

## Oscar G. & Elsa S. Mayer Family Foundation 2010 Grant Interim Report

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Project Title: Magnesium sulfate during pregnancy: a costly start for the newborn?

To the Oscar G. & Elsa S. Mayer Family Foundation,

I am happy to report that our research group at Stanford University continues to achieve our outcomes in a timely manner.

We have identified the control group, extensively reviewed all charts, and completed data collection for this case: control study. Ultimately we enrolled 190 women/newborn pairs who were exposed to magnesium sulfate (MS) prior to delivery (cases) and 74 women/newborn pairs where the mother was exposed to MS after delivery (controls). All maternal cases were exposed to MS because of the diagnosis of preeclampsia, and all carried singleton pregnancies. The gestational age at delivery was  $\geq 37$  weeks.

In our original proposal, we intended to match 2 controls (unexposed woman/newborn pairs) to each case (exposed woman/newborn pair). We found the number of unexposed women was smaller than expected. After meeting with a Stanford statistician, we were advised that rather than extending the time window to develop a larger control group, we should keep the time window the same for both groups and simply have a larger exposed/case group than our control group. An extension of the time window could have cast doubt on any findings, as clinical practice styles change with time. Our statistician felt that the numbers in our existing case: control study (above) were adequate to produce a statistically robust result. In addition, we originally planned to enroll women/newborns who delivered greater than 35 weeks. When we received the lists of potentially eligible patients from Medical Records, we found that there were surprisingly few women/newborn pairs who delivered between 35 and 37 weeks. Our primary outcome, neonatal intensive care unit (NICU) admission, is much less likely as the gestational age increases, and the attribution of NICU admission to MS is much more relevant and plausible among an older group of newborns; among a younger group, prematurity is a significant contributor to NICU admission. For these reasons, we chose to assess newborns born  $\geq 37$  weeks, rather than  $\geq 35$  weeks as originally planned.

We are currently in the process of completely analyzing our data. On initial evaluation, it appears that antepartum MS was associated with NICU admission among term newborns (28/190 of exposed were admitted to the NICU, and 4/74 not-exposed were admitted,

p=0.037), and with feeding difficulties. Our statistician is in the process of analyzing multiple outcomes, and plans to complete this analysis August 1.

Next steps/other major outcomes:

Following complete data analysis, we will submit early in August an abstract to the Society for Maternal-Fetal Medicine annual meeting. I will be happy to forward this abstract, with our findings, to the Oscar G. & Elsa S. Mayer Family Foundation in the next couple of weeks. From there, we will write the paper for submission to *Obstetrics & Gynecology*, and disseminate our results. If we do find evidence of neonatal harm, we will work toward the development and establishment of NICU protocols for the acute care of MS-exposed newborns.

I appreciate the support of your family foundation, and am very much looking forward to reviewing our complete data analysis, sharing the results with you, and moving on to the next stages of this exciting project.

Sincerely,

Deirdre J. Lyell, MD