Information Collection Request
New

Assessment and Evaluation of the Role of Care Coordination (Case Management) in Improving Access and Care within the Spina Bifida Clinic System

Supporting Statement Part A and Part B

Submitted by

Judy Thibadeau
Centers for Disease Control and Prevention
1600 Clifton Road, NE, MS E-88
Atlanta, GA 30333

Phone: 404-498-3559
Fax: 404-498-3060
Email: csn2@cdc.gov

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Assessment and Evaluation of the Role of Care Coordination (Case Management) in Improving Access and Care within the Spina Bifida Clinic System

A. Justification

A.1. Circumstances Making the Collection of Information Necessary

Spina bifida is one of the most common birth defects, affecting approximately 3 per 10,000 live births in the United States annually.[1] Providing care for people who are born with spina bifida is complex and challenging.[2] Multiple physicians and many other professionals and services are involved regularly in addressing the many medical and non-medical issues that these individuals and their families face. The types of medical and non-medical services commonly involved in the care of individuals with spina bifida include – but are not limited to – general pediatrics/internal medicine/neurology, neurosurgery, urology, orthopedics, general nursing, bladder care, bowel care, skin care, general surgery, ophthalmology, vision care, rehabilitation services, developmental services, nutrition, neurocognitive assessment, physical therapy, occupational therapy, speech/language therapy, and recreational therapy.[3]

Care coordination has been utilized for individuals with complex health conditions such as cystic fibrosis and sickle cell anemia and been found to be beneficial for assisting patients and their families.[4-9] However, a limited number of empirical studies have examined care coordination within the spina bifida clinic setting.[7,10-13] No studies to date have examined in-depth the extent to which both caregivers and clinic staff perceive care coordination for spina bifida to be effective and the factors these groups believe help or hinder providing effective care coordination.

This project will use qualitative methods to 1) examine the extent to which care coordination in spina bifida clinics is perceived to be effective; 2) identify perceived barriers to providing care coordination in spina bifida clinics; and 3) identify potential best practices related to providing care coordination in spina bifida clinics. The purposes of this project are consistent with the national research agenda of the Center for Disease Control and Prevention's (CDC's) National Spina Bifida Program which aims to find answers to improve the quality of healthcare and the quality of life for men, women, adolescents, and children who live with spina bifida.

The proposed data collection is authorized by the *Birth Defects and Developmental Disabilities Prevention Act of 2003* which amended Section 317C of the Public Health Service Act (42 U.S.C. 247b-4) to include support for a National Spina Bifida Program (See Attachment A).

A.2 Purpose and Use of the Information Collection

The National Center on Birth Defects and Developmental Disabilities (NCBDDD), CDC plans to collect data from two groups using qualitative data collection techniques: 1) focus groups will be conducted one time only with individuals who provide direct care for an individual with spina bifida (caregivers) and 2) interviews will be conducted one time only with staff at spina bifida clinics. We expect to conduct one focus group and five interviews at each of 10 spina bifida clinics currently implementing care coordination. We will ultimately obtain focus group data from about 80 caregivers (10 clinics x 8 caregivers) and interview approximately 50 spina bifida

clinic staff (10 clinics x 5 staff members). Copies of the focus group moderator guide and the interview guides are included in Attachment C. Data collected for this project will be summarized in two types of reports. Ten case study reports (one report per clinic) will summarize the findings for the individual clinics. A project summary report will summarize the results of the cross-site analyses, including potential best practices for care coordination; detailed descriptions of barriers that clinics and caregivers have encountered in providing and using care coordination; recommendations for overcoming these barriers; and lessons learned that can be disseminated to other clinics wishing to provide or improve care coordination. Prior studies have not effectively addressed these topics.

This is a formative research effort and will not provide results that can be generalized to all spina bifida clinics. This study will provide CDC with detailed information from caregivers about critical components and procedures of care coordination, functions and roles of care coordinators, barriers and facilitators to care coordination, satisfaction with and effectiveness of care coordination, and recommendations for improving care coordination. Interviews with clinic staff will provide CDC with information about how care is coordinated in each clinic, services provided to help families plan for transition, interaction with other health and service systems, and barriers and facilitators to the provision of care coordination. CDC will use the information gathered from this study to 1) design specific practical strategies for improving care coordination for spina bifida patients and their families and 2) guide the initiation of care coordination in clinics that do not currently provide these services. Without the proposed study, CDC will not have scientific evidence on which to base the development of these strategies and guidelines.

Funding for this project comes from a Congressional allocation to CDC for the purpose of establishing and funding a National Spina Bifida Program. The National Spina Bifida Program, including the activities described here, is supported by the President's FY2007 budget request.

A.3 Use of Information Technology and Burden Reduction

This study will not employ automated, electronic, mechanical or other technological collection techniques for these one-time focus groups with caregivers and interviews with spina bifida clinic staff. Participants' use of information technology is not applicable since all data from focus groups and interviews will be collected through interpersonal interactions, not self-administered instruments. Focus groups as a data collection method do not lend themselves to the use of information technology. Conducting interviews with clinic staff using a face-to-face interview method – rather than telephone methodology – is necessary in order for the researchers to understand interviewees' responses within the clinic environment. Telephone interviews would not provide information about the environmental context in which the staff members work.

A.4 Efforts to Identify Duplication and Use of Similar Information.

No similar data are available that meet the needs of the proposed study. Our efforts to identify other data collections addressing the topic of care coordination in spina bifida clinics included several extensive literature reviews. Because spina bifida is a very complex disorder involving multiple types of medical and non-medical services, collecting information relating specifically

to care coordination for this patient population is critical to understanding the factors that may help or hinder the provision of effective care coordination. Because the specific kinds of services utilized by spina bifida patients differ from those utilized by patients with other types of chronic conditions, published information about care coordination for other complex conditions cannot substitute for primary data collection efforts like the proposed one.

The first literature search involved searching spina bifida literature generally with specific reference to care coordination. A second search of the health economics literature was done to attempt to identify articles on the cost benefits of care coordination. A third search was conducted using the MEDLINE, EMBASE, Social SciSearch, PsychInfo, and NTIS (National Technical Information Service) databases from 1995-November 2005. This search employed keywords related to care coordination for spina bifida and other complex health conditions. Unpublished literature on the same topic was identified by searching HSTAT (Health Services/Technology Assessment Texts), the New York Academy of Medicine Gray Literature Report, the National Library of Medicine (NLM) Locator Plus, the Centers for Medicare and Medicaid Services (CMS) website, the Academy Health website (abstracts from annual conferences from 1995-November 2005), and www.guidelines.gov.

Together, these three searches yielded a limited number of studies that discussed some aspect of the topic of care coordination within the spina bifida clinic setting.[7,10-13] However, none of the studies that were identified adequately addressed critical components and procedures of care coordination; functions and roles of the care coordinator; barriers and facilitators to care coordination; satisfaction with and effectiveness of care coordination; recommendations for improving care coordination; how care is coordinated in each clinic; services provided to help families plan for transition; interaction with other health and service systems; and barriers and facilitators to the provision of care coordination.

NCBDDD has discussed plans for this project with leaders from the Spina Bifida Association (SBA) and the Agency for Healthcare Research and Quality (AHRQ). These discussions have confirmed that there are no research efforts completed or underway that address these issues.

A.5 Impact on Small Businesses or Other Small Entities

One-third of the sample for the proposed study will consist of staff from spina bifida clinics. Every effort has been made to minimize the burden of the interviews on small businesses. First, the interviews will be completed only one time. Second, in designing the interview instruments, the number of questions has been held to the minimum necessary for addressing the objectives of the proposed study.

There will be minimal impact on clinic staff members' practices attributable to the administration of the interviews. Based on the administration of similar interviews, we estimate that the proposed interviews will take between 30-60 minutes (an average of 45 minutes) to complete. Interviews with clinic staff will be scheduled so as not to interfere with patient care activities or other needs or concerns expressed by spina bifida clinic staff.

A.6 Consequences of Collecting the Information Less Frequently

We are requesting permission to conduct one-time-only focus groups with caregivers of spina bifida patients and interviews with staff members at spina bifida clinics. Without the proposed study, CDC/NCBDDD will not have scientific evidence on which to base future efforts to provide strategies for improving care coordination for spina bifida patients and their caregivers/families and for guiding the initiation of care coordination in clinics that do not currently provide these services. There are no legal obstacles to reduce the burden.

A.7 Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This study complies fully with the guidelines of 5 CFR 1320.5. No exceptions to the guidelines are required.

A.8 Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

Federal Register Notice. A 60-day Federal Register Notice was published in the *Federal Register* on May 17, 2006, Vol. 71, No. 95, p. 28703-28704 (Attachment B1). Only one response – a letter from the SBA Albany/Capital District Chapter in support of the study -- was received (Attachment B2).

Efforts to Consult Outside the Agency. Between 2004 and 2005, CDC consulted with the CEO of the SBA as well as the Senior Advisor on Child Health and Quality Improvement at AHRQ on the availability of data on care coordination for individuals with spina bifida. These individuals are well acquainted with research and policy related to care for individuals with spina bifida. Contact information for these individuals follows:

Cindy Brownstein, CEO
Spina Bifida Association
4590 Mac Arthur Boulevard NW
Washington, DC 20007
Phone: 202-944-3285 x 14
Email: cbrownstein@sbaa.org

Denise Dougherty, Ph.D.
Senior Advisor, Child Health and Quality Improvement
Agency for Healthcare Research and Quality (AHRQ)
540 Gaither Road, Room 2010
Rockville, Maryland 20850
Phone: 301-427-1868
Email: ddougherty@AHRQ.gov

In early 2006, the Battelle Centers for Public Health Research and Evaluation (the contractor funded to conduct this study) consulted with three experts who work in the field of spina bifida care and research. These individuals reviewed a summary of the data collection protocol for the study as well as the data collection instruments. Contact information for these individuals is provided below:

Eric Levey, M.D.
Director, Center for Spina Bifida and Related Conditions
Kennedy Krieger Institute
707 North Broadway, Room 100-K
Baltimore, MD 21205
Phone: 443-923-9130
Email: Levey@kennedykrieger.org

Kathleen J. Sawin, DNS, CPNP, FAAN
Professor and Joint Research Chair
UW-Milwaukee College of Nursing
Box 413, Cunningham 637
Milwaukee, WI 53201
Phone: 414-229-5318
Email: sawin@uwm.edu

Jennifer M. Cernoch, Ph.D.
Executive Director, Family Voices, Inc.
2340 Alamo SE, Suite 102
Albuquerque, NM 87106
Phone: 210-650-4817
Email: jcernoch@familyvoices.org

A.9 Explanation of Any Payment or Gift to Respondents

Focus Groups. We plan to use a monetary incentive to motivate caregivers to participate in the focus groups. In order to encourage a minimum of 8 caregivers from each clinic site to participate, we plan to give each caregiver a $40.00 cash incentive to participate. A substantial body of experimental research indicates that the use of financial incentives assists with recruitment efforts for survey research.[14] Experts in the field of focus group research recommend the use of monetary incentives to encourage individuals to participate in focus group research because they encourage participants to 1) show up for the focus group; 2) show up on time; and 3) hold open the time of the scheduled focus group. Further, offering an incentive communicates to focus group participants that the focus group is important.[15]

We carefully considered the amount of the incentive and concluded that $40.00 would encourage caregivers to participate but would not be so great as to be considered an inappropriate influence. Caregivers of persons with spina bifida are a highly selective group, and thus it is difficult to obtain their participation in studies that require them to travel to a study site. A goal of the study is to obtain 80 participants, and a lower response rate is likely to result without such an incentive. Similar CDC-sponsored focus groups have offered incentives at approximately this level and have found this amount to result in acceptable response rates.

Interviews. No gifts or compensation will be given to spina bifida clinic staff who participate in this project (interview). Conversations with a consultant who works in the field of spina bifida care suggested that spina bifida clinic staff would likely be willing to participate in this kind of research in the absence of an incentive payment.[16]

A.10 Assurance of Confidentiality Provided to Respondents

The CDC Privacy Act Coordinator has reviewed this application and has determined that the Privacy Act is not applicable. Respondents will not provide personal information but will be speaking from their roles as caregivers for children with spina bifida, or from their roles as health professionals involved in providing health services to children with spina bifida. Respondents will provide perspectives on the types of services needed by spina bifida patients, the types of services provided by clinics, and the overall coordination of health care services.

Data collection will occur in a focus group setting, personal interview or telephone interview. The data collection contractor, the Battelle Centers for Public Health Research and Evaluation, requires the name and contact information of each potential respondent in order to schedule participation in a personal interview or focus group. The Battelle study coordinator will work with a clinic representative at each participating site to obtain names and contact information for health care professionals, and will then follow up with those individuals to obtain their consent

and to schedule staff interviews. The Battelle coordinator will also work with the clinic representative to recruit caregivers for the focus group discussions, however, interested caregivers will generally initiate contact with the Battelle coordinator or the clinic representative (see Attachment C5, Focus Group Response Form and Attachment C4, Focus Group Recruitment Flyer). This recruitment approach was developed to avoid needing to have clinics release the names of clients directly to the data collection contractor. Names and contact information will not be used after the interview or focus group has been scheduled, and the personally identifiable information will be deleted no longer than three months after when data collection is completed. Respondents' full names will not be recorded with response data collected during an interview or focus group discussion. Field notes from the health care staff interviews will identify respondents only by their role, and the focus group discussion notes will identify respondents only by first name or pseudonym. In the permanent study records, first names will be deleted and each respondent will be identified only by a unique code.

Participants will be told verbally and in writing (on the consent form) that all data gathered for the study will be treated in a secure manner. They will also be informed that CDC plans to publish only anonymized, aggregate data and reports.

Research participants will be addressed only by their first names during the focus groups and interviews. No other personal identifying information will be collected during the focus groups or interviews. Last names will never be provided to the transcriptionist, the research assistants, or the data analysts. The names of specific clinics will not be identified in any of the case study reports or the final project report. Staff comments in individual clinic case study reports will not be reported by staff role to avoid indirectly identifying respondents. All information related to the project will be stored in locked filing cabinets. We will permanently erase all audio recordings when the study is over.

The research protocol has been reviewed and approved by the Institutional Review Board (IRB) at Battelle. A copy of the IRB approval letter is included in Attachment D1.

A.11 Justification for Sensitive Questions

The interview guides and focus group moderator guide do not contain any personal questions of a sensitive nature, such as sexual practices, alcohol or drug use, religious beliefs or affiliations, immigration status, and employment history. It is possible that the focus group discussions or interviews could elicit complaints about the clinic which could be considered sensitive; however, the intent of the project is to describe policies and practices that promote the coordination of care services or reduce barriers to such coordination, not to describe issues or situations with individual staff or patients.

This data collection does not request information about the respondent's Race and Ethnicity, which may be considered sensitive. Race and Ethnicity would not be attributes of interest for data analysis.

A.12 Estimates of Annualized Burden Hours and Costs

Annualized Burden Hours. The estimates of annualized burden hours are based on the results of pilot testing, past experience with recruitment, and the administration of similar focus groups and interviews. Interviews with spina bifida clinic staff will be scheduled so as not to interfere with patient care activities. Interviews will be conducted with 5 staff members at each clinic. Four versions of the staff interview instrument have been developed (the core themes are the same, but each version has questions that are customized to a particular type of job description; see C12, C13, C14, C15). The burden estimate for each version of the instrument is the same. Depending on the staff member's role and responsibilities, the interviewer will select the appropriate version of the staff interview guide.

Overall, we estimate that the total annual burden for participation in this study is 244 hours.

Table A.12-1. Estimates of Annualized Burden Hours

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
Caregivers	Focus Group Response Form	100	1	5/60	8
	Focus Group Telephone Script	100	1	15/60	25
	Focus Group Moderator's Guide	80	1	2	160
Clinic Staff	Clinic Recruitment Script	14	1	15/60	4
	Clinic Staff Telephone Interview Script	55	1	10/60	9
	Clinic Staff Interview Guide	50	1	45/60	38
				Total	244

Annualized Cost to Respondents.

Focus group respondents. There will be no costs to caregivers who participate in this study other than their time. Time estimates are presented in Table A.12-1. Focus groups will be held in the evenings, after the close of standard business hours. For this reason, we anticipate that caregivers will not need to take any time off from work to complete the focus groups and will thus not lose any wages as a result of their participation. Nevertheless, recognizing the implicit value of volunteer time, we estimate that the dollar value of time contributed to the study by a caregiver is equivalent to the Federal Minimum Wage rate of $5.15 per hour (as of December 31, 2006).

Interview respondents. Three types of clinic staff will participate in a study interview: pediatricians, surgeons, and allied health professionals (e.g., nurses, occupational therapists). Annualized cost estimates to potential interview respondents are presented in Table A.12-2 and are based on mean (average) hourly wage estimates obtained from the U. S. Department of Labor, Bureau of Labor Statistics for Healthcare Practitioners and Technical Occupations (http://www.bls.gov/oes/current/oes_29He.htm). The estimates for the pediatricians ($67.31 per hour) and the surgeons ($87.43 per hour) were taken directly from the November 2004 U.S. Department of Labor report. There are many varieties of allied health professionals including nurses, occupational therapists, physical therapists, recreational therapists, speech-language pathologists and so on. The average hourly wage estimate for allied health professionals ($25.83

per hour) was obtained by averaging the hourly wage of nurses, occupational therapists, physical therapists, recreational therapists, and speech-language pathologists. The exact number of pediatricians, surgeons, and allied health professionals will vary by each clinic; thus the amounts in the table below represent the average of the different wage rates.

Table A.12-2. Annualized Costs to Respondents

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Average Hourly Wage	Total Burden (in hours)
Caregivers	Focus Group Response Form	100	1	5/60	$5.15	$43
	Focus Group Telephone Script	100	1	15/60	$5.15	$129
	Focus Group Moderator's Guide	80	1	2	$5.15	$824
Clinic Staff	Clinic Recruitment Script	14	1	15/60	$60.19	$211
	Clinic Staff Telephone Interview Script	55	1	10/60	$60.19	$552
	Clinic Staff Interview Guide*	50	1	45/60	$60.19	$2,257
					Total	$4,016

A.13 Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

There are no capital, start up, operation, or maintenance costs to respondents associated with this proposed collection of information.

A.14 Annualized Cost to the Federal Government

This project will take two years to complete. The total cost to the government will be $330,222 This figure includes $296,894 in contract costs to Battelle and $33,328 in other costs to the federal government. The other federal costs relate to salary, fringe, and travel related to the involvement of one contractor (.1 FTE) and 4 federal employees (.01 FTE each). The resulting annualized cost to the government is $165,111 (total costs/2 years).

A.15 Explanation for Program Changes or Adjustments

This is a new data collection.

A.16 Plans for Tabulation and Publication and Project Time Schedule

Plans for Tabulation. Data for this project will be tabulated for each individual clinic, as well as all 10 clinics together.

During the first phase of the data tabulation process, we will summarize the characteristics of each of the study clinics, including the geographic region where it is located, the number of patients seen on a routine clinic day, the number of care coordination functions offered at the clinic, and so forth. We will then tabulate the number of individuals who participated in the study, stratified by the data collection technique (focus group vs. interview). We will also tabulate the number of interview respondents with each type of clinic staff role (e.g., director, care coordinator, clinician/provider).

The next phase of the data tabulation will involve content analyzing textual data gathered during the focus groups and interviews using QSR N6 software. The data analysis plan has been designed to answer the following eight questions:

1. What are the goals of care coordination in spina bifida clinics currently implementing a system of care coordination?

2. What are the critical components of care coordination and the functions of care coordinator(s) in spina bifida clinics currently implementing a system of care coordination?

3. How are plans of care developed, implemented, and evaluated in spina bifida clinics?

4. What are the perceived barriers to the provision and utilization of care coordination in spina bifida clinics?

5. What are the perceived facilitators to the provision and utilization of care coordination in spina bifida clinics?

6. How do spina bifida clinics that are currently implementing a system of care coordination address the transition from pediatric to adult-centered care?

7. How effective do caregivers and clinic staff perceive care coordination to be in spina bifida clinics?

8. What recommendations do caregivers and clinic staff have for improving the provision of care coordination in spina bifida clinics?

First, audio recordings of each focus group and interview will be transcribed by a professional. These transcripts will be uploaded into a QSR N6 database. Electronic versions of handwritten field notes generated during interviews and focus groups will also be uploaded into the database.

Experienced qualitative researchers will then code each paragraph of text using a pre-developed codebook. A hierarchy of codes will be developed for each expected and emergent theme. For example, the key research questions can be extrapolated to develop expected themes that act as higher-level codes. Lower-level codes create specific aspects of the overall theme in the higher-level code. Emergent themes will be incorporated as higher-level or lower-level codes as appropriate. For example, a higher-level code for research question #7 "How effective do caregivers and clinic staff perceive care coordination to be in spina bifida clinics?" may be "satisfaction" and lower-level codes may be "among clinic staff" and "among caregivers/consumers." Sub-codes under these lower-level codes may include "specialist care" and/or "community services" and/or "school-related" and/or "mental health" to capture the various types of services with which consumers may express a degree of satisfaction.

The coded textual data will then be sorted in order to examine text relating to each of the eight research questions listed above. Content analysis will be based on matching patterns of observation across multiple interviews and focus groups within each site and across sites. The data will be summarized by the key variables identified in the research questions listed above. The data will be summarized primarily in narrative format. Supplementary tables similar in style to Tables A.16-1 and A.16-2 will also be used to summarize the study data.

Table A.16-1. Summary of Textual Data Relating to the Goals of Care Coordination

Theme	Description of Theme	Illustrative Quotes
Plan of Care		
Access		
Communication		
Quality of Life		

Table A.16-2. Summary of Textual Data Relating to Critical Components of Care Coordination

Theme	Description of Theme	Illustrative Quotes
Assessment		
Planning		
Implementation		
Communication		
Coordination		
Monitoring		
Evaluation		

Plans for Publication. NCBDDD staff anticipate using two forums to disseminate findings from this research. First, the 10 case study reports (one report per clinic) and the overall project

summary report to be prepared by Battelle will be presented to CDC management staff in writing.

CDC will disseminate copies of all case study reports and the final project summary report to SBA and AHRQ. Each of the individual study clinics will receive a copy of its own case study report as well as a copy of the overall project summary report. Second, highlights from the final project summary report will be shared during professional meetings.

This effort will be published in an appropriate journal as the subject matter will hold impact for the care system for persons with spina bifida.

Project Time Schedule. In preparation for requesting OMB clearance, we pilot-tested the focus group moderator and interview guides. We also obtained IRB approvals from the appropriate committee at Battelle. While the OMB package is undergoing review, we will select 10 spina bifida clinics where the data collection activities will occur, and will work with SBA to recruit these clinics. After the clinics have been identified, we will work with their individual IRBs to complete any necessary paperwork and obtain local IRB approvals. We will train all data collection personnel while we are awaiting OMB approval as well. We anticipate beginning data collection activities immediately following receipt of OMB clearance.

Table A.16-3. Project Time Schedule

Activity	Time Schedule
Submit package to OMB for Approval	May-June 2007
Schedule site visits to clinics	1 month after Clearance
Recruit focus group and interview participants	1-4 months after Clearance
Conduct site visits at clinics; collect interview and focus group data	2-5 months after Clearance
Transcription of interview and focus group data	3-5 months after Clearance
Coding of interview and focus group data	6 months after Clearance
Analysis of interview and focus group data	7-8 months after Clearance
Write draft reports	8 months after Clearance
Submit final reports to CDC	9 months after Clearance
Copies of reports submitted to SBA, AHRQ, and clinics	14 months after Clearance
Presentation of results at professional meeting	18 months after Clearance

A.17 Reason(s) Display of OMB Expiration Date is Inappropriate

Not applicable. Display of OMB Expiration Date is appropriate for this study.

A.18 Exceptions to Certification for Paperwork Reduction Act Submissions.

There are no exceptions to the certification.

B. Collections of Information Employing Statistical Methods

Because this is qualitative research, statistical methods will not be used to analyze the study data. In addition, the participants will be drawn from existing spina bifida programs and clinics. Additional information regarding clinic selection and participant recruitment is included in section B.1.

Below we describe our recruitment and data collection procedures.

B.1 Respondent Universe and Sampling Methods

Clinic Selection and Recruitment. A total of 10 spina bifida clinics currently providing care coordination will be selected from the universe of 68 clinics that responded to a recent SBA Program Survey. Clinics will be selected such that they represent diverse clinic characteristics (e.g., patient volume, percentage of caseload supported by Medicaid funding), geographical locations (East, South, Midwest, West, Pacific), and number and types of services offered.

Initial clinic recruitment efforts will be conducted by SBA. The CEO of SBA will mail an introductory letter (Attachment C9) and brochure (Attachment C10) to the clinic director at each of the 10 selected clinics. The letter and brochure will describe the study and its purposes, as well as what participating in the study would entail for the clinic and staff. About one week after the letters have been mailed, the CEO of SBA will call each clinic director to answer any questions and to determine whether the director is interested in having his/her clinic participate in the study (a list of discussion topics is presented in the Clinic Recruitment Script (Attachment C11).

In the event that a clinic director is not interested in having his/her clinic participate in the study, Battelle will select an alternate clinic with similar characteristics.

The Battelle Project Director will place follow-up calls to all interested clinic directors to answer any remaining study-related questions (Attachment C11), to establish a point-of-contact, and to address relevant logistical concerns related to study implementation (i.e., best times to schedule site visits, availability of meeting space for holding focus groups, potential participant recruitment techniques), as well as any IRB requirements their facility might have. Battelle will assist facilities with the completion of any required local IRB paperwork.

Participant Recruitment. Approximately 20 primary caregivers of persons with spina bifida (with the goal that at least 8 caregivers will be present in each group) will be invited to participate from each of these 10 clinics. To increase the homogeneity of the focus groups, 5 of the focus groups will be conducted with caregivers of younger children with spina bifida (i.e., children ages 2-10) and 5 of the focus groups will be conducted with parents of older children with spina bifida (i.e., children ages 11-21). Approximately 5 staff members from each of the 10 participating spina bifida clinics will be invited to participate.

Focus group recruitment. Procedures to invite volunteers to participate in the focus groups will be worked out with the local clinics, but in all cases the caregivers' initial point of contact for the

study will be a designated staff person at the clinic. Potential recruitment techniques include mailing informational brochures (Attachment C2) and recruitment letters (Attachment C3) to the caregivers of children seen at the clinic and posting flyers advertising the study at the clinics (Attachment C4). Caregivers who express interest in the study by calling the Battelle Project Coordinator or by mailing or faxing a completed response form to Battelle (Attachment C5) will receive a follow-up call from the Battelle Project Coordinator (Attachment C7) who will screen to verify his/her eligibility, review the informed consent form (Attachment C8) by reading it verbatim, and will schedule him/her into the focus group, and then follow up with a confirming letter (Attachment C6) and a copy of the written consent form that will also be distributed at the focus group discussion (Attachment C8). Note that the reading level of this consent form is grade 7.1, based on the Flesch-Kincaid algorithm used by *Microsoft Word*. The Battelle Project Coordinator will call each participant 2 days before the scheduled focus group to remind him or her about the focus group.

Caregivers will be contacted in the order in which their completed response forms are received by the Battelle Project Coordinator. In the event that more than 12 caregivers mail a completed response form to Battelle, the first 12 will be contacted by phone as described above. The remaining caregivers will be contacted by phone to let them know that they have been scheduled as alternates and that they may be contacted in the event of a cancellation. In the event that a focus group participant cancels, the Battelle Project Coordinator will call an alternate to determine whether s/he is still available and willing to participate. When selecting alternates, the Battelle Project Coordinator will give priority to caregivers whose children have attended the clinic for the longest period of time.

To be eligible for participation in a focus group, the volunteer must be 1) a primary caregiver of a child with spina bifida age 2 and above, and 2) be at least 19 years of age. Caregivers of children younger than age 2 are not eligible to be included in the study because these individuals are likely to be overwhelmed by learning how to take care of a child with spina bifida and may also be less familiar with the processes of care coordination.

Staff interview recruitment. Battelle will work with the local spina bifida clinic point-of-contact to identify 5 clinic staff with different responsibilities at that clinic who work directly with spina bifida patients and their families/caregivers (e.g., the clinic director, clinicians/care providers, the care coordinator, administrators, nurses, therapists, or social workers), and thus can discuss relevant issues related to care coordination (for example, goals of care coordination, critical components and procedures of care coordination; barriers and facilitators to effective care coordination). Procedures to invite staff members to participate will be worked out with the local clinic based on their unique scheduling patterns, but in all cases the participants will be volunteers. Potential approaches may include mailing or emailing selected staff members an invitational letter requesting their participation (Attachment C16) along with an informational brochure (Attachment C10) and/or posting recruitment flyers in the clinic (Attachment C17). Staff members who express an interest in participating in the study will receive a follow-up call from the Battelle Project Coordinator who will screen to verify his/her eligibility, review the informed consent by reading it verbatim, and schedule an interview time for him/her (Attachment C17). The Battelle Project Coordinator will send a follow-up confirmation letter via mail or email (Attachment C19) along with a copy of the consent form (Attachment C20). The

Battelle Project Coordinator will contact each participant 2 days before his/her scheduled interview as a reminder. In the event that a staff member is not available for an in-person interview during the Battelle site visit, arrangements may be made to interview the staff person via phone on a different day.

B.2 Procedures for the Collection of Information

Information for this study will be collected using focus groups with caregivers of individuals with spina bifida and interviews with spina bifida clinic staff.

Focus Groups. All 10 focus groups will be conducted by a 2-person team consisting of 2 experienced qualitative researchers. One person will serve as the moderator and will be responsible for reviewing the consent form and asking questions using the moderator guide (Attachment 2A). The second person will serve as the assistant and will take detailed notes. All interviews will be audiotaped and transcribed by a professional transcriptionist at a later date. Each focus group will last approximately 2 hours and light refreshments will be provided.

The focus group moderator's guide (Attachment C1) will be followed to ensure that all of the important topics are addressed in each group. Focus group topic development was based on the study aims and on our review of recent literature concerning care coordination for spina bifida and other complex health conditions. Discussion topics will include critical components and procedures of care coordination, functions and roles of care coordinators, barriers and facilitators to care coordination, satisfaction with and effectiveness of care coordination, and recommendations for improving care coordination.

Interviews. Each staff member interview will begin with a review of the consent form (Attachment C20). Although we anticipate that interviews will be conducted with individuals who have graduate degrees in medicine, nursing, social work, or another allied health profession, the consent form a has reading level of grade 12.0 according to the Flesch-Kincaid algorithm mentioned previously. Then, an interview, lasting approximately 30 and 60 minutes (an average of 45 minutes), will be conducted by 2 experienced qualitative researchers. One person will serve as the lead interviewer and will be responsible for reviewing the consent form and asking questions from the interview guide (Attachments C20, C15). Various versions of the interview guide will be used, depending on the staff person's role in the clinic (i.e., whether they are the clinic director, care coordinator, clinician/provider, or other staff member). The second person will serve as the assistant and will take detailed notes. The assistant will be invited to ask clarifying questions. With the permission of the subject, interviews will be audiotaped and transcribed by a professional transcriptionist at a later date. Detailed field notes will be typed for further content analysis, and the key informant's name will be replaced by an unambiguous but confidential identifying label.

B.3 Methods to Maximize Response Rates and Deal with Nonresponse

Statistical methods will not be used to select respondents for this study. Therefore, it will not be appropriate to calculate participant response rates. At each spina bifida clinic we will attempt to recruit at least 8 caregivers to participate in a focus group and 5 staff to participate in individual interviews.

B.4 Tests of Procedures or Methods to be Undertaken

Both the Focus Group Moderator's Guide and all of the Interview Guides were reviewed in detail by three experts who work in the field of spina bifida care and research (Drs. Levey, Sawin, and Cernoch). The experts' suggestions were incorporated in subsequent versions of the Interview Guides. These suggestions included adding items relating to how care coordination is funded within the clinics; which staff are responsible for getting insurance approval; and which staff are responsible for collating patient information. In addition, the Focus Group Moderator's Guide was pilot-tested over the telephone with 1 caregiver. The pilot test identified a few minor problems with the way the questions were organized, and the Focus Group Moderator's Guide was subsequently revised. The Interview Guide was pilot-tested with one clinic staff member. This pilot test revealed no problems with the wording or organization of the items on the Interview Guide.

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

The data collection and data analysis plans for this study were developed jointly by the experienced public health researchers listed below from NCBDDD/CDC and the Battelle Centers for Public Health Research and Evaluation. The Battelle team has also been authorized and funded by contract 200-2001-00121 to collect, analyze, and report all study data for this project.

CDC Project Staff

- Sandra Coulberson, MPH is the CDC Technical Monitor. She has overall responsibility for the financial aspects of the study. Phone: 404-498-3058; Email: scoulberson@cdc.gov
- Judy Thibadeau, RN, MN is the CDC Study Coordinator. She has overall responsibility for the design, conduct, and analysis of the research. Phone: 404-498-3559; Email: jthibadeau@cdc.gov.
- Vince Campbell, Ph.D. is a Health Scientist at CDC. He provided input on the development of the research protocol and data collection instruments. Phone: 404-498-3012; Email: vbc6@cdc.gov
- Ed Brann, M.D. is a Medical Epidemiologist at CDC. He reviewed the research protocol and data collection instruments for the study. Phone: 404-498-3038; Email: Ebrann@cdc. gov
- Ronda Talley, Ph.D., MPH is a Health Scientist at CDC. She provided input on the development of the research protocol and data collection instruments. Phone: 404-498-3562; Email: rkt6@cdc.gov

Battelle Staff

- Jennifer Brustrom, Ph.D. is a Senior Health Research Scientist at Battelle. She is serving as the overall Project Director on this study. She had primary responsibility for the development of the data collection protocol, overseeing the data collection and analysis, and writing the final project reports. Phone: 209-726-3458; Email: brustromj@battelle.org
- Ken Goodman, MA is a Health Research Scientist at Battelle. He assisted with the development of the data collection protocol, designed the interview guides, and will assist with data collection. Phone: 770-451-0882 x30; Email: goodmanj@battelle.org
- Lisa John, MSW is a Project Director at Battelle. She assisted with the development of the data collection protocol and will oversee the data collection process. Phone: 314-993-5234x141; Email: johnl@battelle.org
- Donetta Ghosh, MA, MPH is a Health Research Scientist at Battelle. She assisted with the development of the data collection protocol and will assist with both data collection and data analysis. Phone: 206-528-3149; Email: ghoshd@battelle.org
- Shyanika Rose, MA is a Principal Health Research Scientist at Battelle. She assisted with the development of the data collection protocol; designed the focus group moderator guide; will assist with data collection; and will analyze the study data. Phone: 919-544-3717x118 ; Email: rosesw@battelle.org
- Lowell Sever, Ph.D. is a Health Research Leader at Battelle. He reviewed and edited the protocol and data collection instruments for the project. Phone: 713-500-9344; Email: Lowell.e.sever@uth.tmc.edu

Consultants

- Eric Levey, M.D. is the Director of the Center for Spina Bifida and Related Conditions at the Kennedy Krieger Institute. He reviewed a summary of the data collection protocol for the study as well as the data collection instruments. Phone: 443-923-9130; Email: Levey@kennedykrieger.org
- Kathleen J. Sawin, DNS, CPNP, FAAN is Professor and Joint Research Chair at UW-Milwaukee College of Nursing. She reviewed a summary of the data collection protocol for the study as well as the data collection instruments. Phone: 414-229-5318; Email: sawin@uwm.edu
- Jennifer M. Cernoch, Ph.D. is Executive Director of Family Voices, Inc. She reviewed a summary of the data collection protocol for the study as well as the data collection instruments. Phone: 210-650-4817; Email: jcernoch@familyvoices.org

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