

BABY'S BREATH STRATEGIC PLAN 2014-2019



Introduction

For more than 40 years, Baby's Breath (formerly known as the Canadian Foundation for the Study of Infant Deaths) has been Canada's national Sudden Infant Death Syndrome (SIDS) foundation. To this day, SIDS remains the leading cause of death for infants between one month and one year of age. A few years ago, and following the example of other SIDS foundations in other countries, the foundation has expanded its mandate to include all sudden and unexpected infant deaths (of known or unknown causes), and stillbirths. Every year in Canada, up to 250 apparently healthy infants die suddenly and unexpectedly, and another 2,800 are stillborn.

In recent years, the Canadian SIDS community has faced new challenges caused in great part by the continued emphasis put on so-called modifiable risk factors (particularly environmental risk factors such as sleeping environment). At the same time, and despite recent advances in molecular medicine, there has been very little done to investigate underlying physiological and biological factors/defects that, in vulnerable babies, can lead to infant death. These defects, which are only evident at sub-cellular and molecular levels, are not currently being investigated during autopsies since their investigative methods lie outside of the Coroner's office mandate. Recently, this issue became aggravated further by a decision by coroners across the country to drop the terms SIDS and SUDI (Sudden Unexpected Death in Infancy) and use the term "undetermined" to qualify most sudden infant deaths, whether unexpected or unexplained. As a result, there are no longer reliable statistics on SIDS and other unexpected infant deaths in Canada, making research nearly impossible.

As it is the case with sudden infant deaths, many stillbirths are not easily explained. Placental abnormalities and defects are believed to be a major source of fetal death occurring in the womb. However, there is a lack of standardized reporting by pathologists of the integrity of the placenta.

In the Spring of 2014, the Canadian Foundation for the Study of Infant Deaths transitioned its name to Baby's Breath to reflect its new and enlarged mandate, to mobilize support, and to refocus its advocacy efforts. The foundation has now developed a new action oriented strategic plan that will direct its efforts for the next five years. The plan identifies strategic priorities and actions to be taken by the foundation. The plan focuses on advocating for the cause, attracting new supporters, increasing awareness, and mobilizing the infant death community to act to reverse current Canadian trends.

Vision

To end all sudden unexpected infant deaths and stillbirths.

Mission

To prevent sudden and unexpected infant deaths and stillbirths. We:

- Advocate for and support research
- Disseminate information
- Provide bereavement support to families

Values

- Compassion
- Respect
- Accountability and transparency
- Inclusiveness
- Engagement
- Trust
- Support

Strategic Priority 1

Build awareness of the issues surrounding the current methods of investigating and classifying sudden infant deaths, and the lack of support for scientific research.

Key initiatives

- Advocate for a nation-wide acceptance and understanding that sudden infant deaths are not caused by environmental factors alone, but rather by an underlying medical condition/biological defect not yet understood.
- Mobilize and engage key enablers to recognize that medical and scientific research is needed to understand the cause of sudden infant death and to develop rational treatment and prevention strategies.
- Advocate for more funding to support scientific research, open access to human tissue samples from deceased infants to conduct research, as well as the establishment of a bank of human tissue samples from deceased infants, also to be used for research purposes.
- Identify key national and provincial level committees and ensure that Baby's Breath has representation and influence.
- Advocate for a reform of the protocols and procedures used in the investigation of infant deaths; and promote a multidisciplinary approach that works in collaboration with pediatric pathologists, academic paediatric hospitals and research teams.
- Mobilize support for a reform of the classification system for sudden unexpected infant deaths (at the national level), as a collaborative effort with input from coroners and medical examiners, paediatric pathologists, parents and other key stakeholders.
- Advocate for genetic and molecular testing to be an integral part of all investigations of sudden and unexpected infant deaths using molecular autopsies performed in collaboration with pediatric forensic pathologists, molecular biologists and clinical geneticists.

Strategic Priority 2

Establish Baby's Breath as the national leader for grief and peer support for families experiencing the sudden and unexpected death of an infant or a stillbirth.

Key initiatives

- Establish and maintain relationships with key partners who are in close contact with grieving families after the loss of an infant (such as hospital staff, funeral homes, coroners and medical examiners, police, first responders, victim services).
- Review and develop electronic and print resources (kit) that can be distributed to newly bereaved families (shortly after their loss) by hospitals (neonatologists, paediatricians, paediatric pathologists, NICU nurses), funeral homes, coroners and medical examiners, crisis/victim services, police and first responders.
- Review and adapt the content on Baby's Breath website to reflect its expanded mandate, and to include more resources to support grieving families.
- Review and adapt the peer support training manual for volunteers; and develop and online training module for volunteers.
- Recruit and train new volunteers for our peer support program.
- Promote our peer support program through our key partners (printed kit), our website (electronic kit) and social media.
- Review our current use of social media and adopt a model of open discussion and sharing between grieving families.
- Advocate for open access to public records on infant deaths so that affected families can receive timely and appropriate support.

Strategic Priority 3

Ensure the foundation's financial stability and sustainability, and establish Baby's Breath as a credible and trusted organization.

Key initiatives

- Design and launch a national marketing campaign to:
 - inform the infant death community, stakeholders, partners, members and other agencies of the foundation's new name, visual identity, branding and strategic direction,
 - promote and raise awareness of Baby's Breath,
 - attract new donors.
- Establish Baby's Breath as a national leader and a key enabler with provincial and national policy makers.
- Bring recognition that sudden unexpected infant deaths and stillbirths are a worthy cause that deserves the attention and the financial support of governmental bodies, individuals and corporations.
- Develop and launch a downloadable toolkit for fundraising events, while supporting and encouraging fundraising efforts by individuals and private businesses.
- Build strategic partnerships with donors and sponsors willing to support our cause.
- Re-establish research grants and studentship award programs to support research into the causes and mechanisms of sudden unexpected infant deaths and stillbirths.

Looking Ahead

The transition to the new name Baby's Breath came out of the need to reposition the foundation at the national level as a key influencer for policy making, research and advocacy in the field of sudden unexpected infant deaths and stillbirths.

Canadian policy makers and governments need to shift their attitudes and support efforts for true medical advances to reduce all sudden unexpected infant deaths and stillbirths.

This strategic plan sets the foundation's advocacy, awareness and mobilization efforts over the next five years. We are confident that with the support of the infant death community, we can reposition ourselves and work actively to bring significant changes that will help reduce the number of infant deaths.

Putting Strategic Priority 1 into Context

For the first time in 2012, not a single case of SIDS was recorded in Ontario. This diagnostic shift was the result of the adoption by the Office of the Chief Coroner for Ontario (OCCO) of a new infant death classification approach.

Under this new classification system, most cases of SIDS are now classified as undetermined, implying a possibility that some untoward factors or circumstances are involved in the death of these infants. Under the new system, a diagnosis of SIDS is automatically excluded as soon as some known risks factors for SIDS are present, making it literally impossible for any infant death to be classified as SIDS. The exclusion criteria for SIDS are confused with recognized risk factors which may be contributory, but are not the cause of death.

Under the Ontario classification system of infant deaths:

- Unsafe sleeping environment is interpreted as an actual cause of death, rather than a risk factor in a vulnerable infant with an underlying disease or biological defect that may make them susceptible to infant death. Data shows that in normal infants, these risk factors are innocuous, as normal infants recover by auto-resuscitation.
- Social risk factors are identified during investigation. These are highly prejudicial, since there is no evidence of wrong-doing, yet there is presumption of guilt even though no crime has been committed.

Undetermined cases place an indefinite cloud of suspicion over grieving parents, curtail research funding, reduce the ability to conduct research into biological deficiencies and prevent scientific advances that could prevent sudden infant deaths.

In June of 2012, the majority of Canadian Chief Coroners and Chief Medical Examiners followed in the steps of Ontario and agreed to adopt the classification “Undetermined” to describe unexpected infant deaths where no cause is identified following complete autopsy, examination of the death scene, and review of the clinical history. As a result, Canada will no longer have reliable statistics on sudden infant death syndrome.

When there is no data, there is no issue, when there is no issue, there is no research.

Submitted by Dr. Ernest Cutz MD, FRCPC

Senior Staff Pathologist, Paediatric Laboratory Medicine, The Hospital for Sick Children
Senior Associate Scientist Physiology & Experimental Medicine, Research Institute
Professor, Department of Laboratory Medicine & Pathobiology, University of Toronto

Critical Issues at Stake

Current protocols used for the investigation of sudden infant deaths, and the manner in which infant deaths are classified in Canada, are two critical issues that need to be addressed urgently. While these two issues are present in most Canadian provinces, it is particularly true for Ontario.

Protocols for investigating sudden and unexpected infant death

Current protocols used for the investigation and classification of sudden and unexpected infant deaths in most Canadian provinces present numerous issues. They:

- are based on misinformation and misconception,
- Stigmatize the parents,
- Are an obstruction to research and progress,
- Deny accurate answers to grieving families.

The current diagnostic shift that has practically eliminated the use of the term SIDS and replaced it with “undetermined” removes any rallying point for affected families to organize, seek government support and fundraise for research. Under the current protocols, valuable resources are spent in unnecessary examinations and investigations, while the search for medical causes is ignored. It appears that similar protocols have been adopted across Canada and that the term SIDS has been dropped and replaced by the term “undetermined” in most provinces.

Under current protocols in most provinces, every infant death is considered suspicious until proven otherwise, and are based on the outdated and unsubstantiated concept that sudden infant deaths are either concealed homicide or the result of a preventable accidental death such as suffocation (sleeping position, blankets, objects in crib, bed sharing) that could not be proven. Under these protocols, recognized risk factors for SIDS are confused with actual causes of death.

However, we today know that SIDS is a disease recognized by the World Health Organization as a distinct pediatric medical disease entity. Current advances in molecular medicine indicate that an underlying biological abnormality due to genetic or molecular disorders (such as defects in cardiac or neuronal ion channels) may be responsible for a large proportion of sudden infant deaths. These are now detectable by

modern techniques of molecular pathology. However, these tests are often not performed by pathologists and medical examiners doing autopsies on infants in Canada.

Classification of sudden and unexpected infant deaths

The issue of sudden infant classification is closely linked to the protocols of investigation. The classification system reflects the same attitude and approach of treating every infant death as suspicious unless proven otherwise. When a natural cause of death, such as a disease, infection, or birth defect cannot be found, most cases are then classified as undetermined, instead of SIDS, meaning that no manner of death has been excluded (natural, accidental or homicide), that the file remains open indefinitely and that the suspicion of possible wrongdoing persists, even when there are no signs or evidence of abuse or injury.

Current classification and categorization of infant deaths significantly restricts, and sometimes even excludes, the diagnosis of SIDS, a recognized medical condition based on potential biological and genetic defects. It casts unjustified suspicion over the parents' head, it unfairly puts blame and stigmatizes the parents for their infant's death, and it prevents critical research.

An open letter by E. Cutz MD, FRCPC

Senior Staff Pathologist, Paediatric Laboratory Medicine, The Hospital for Sick Children
Senior Associate Scientist, Physiology & Experimental Medicine, Research Institute
Professor, Department of Laboratory Medicine & Pathobiology, University of Toronto

The Demise of SIDS Research: An Appeal for Urgent Action

Over the last decade, Pediatrics and other leading journals dedicated to the dissemination of latest findings in research and practice of pediatric medicine have published series of articles on Sudden Unexpected Infant Death (SUID), including Sudden Infant Death Syndrome (SIDS). These articles reported the findings and recommendations derived from various epidemiological and death scene investigation studies, warning the public of dangers of infant care practices such as bed-sharing and sleeping on surfaces not intended for the infants. While such studies and resulting literature have raised the awareness of the so-called modifiable risk factors that could potentially reduce the incidence of these tragic deaths, there are perhaps unintended negative side effects that need serious reflection and consideration.

The heightened focus and emphasis on the death scene investigation has led to an unfortunate conclusion that many infant deaths previously diagnosed as SIDS could in fact be due to the accidental suffocation of perfectly healthy infants, implying that these deaths are entirely preventable by changing infant care practices. However, the evidence for accidental suffocation hypothesis, as the predominant mode of death in SUID and SIDS, is circumstantial at best, and lacks scientific credibility. Yet it seems to have been accepted without reservation. This has also created an impression that since a simple solution has now been found to prevent SUID and SIDS, there is no need for basic research into the biological underpinnings of SIDS. Such interpretation is misguided. It ignores a considerable body of scientific evidence that suggests that SIDS infants may in fact have an innate defect in critical physiologic control mechanism (i.e. respiratory/cardiac channelopathies) that make them vulnerable to recognized risk factors (i.e. prone sleeping position, maternal smoking, mild URI). This is supported by the triple risk model, where the risk factors may be contributory, but are not considered the actual cause of death. This alarming trend is a basis for my concern regarding the demise of research into the pathobiology of SIDS.

The recent policy statement of the Task Force on Sudden Infant Death Syndrome of the American Academy of Pediatrics makes up to 18 recommendations for safe infant sleeping and child rearing practices. It is regrettable however, that while the article also reviews the current scientific literature on potential biological defects underlying SIDS, it fails to acknowledge the importance of this work, or to make recommendations to support further research and the inclusion of genetic molecular testing as a part of the investigation into SUID and SIDS. This is surprising given recent estimates suggesting that between one third to half of SUID and SIDS deaths could be based on demonstrable genetic mutations affecting genes involved in neurotransmission, energy metabolism, autonomic response, response to infection, and duration of cardiac action

potential. It should be pointed out that in most of these disorders, there are no overt anatomical findings, and hence a negative autopsy (as is the case for SIDS) since the defects involve submicroscopic, cellular and molecular mechanisms.

Furthermore, this approach has led to a diagnostic shift because of the confusion between recognized risk factors for SIDS and the actual cause of death. As a consequence, a majority of SUID cases in many jurisdictions are now categorized as “possible suffocation” or undetermined. An extreme example of such a diagnostic shift has occurred in Ontario in 2012, with no cases of SIDS for the first time in recorded history. This outcome does not seem to be unique to Ontario since similar statistics were reported by Wayne County (Michigan) Medical Examiner’s Office that recorded a 94.7% decrease in the diagnosis of SIDS between the year 2000 and 2004. Similarly, the OCME for New York City reported that between 1996 and 2006, there was 84% decline in the incidence of SIDS, with a 93% increase in injury-related deaths.

There is a number of reasons for these discrepancies, the major one being confusion between what is and what is not SIDS. SIDS is considered a medical pediatric disorder or disease, recognized by the World Health Organization. SIDS is not due accidental or intentional suffocation, or concealed homicide, theories favored by some forensic authorities.

SIDS was first defined in 1969 as the sudden death of any infant or young child which is unexpected by history, and in which a thorough post-mortem examination fails to demonstrate an adequate cause of death. This definition was revised in 1989, when the National Institute of Child Health and Human Development convened an expert panel to address the issue of variability and reproducibility of SIDS research findings. The revised SIDS definition limited the age to under one year and included additional investigations such as the review of the clinical history, to rule out a pre-existing medical disease, and the death scene investigation, to rule out accidental (mechanical) asphyxia and unnatural death. The main goal was to provide clear guidelines for the diagnosis of SIDS and to avoid “contamination” of SIDS study cases.

The next significant development occurred during the early 1990-ties when prone sleeping position was recognized as a significant risk factor for SIDS. Further re-examination of the SIDS definition was prompted by these new developments, including a realization that SIDS is not a uniform entity but rather a heterogeneous multifactorial disorder with variable triggering and potentiating factors. An international panel of experts from Europe, North America and Australasia was convened in 2004 in San Diego, California, consisting of pediatric pathologists, forensic pathologists and pediatricians, all of whom had extensive experience with sudden infant death. The proposed new classification confirmed the validity of 1989 SIDS definition, but added sub categories based on clinical and autopsy findings, as well as the death scene investigation and circumstances of death. This updated classification was designed to facilitate research into SIDS, now subdivided into well defined subgroups. This classification schema was well received and approved by several national pediatric and forensic organizations, but regrettably, is used only in some jurisdictions.

Moving forward and to reverse this clearly unacceptable situation, a more balanced approach is required:

1. The recommendations for safe sleep should be widely disseminated and implemented as proposed. These measures are relatively simple and low cost and may potentially reduce numbers of SUID and SIDS.
2. The search for an underlying biological defect (vulnerability) in SIDS should be intensified given the great advances in molecular biology and molecular medicine. Consequently, genetic (molecular) analysis should be an integral part of the investigation of all cases of SUID and SIDS. This can be best achieved by the performance of a molecular autopsy as a collaborative effort between pediatric pathologists, forensic pathologists, molecular biologists and clinical geneticists.

The sudden death of an infant has devastating effects on the parents and the family; especially if the cause of death remains unascertained. The availability of a robust diagnostic test should alleviate the uncertainty and remove the indefinite cloud of guilt and suspicion, which at the present, affects these families. It is hoped that the combination of rational preventive measures, and further research to enhance better understanding of the biological causes of SIDS, will result in the significant reduction and eventual elimination of these tragic deaths.

Submitted by Dr. Joel G. Ray

Scientist in the Keenan Research Centre of the Li Ka Shing Knowledge Institute of St. Michael's Hospital
Assistant Professor, Department of Medicine, University of Toronto
Associate Professor, Department of Obstetrics and Gynecology, St. Michael's Hospital
Associate Professor, Division of Endocrinology and Metabolism, St. Michael's Hospital
Associate Professor, Department of Health Policy, Management and Evaluation, University of Toronto

Fetal Stillbirths

Fetal stillbirth has recently gained recognition as a major contributor to parental distress, anxiety and depression. The rate of stillbirth among industrialized nations is about 6 per 1,000 total births, of which half occur after 27 weeks gestation. In poorer countries, the stillbirth rate is up to five times higher.

Stillbirth is commonly defined as a fetal death arising ≥ 23 weeks gestation, and at a weight of 500 g or more. One major risk factor for stillbirth is fetal intrauterine growth restriction (IUGR), wherein the fetus is small for gestational age because of some pathological abnormality.

Maternal, pregnancy surveillance and peripartum interventions are currently being considered for the prevention of stillbirths in both low-income and industrialized countries. Within new-industrialized and industrialized nations, it is believed that a substantial proportion of stillbirths arise from placental pathology. Maternal obesity, diabetes mellitus and hypertension introduce a higher risk of placental vascular disease, at both the lowest and highest percentiles of fetal growth. Future stillbirth reduction initiatives, especially those aimed at reducing placental disease, may wish to also focus on the prevention and management of severe small for gestational age birthweight/IUGR. One such initiative is the use of low-dose aspirin in women at risk, starting at 12-16 weeks and continuing to delivery.