

## First-year Follow-up Results on Secondary Outcome Variables

### 6.1 Sentinel events by group

Sentinel events have occurred for two children enrolled in the study: one child suffered a stroke and one has been diagnosed with epilepsy. All three of the neurobehavioral domain scores decreased at first-year follow-up relative to baseline for each of these two children; however, none of the decreases were greater than 1.25. The child with epilepsy had a decrease of 1.25 for the memory domain z score, and all of the other decreases observed for either child were less than 0.61.. In addition to monitoring of sentinel health events, we have also monitored changes in key endpoints. We identified 12 subjects with a decrease of 1.25 or more in one of the neurobehavioral domain Z-scores (6 subjects in each treatment group). We also identified 7 children with increases of 5 ug/L or more in urinary mercury (6 in the amalgam group and 1 in the composite group). One of these children with a large change in urinary mercury level also was one of the 12 with a large decrease in one of the neurobehavioral Z-scores. However, there were no other overlaps between these two groups of children. We have also monitored the status of the child with baseline blood lead of 16 ug/dL: this child did not have large decreases in neurobehavioral Z-scores.

### 6.2 Health history

At the suggestion of the DSMB, an annual health history questionnaire is completed for each child by the parents or guardians for the purpose of monitoring hospitalizations, illnesses, medications, and allergies. Note that any serious health events are reported as sentinel events in Section 6.1. The results from the first follow-up are provided in Table 6.1. The treatment groups were similar at follow-up on all items.

Table 6.1. Follow-up health history information by treatment group.

|                                          | Group A           |         | Group B           |         |
|------------------------------------------|-------------------|---------|-------------------|---------|
|                                          | Number with Event | Percent | Number with Event | Percent |
| Hospitalized in the last year?           | 23                | 9.1     | 20                | 7.9     |
| Have any disease in the last year?       | 52                | 20.6    | 44                | 17.3    |
| Taking any medications in the last year? | 88                | 34.8    | 81                | 31.9    |
| Taking any medications today?            | 33                | 13.0    | 26                | 10.2    |
| Had any allergies in the last year?      | 28                | 11.1    | 25                | 9.8     |

### 6.3 Neurological

The prevalence of neurological abnormalities by treatment group is given in Table 6.2. In addition the prevalence of any abnormality is given in the last line of the table. Prevalences of abnormalities remain low and similar in the two treatment groups.

