

Bringing Hope to Newborn Babies and Their Families

Neonatal Drug Development Fund (NDDF)

Fund Mission Statement

The purpose of the *Neonatal Drug Development Fund* is to support clinical trial and research expenses related to the clinical development of CC10 and other novel drugs to treat and prevent life-threatening and life-altering conditions unique to premature and newborn infants. The *Neonatal Drug Development Fund* (NDDF) was established at the Floating Hospital for Children at Tufts Medical Center in Boston, MA and created through the generosity of Clarassance, Inc.



Challenges for at risk babies, their families, and society

Premature infants: Each year over 500,000 babies are born premature in the United States. Of those, about 60,000 experience respiratory distress syndrome (RDS) because their lungs are not ready to support breathing. This is an immediate and life-threatening challenge. These infants require extra oxygen, mechanical ventilation, and artificial lung surfactant to survive. An estimated 10,000 infants with RDS develop neonatal bronchopulmonary dysplasia (BPD), which is a chronic lung disease. In its most severe form, BPD results in scarring, which can lead to death or need for a lung transplant as the child matures. Currently, there is no way to prevent BPD. The cost to the American healthcare system of caring for infants with neonatal BPD in their first year of life was \$26 billion in 2006.

Newborn infants: Approximately 25,000 newborn infants are diagnosed with meconium aspiration syndrome in the US each year. MAS occurs when the infant has a bowel movement while still in the womb. The fecal material, called meconium, mixes with the amniotic fluid, and enters the lungs of the infant prior to birth and causing a very strong inflammatory response in the lungs. Consequently, the baby can experience RDS at birth, which is treated similarly to the RDS in premature infants, with extra oxygen and mechanical ventilation. These infants often go on to develop chronic lung disease similar to infants with BPD, ranging in severity from mild asthma to severe, progressive pulmonary fibrosis that can be life-threatening and leaves the child more susceptible to infections.

Infant respiratory distress syndrome: Approximately 125,000 infants under 12 months of age are admitted to US hospitals each year for severe respiratory symptoms that lead to RDS. These infants develop RDS as a result of an infection with influenza, respiratory syncytial virus (RSV), or other respiratory viruses, including viruses that cause “the common cold”. Infants who are born premature, or who have been diagnosed with BPD or MAS, are very susceptible to these infections and experience significantly more severe infections than other infants. RDS in these older infants is also treated with extra oxygen and mechanical ventilation. Despite the use of specific anti-viral drugs, these infants spend several days to a few weeks in the pediatric intensive care unit recovering from these infections.

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Unmet Medical and Philanthropic Needs

There are no therapies that safely and effectively treat or prevent BPD, MAS, or RDS in these critically ill infants, so the NDDF aims to address these unmet medical needs. A few non-profit organizations only track the statistics and sponsor a small amount of basic research, while government-sponsored clinical trials have not produced useful therapies to treat and prevent these conditions. Therefore, Tufts and Clarassance have partnered to create the NDDF for the express purpose of advancing the clinical development of innovative therapies aimed these underserved patients.



The first drug to be supported by the NDDF is the CC10 protein (shown at left). In its first clinical trial, CC10 showed potent anti-inflammatory activity in the lungs of preterm infants and a significant long term benefit in preventing respiratory hospitalizations for at least six months. CC10 has recently been recognized by the National Institute of Child Health and Human Development as one of the most promising drugs on the horizon for treating RDS and preventing BPD.

Dr. Jonathan Davis

Dr. Jonathan Davis is the Chief of Newborn Medicine at the Floating Hospital for Children at Tufts Medical Center and Professor of Pediatrics at Tufts University School of Medicine. He is a neonatologist and a pioneer in the development of new drugs and therapies to treat conditions of premature and newborn infants. He has worked tirelessly for the past 30 years to improve the lives of his patients and their families. Dr. Davis is an highly experienced clinical investigator, having planned, led, directed, and managed several clinical trials in at-risk infants, coordinating multiple clinical centers across the country over the past 18 years, including the first clinical trial with CC10 in preterm infants. The NDDF was created to support Dr. Davis' clinical research work.

About the Floating Hospital for Children at Tufts Medical Center

- With 41 beds, Floating Hospital's neonatal intensive care unit (NICU) is the second largest NICU in Boston, treating approximately 650 infants annually.
- Tufts' 21 highly specialized neonatologists cover the nurseries at six other local hospitals and is a major regional referral center for high risk cases.
- Tufts NICU is a national leader in clinical research and the only NICU in Massachusetts selected to participate in the Neonatal Research Network of the National Institutes of Health (NIH), which sets the standard for new therapies for the care of critically ill newborns in NICUs throughout the United States.
- University HealthSystem Consortium's 2010 Quality and Accountability Study has designated Tufts Medical Center as #6 in the country and the only medical center in New England in the top 10 in the quality of patient care and patient satisfaction data.
- Tufts Medical Center has a robust research enterprise and ranks among the top 10% of NIH-funded research institutions. Our specialty research institutes include: Molecular Cardiology Research Institute, Molecular Oncology Research Institute, Institute for Clinical and Translational Science Institute and the newly formed Mother Infant Research Institute.

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Information on neonatal lung disease

For more information on neonatal lung disease, please see the websites for the American Lung Association (www.lungusa.org), the March of Dimes (www.marchofdimes.org), or the National Heart Lung and Blood Institute (www.nhlbi.nih.gov), or access specific URLs as follows:

1. <http://www.lungusa.org/lung-disease/bronchopulmonary-dysplasia/living-with-bronchopulmonary-dysplasia/symptoms-diagnosis-treatment.html>
2. <http://www.modimes.org/mission/prematurity.html>
3. http://www.nhlbi.nih.gov/health/dci/Diseases/rds/rds_what.html

Suggested search terms: neonatal BPD, bronchopulmonary dysplasia, respiratory distress syndrome, RDS, meconium aspiration syndrome, MAS, surfactant, CC10

Case Studies

#1: Dina came into the world, after only 6 months of pregnancy, born to an African-American teen mother who never received prenatal care. She weighed just 1.2 pounds and could not breathe on her own. She had respiratory distress syndrome, called “RDS”. A breathing tube was placed in her windpipe to force air into her immature lungs in order to keep her alive. It was difficult to see her with all the tubes and wires attached to her tiny body. Dina’s mother couldn’t even touch her without gloves to prevent exposing her to everyday germs. The breathing tube was eventually removed and she slowly started to gain weight, but continued to need extra oxygen. Dina’s chest X-rays showed that she had bronchopulmonary dysplasia, called “BPD”, meaning extensive scarring of her lungs. Dina was discharged from the NICU (neonatal intensive care unit) four months after she was born. She did not grow well at home and experienced asthma-like difficulties in breathing. Two months after Dina went home, she was admitted back to the hospital with severe respiratory distress and subsequently died from respiratory failure. Contributions to the NDDF can help change stories like Dina’s by supporting the development of drugs like CC10 that may reduce the severity of chronic lung disease or prevent it altogether.

#2: Danny, Evelyn, and Ella were premature triplets weighing just 1.4 pounds, 1.8 pounds, and 2.2 pounds at birth. Their mother had undergone fertility treatments in order to get pregnant. The triplets’ mother had excellent prenatal care but went into labor at just 7 months of pregnancy. The triplets all experienced RDS at birth and the breathing tube was removed within two days. Evelyn and Ella were fine after that, but Danny’s lungs could not keep sufficient oxygen in his blood so the breathing tube had to be reinserted. He underwent several more attempts to wean him from the ventilator over the next week, but his lungs could not maintain sufficient oxygen in his blood. So he was kept on the ventilator for several more weeks, the hallmark of severe BPD. His sisters grew well and got to go home six weeks after they were born, but not Danny. He grew very slowly. After 2.5 months, he could go home but his lungs still could not maintain high enough oxygen so he received a head box, which surrounds the head and pushes extra oxygen into the lungs. Danny had to wear the head box for the next six months. At two years old, he takes several daily medications, coughs and wheezes when he runs or gets excited, and is very susceptible to severe colds. Danny faces a lifetime of respiratory challenges, which will not only impact quality of life, but also be a significant economic burden for he and his family. His life might have been more normal if an effective drug had been available when he was born to prevent his chronic lung disease. Your contribution to the NDDF could make an enormous impact in the lives of these infants and children.

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To make a donation

Instructions to Donate Online

- www.tuftsmedicalcenter.org
- Select on “Giving” on left side of page
- Select “Other Ways to Give”
- Select “Donate Now”
- Under “Donation Amount” insert gift amount
- Under “Gift designation”, go to box “If other, specify...” In that box, insert “**Neonatal Drug Development Fund**”

For Contributions by Check

- Make check payable to Floating Hospital for Children at Tufts Medical Center
- Make note on check “**Neonatal Drug Development Fund**”
- Mail to Tufts Medical Center, **Box #231**, 800 Washington St., Boston, MA 02111

Be sure to designate the Neonatal Drug Development Fund or NDDF on your contribution.

You will receive a letter verifying your tax-deductible contribution within 2-3 weeks of the date of the donation.

Questions about donating?

Please contact Betsy Rudnick, Philanthropy Officer at Tufts Medical Center

- brudnick@tuftsmedicalcenter.org
- 617-636-8276



*Support the NDDF
because every baby
deserves a healthy start
in life.*

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