

Supporting Statement B

Assessment of the Psychosocial Impact of Newborn Screening for Congenital Cytomegalovirus Infection

New

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B. Collections of Information Employing Statistical Methods

1. Respondent Universe and Sampling Methods

Overview

This data collection is intended for the parents of children who are subjects from a previous CMV study cohort. The parents are stratified into four categories:

- Parent Group 1 (PG1) – Child screened positive for congenital CMV at birth, asymptomatic at birth, but did not develop sequelae
- Parent Group 2 (PG2) – Child screened positive for congenital CMV at birth, asymptomatic at birth, but did subsequently develop sequelae
- Parent Group 3 (PG3) – Child screened positive for congenital CMV at birth, symptomatic at birth, and may or may not have subsequently developed sequelae
- Parent Group 4 (PG4) – Child screened negative for congenital CMV at birth, asymptomatic at birth, and did not develop sequelae

There are two main data collections for this project. One is for qualitative and one for quantitative. The qualitative data will be collected by a contractor to Baylor College of Medicine (BCM), Kirby Marketing Solutions (KMS). KMS is a public health communication research firm headed by Susan D. Kirby, Dr.PH. Dr. Kirby holds a doctorate in public health and was formerly a Senior Communication Scientist at CDC. KMS has hired two additional consultants to conduct these data collections. All consultants have significant public health and health care research experience with individual subjects.

Sampling

Participants in this study are all parents of patients who have been in previous CMV studies conducted at BCM. Only a small number of births are given CMV screening at birth. It is not a required element of newborn screening at this time. The proposed study is designed to help answer questions about the positive and negative psychosocial impacts of including CMV in newborn screening. The CMV project at BCM has the largest concentration of CMV screened children's parents. The BCM study populations are relatively limited. To maximize our results we are proposing conducting the qualitative study with relatively large proportions of the overall study population. We plan to randomly select parents from Parent Group 1 for the focus groups and Parent Groups 2 and 3 for interviews.

For the quantitative mail survey we are proposing recruiting the entire study population. Please see Table B2 for the sampling plan.

Table B.2

Sampling Plan			
Parent Category	Total Number of Parents in Study Population	Number and % of Parents for Qualitative	Number and % of Parents for Quantitative
Parent Group 1 (PG1) – Child screened positive for congenital CMV at birth, asymptomatic at birth, but <u>did not</u> develop sequelae	105	36/34%	105/100%
Parent Group 2 (PG2) – Child screened positive for congenital CMV at birth, asymptomatic at birth, but <u>did</u> subsequently develop sequelae	20	10/50%	20/100%
Parent Group 3 (PG3) – Child screened positive for congenital CMV at birth, <u>symptomatic</u> at birth, and <u>did</u> subsequently develop sequelae.	55	15/27%	55/100%
Parent Group 4 (PG4) – Child screened negative for congenital CMV at birth, asymptomatic at birth, and did not develop sequelae.	50	0/0%	50/100%
Totals	230	61/27%	230/100%

Stratification

The population of parents whose children have been in CMV studies at BCM is the universe from which we are recruiting. We stratified the population based on the child's CMV status at birth and then on symptomatic at birth status, and finally on the development of sequelae within the asymptomatic at birth group. This stratification provides us the most insight as to how all parents whose children tested positive for CMV coped with the immediate diagnosis. Then we can further compare perceived parental stress among the CMV positive and CMV negative groups. We can gain insight from the parents whose children developed sequelae (PG2 and PG3). Finally we can gain some insight into the differences between parents whose children were born symptomatic and those who developed sequelae within the critical follow-up years. These are the groups which will interest policy and decision makers, as well as future parents. These are the groups that will also provide insights as to how better serve their information needs to help mediate parental stress as much as possible.

B.2. Procedures for the Collection of Information

Procedures

The qualitative research interviews and focus groups will be conducted with Parent Groups 1, 2, and 3. BCM, where participants have frequently visited in the past, will be the site where all interviews and focus groups will be conducted. BCMV staff will greet the parents, remind them again of their consent options, provide parking passes or tokens, and provide participants with a small incentive of \$25 as a token of appreciation for their interest.

The interviews and focus groups will be conducted by trained interview and focus group moderators. Two of the consultants have conducted focus group training for academic institutions, as well as for CDC over the past 20 years. All consultants have conducted

interviews with adults, parents, and those experiencing difficult health issues over a period of 20 years. All consultants have been through IRB training, as well.

The interview/focus group data will be digitally audio recorded and handwritten notes will also be recorded. The digital audio recordings will be transcribed by an outside transcription service using a secure website. The handwritten notes are digitally captured and will be scanned by OCR recognition software and stored on KMS computers. The handwritten notes are used to capture and summarize key points that a verbatim transcription does not provide. The digital transcriptions will be entered into Nvivo, a text analysis software program. The software allows researchers to code phrases and words in the text data. The coded transcriptions are then summarized by selected coded phrases and words and comparisons are made within and between parent groups.

The mail survey will include all four parents groups. BCM will send a recruitment letter and survey to all potential participants. For the survey, parents will answer 36 items of the Parent Stress Index- Short Form using four or five point Likert scales. The survey should take between 8-10 minutes to complete.

Only parents who participate in the focus groups or interviews will be contacted a second time for possible participation in the mail survey. No other follow up contact will occur. Since the overall population is small, we are proposing including parents from the qualitative survey in the quantitative survey to provide for larger sample sizes so statistical testing can be valid.

The completed surveys will not have participant identifiers. They will be kept in a locked file cabinet at BCM. BCM staff will clean and analyze the data for analysis and summary reporting. When the research project is complete and all reports have been accepted as final, the qualitative will be removed from any KMS computers and delivered to BCM for archival storage.

B.3. Methods to Maximize Response Rates

Respondents' ongoing participation in CMV studies at BCM will likely increase the chances of enrolling participants in the qualitative and quantitative data collection efforts for this study. For the qualitative data collection, a convenience sample need not be representative in order for the data to be useful. The quantitative data collection is not intended to be based on a probability sample.

There are no plans to convert parents who, after being informed about research objectives and participation, decline to participate in the study.

B.4. Test of Procedures or Methods to be Undertaken

No pretests are proposed for the qualitative interviews and focus groups. We will seek advice from the CMV project staff at Baylor who have regular contact with parents and can provide some guidance as to difficulty and clarity of questions. No pretests of the mail survey are planned as the Parent Stress Index has been administered thousands of times across the globe and falls within the 8th grade reading level currently recommended for public surveys.

The data from the mail survey is measured using both 4 point and 5 point Likert scales. There are thirty-six items in the Parent Stress Index-Short Form which are broken into three domains: Parental Distress (PD), Parent-Child Dysfunctional Interaction (P-CDI), and Difficult Child (DC), which combine to form a Total Stress scale. We will calculate overall scores and specific domain scores for each of the three parent domains. We will also calculate means, standard deviations, range, and correlations among various measures. The overall and domain scores will then be compared between various pairs of the four different parent groups using standard statistical tests of significance.

Because all survey recipients have been involved in follow-up with Baylor for many years, we anticipate a very low percentage of non-response. For the non-response that does occur, we will be able to compare the characteristics of those who do and do not respond because Baylor already has demographic and other types of data on all those to whom the survey will be sent.

B.5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

The CDC team is working through a cooperative agreement with BCM. BCM has a subcontract with KMS to conduct the interviews and focus groups, and to prepare the survey. The following are the contacts requested.

The following individuals will conduct focus groups:

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