identifying potential biomarkers for SIDS**
Finding distinctive chemical “biomarkers” that differentiate individuals at risk of SIDS/SUID from others is central to advancing research on what causes these tragic deaths, with a goal of ultimately developing effective preventing strategies. One group of researchers, using systematic investigation of all metabolites – key chemicals for certain processes within a
physiological system – recently identified several biomarkers that could possibly be used to predict SIDS. The researchers focused on the brainstem, the area of the brain responsible for breathing and other autonomic functions. They made their discovery by finding significant metabolite differences between post-mortem tissue samples from SIDS cases and other “control” cases matched for gender and age. https://www.ncbi.nlm.nih.gov/pubmed/?term=27608295

*Children’s Book Versus Brochures for Safe Sleep Knowledge and Adherence in a High-Risk Population*

Sleep-related infant deaths have plateaued in the past decade, disproportionately affecting low socioeconomic status (SES) families. Printed materials are widely used for anticipatory guidance, yet none for safe sleep has been studied. With NICHD support, researchers tested the efficacy of a specially designed children's book, compared to brochures for safe sleep knowledge and adherence. They hypothesized that the specially designed book would be more effective, due to superior readability and engagement. A randomized controlled trial among 282 low-SES mothers enrolled in a home visiting program showed that the book and the brochures were equally effective conveying safe sleep knowledge to these mothers, but that adherence to exclusive crib use and avoiding bed sharing – both known to enhance infant safety -- were greater in the book group. The researchers attributed this affect to the book’s enhancements -- dialogue, readability and emotional engagement. Children’s books are a promising mode of anticipatory guidance. https://www.ncbi.nlm.nih.gov/pubmed/?term=28450082

*NIH Dissemination of information about Safe Sleep*

For 20 years, the *Safe to Sleep®* campaign has informed new parents, caregivers and health care providers about safe infant sleep practices. Led by NICHD, with numerous public and private sector collaborators and partners, the campaign provides the most current research-based informational materials and media resources to diverse audiences. The campaign focuses on how to reduce SIDS/SUID risk by placing infants to sleep on their backs, in their own safe sleep environment, and following safe infant sleep recommendations, all supported by strong scientific evidence.

Since safe infant sleeping campaigns begin in 1994, the incidence of SIDS has decreased substantially in the U.S. and elsewhere, but despite this success, SIDS remains a leading contributor to infant mortality. The campaign encompasses active outreach within high-risk populations and targeted outreach programs in states with the highest rates of SIDS. Campaign collaborators and partners include CDC, HRSA’s Maternal and Child Health Bureau, the Federal SUID/SIDS Workgroup (multiple federal agencies that coordinate research and outreach related to reducing SIDS and SUID), the Consumer Product Safety Commission, the American Academy of Pediatrics and the American College of Obstetricians and Gynecologists, the Association of Maternal and Child Health Programs, the Kappa Alpha Psi® Fraternity (partnering with NICHD to teach fathers, grandfathers, uncles, brothers and other community stakeholders about ways to reduce the risk of SIDS and other sleep-related causes of infant death), and many others. https://www.nichd.nih.gov/sts/Pages/default.aspx

**CONCLUSION**
Stillbirth, SUID, and SUDC are important public health issues. Through research, surveillance, programs, and partnerships, HHS works to better understand and prevent deaths from stillbirth, SUID, and SUDC and keep infants and children safe and healthy.