Testimony on having a SUPPORT study baby

Carrie Pratt

Kingwood, West Virginia

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Thank you for inviting us to this forum. We, as parents of a DHHS SUPPORT participant, appreciate your willingness to hear our very personal comments regarding what we learned and experienced throughout our daughter's four month residence in Duke Hospital's NICU. We are here to introduce our daughter, Dagen, to you and to share what we experienced with regard to your SUPPORT study.

Dagen was born six years ago. She was delivered via emergency c-section at a very premature 25 weeks gestation. From Dagen's first breath, she has been fighting and working hard to achieve every developmental milestone. In the beginning, when Dagen was a mere 1 pound 11 ounces (eventually dropping to 1 pound 1 ounce), we were approached by Duke's medical staff with the request to be participants in various research studies. As educators, we understand the "study" phase of the research cycle and appreciate the inherent value of the learning phase; we know that it truly is the basis for discovery and evolvement. Many of the studies that we participated in were non-intrusive in nature to include searches through meta data contained within medical records. Others were relatively innocuous such as studying the characteristics of Dagen's cord blood. Carrie even took part in a study on the mental effects of having a child in the NICU. As parents of a premature infant, we thoroughly evaluated the details of each research project before providing our consent and subjecting our medically fragile daughter to testing. We actually declined to participate in in one study related to acid reflux due to certain inherent risks that we believed to be troubling based on the details provided. Then there was the DHHS sponsored SUPPORT study.

After surviving over four months in the NICU to include laser eye surgery from ROP plus disease at two months old, Dagen was eventually released into our care with an apnea monitor. Five and a half weeks following her discharge, Dagen was admitted to the PICU for failure to thrive. As a result of severe reflux, she had a Nissen surgery and a gastrostomy tube inserted. At the age of two, she faced the diagnosis of Cerebral Palsy. Dagen is now a very happy child who thoroughly enjoys life despite her limitations.

Imagine our surprise just a few months ago, as we learned about the risks associated with the DHHS SUPPORT study. Based on new information, it appears as though Dagen was placed into

a random oxygen saturation category instead of a study to monitor her natural oxygen saturation – a random category which may have led to ROP plus disease. A risk that may have yielded Cerebral Palsy which causes her to struggle daily with motor tasks, causes her to wear orthotics on both legs, travel and attend weekly PT/OT, and now at the age of six, is causing her to present identity issues. A risk that caused her pain as she was aggressively moved back and forth from the ventilator, to C-PAP, to nasal cannula within 4 months. Dagen experienced a multitude of health emergencies while in the NICU to include metabolic acidosis, sepsis, apnea, and collapsed lungs.

The DHHS SUPPORT study looked good on paper. We provided the NICU staff with the authorization to record Dagen's oxygen saturation measurements so that the results could provide medical professionals with information to accurately study and hopefully reduce the incidence of ROP plus disease in premature infants. We were approached with the verbiage of something like we are helping other babies by doing the study, and this information will be useful to help catch ROP plus disease early. Then we were guaranteed that the study wouldn't hurt Dagen in any way, and it is was just gathering information. While we appreciated the need to help other babies born with problems like Dagen's, our sole motivation was her health. We assumed her doctors felt the same and were shocked to learn the care she received was based not on what she needed but on what some protocol dictated.

In our minds, DHHS turned Dagen into a *subject* instead of a *participant*. We want you to explain why the intent of study was not originally provided to us as it was envisioned by DHHS. We want to know why the risks and intent of the study were not clear. Why was our child a *subject* in a medical experiment without our knowledge or permission? What "information" did DHHS eventually extrapolate from the experiment? How did the information "help other babies"? Did the study "catch ROP plus disease early" in other infants? Tell me that the SUPPORT study did *not* hurt Dagen in any way? Finally, would you place your own medically fragile, premature children into this SUPPORT study?