Supporting Statement

for

Evaluating Reach, Awareness, and Exposure of Enhanced Implementation of the Learn the Signs. Act Early. Campaign in Four Target Sites

New

December 21, 2011

Project Officer
Linda Marlette, MS
404-639-7763 (Office)
linda.marlette@cdc.hhs.gov

Technical Monitor
Katie K. Green, MPH, CHES
Health Communication Specialist
Centers for Disease Control and Prevention
National Center on Birth Defects and Developmental Disabilities
Prevention Research Branch
1600 Clifton Road, Mail Stop E-86, Atlanta, GA 30333
404-498-3872 (office) 404-498-3550 (fax)
KKGreen@cdc.gov

OMB Submission Point of Contact (alternate):
Denise Levis, MA, PhD
Health Communication Specialist
Prevention Research Branch
National Center on Birth Defects and Developmental Disabilities
P: (404) 498-0237
E: Denise.Levis@cdc.hhs.gov

Table of Contents

LIST OF ATTACHMENTS

Attachment 1: Applicable Laws or Regulations

Attachment 2: 60-day Federal Register Notice

Attachment 3: Information Collection Instruments

3A. Screener (English)
3B. Screener (Spanish)
3C. Pre-implementation Parent Survey (English)
3D. Pre-implementation Parent Survey (Spanish)
3E. Post-implementation Parent Survey (English)
3F. Post-implementation Parent Survey (Spanish)

A. Justification

A.1. Circumstances Making the Collection of Information Necessary

Background

This data collection activity is a new request and is authorized by Section 301 of the Public Health Service Act (42 USC 241) Section 301. A copy of the legislation is included as Attachment 1. The length of data collection requested for OMB-PRA approval is 2 years.

When autism first caught the eye of the scientific community in the 1940s, it was considered a rare, albeit severe, disorder. While no major epidemiological studies were completed during this era, most professional estimates placed prevalence near 1-2 children per 10,000. Prevalence rates from later studies ranged from 0.25 cases per 1,000 (Ritvo, et al., 1989) to 1.60 per 1,000 (Ishii & Takahashii, 1983). Between 1996 and 1998, at least seven other widely read studies were conducted, using diagnostic criteria found in the International Classification of Diseases, 10th edition (ICD-10). Within these studies, prevalence rates ranged from 0.54 cases of autism per 1,000 (Fombonne, et al., 1997) to 6 cases per 1,000 (Kadesjo, Gillberg, & Hagberg, 1999).

The Centers for Disease Control and Prevention (CDC) conducted a very large-scale epidemiological study of autism prevalence in Brick Township, N.J., in 1998. The study utilized diagnostic criteria from the DSM-IV for autism spectrum disorders (ASD). The results of this study indicated a prevalence of autistic disorder at 4.0 cases per 1,000 for children aged 3-10 years. The overall rate for children of the same age who met the criteria for autistic disorder, as defined in DSM-IV, and other spectrum disorders (ASD) was 6.7 cases per 1,000 (CDC, 2006).

Perhaps the most significant prevalence figures yet are the most recent ones produced by the CDC. In February 2007, the CDC announced the results of its first multi-community prevalence study, based on information collected during the reporting years of 2000 and 2002. This study reported the results of data collected across 14 different sites spanning the United States. The study examined the records of 8-year-old children (because most individuals with ASD have been identified by that time). It concluded that autism's prevalence was (on average) around 6.6-6.7 per 1,000 eight year olds, or that approximately 1 in 150 were on the autistic spectrum.

CDC's most recent data show that an average of one in 110 children have an autism spectrum disorder in 2006 (children born in1998). Today, autism is recognized in many circles as an "epidemic" or "crisis" that is directly impacting the lives of many millions of Americans. All the communities participating in both the earlier 2002 and 2006 study years observed an increase in identified ASD prevalence ranging from 27 percent to 95 percent, with an average increase of 57 percent. No single factor explains the changes in identified ASD prevalence over the time period studied. Although some of the increases are due to better detection, a true increase in risk cannot be ruled out.

Evidence has shown that early treatment can have a significant positive impact on the long-term outcome for children with an autism spectrum disorder. Early treatment, however, generally

relies on the age at which a diagnosis can be made, thus pushing early identification research into a category of high public health priority (Pierce, et al, 2010).

To address this important health issue, the CDC's National Center on Birth Defects and Developmental Disabilities (NCBDDD) has launched the "Learn the Signs. Act Early." national campaign and developed partnerships with national autism and health care professional organizations to promote awareness of early childhood developmental milestones and increase early action on developmental concerns.

NCBDDD has funded four grantees to carry out an intensive implementation of the campaign in select target areas. This request for data collection is for the evaluation of the "Learn the Signs. Act Early." campaign to assess the reach of the intensive implementation of the "Learn the Signs. Act Early." campaign and to capture any change in awareness, knowledge, or behavior that may result among the intended audience.

1.1 Privacy Impact Assessment

I. Overview of the Data Collection System

Data collection for the evaluation of "Learn the Signs. Act Early." campaign project will consist of two components: the pre-implementation survey and the post-implementation survey.

The "Learn the Signs. Act Early." program is an ongoing project. The current project is an intensive campaign to be implemented among four grantees. Before the intensive campaign, a pre-implementation survey in pen-and-paper format will be conducted among parents with children aged 0-60 months in the target areas for each of the four grantees. A post-implementation survey in pen-and-paper format will be conducted in the same four target areas as part of the effort to assess the reach and impact of the campaign. The surveys will be conducted in the following target areas:

- Washington: Yakima, Benton, Franklin, and Walla Walla counties
- Missouri: St. Louis City
- Utah: Salt Lake County
- Alaska: Cities of Anchorage, Palmer, Wasilla, Homer, and Kenai

The data collection system includes:

(a) A screener in English and Spanish to select parents who are eligible to complete the pre-implementation and post-implementation surveys (see Attachment 3a for the English screener and 3b for the Spanish screener);
(b) A pre-implementation survey to be administered among parents and or caregivers before the implementation of the intensive campaign (see Attachment 3c for the survey in English and Attachment 3d for the survey in Spanish);
(c) A post-implementation survey to be administered among parents and or caregivers after the implementation of the intensive campaign (see Attachment 3e for the survey in English and Attachment 3f for the survey in Spanish).

II. Items of Information to Be Collected

The types of information to be collected in the baseline and follow-up surveys include information about the participants/parents' demographics, such as age and race/ethnicity and level of education. Information will also be collected on participants' awareness of the "Learn the Signs. Act Early." and knowledge and behavior regarding child development. No individually identifiable information will be collected.

Specifically, information to be collect in the pre-implementation survey will include:

- Age of child (or children) and number of children 5 years old or younger
- The level of awareness of the "Learn the Signs. Act Early." campaign among the target population, the parents and/or caregivers;
- The channel of communication through which the parents and/or caregivers have been exposed to the "Learn the Signs. Act Early." campaign;
- Sources of knowledge about developmental milestones among parents;
- Actions parents will take when parents become concerned about their child's development;
- Parents' search of information/knowledge to make sure their child's development is on track for his or her age;
- Parents' communication with their child's doctor and/or nurse about their child's development; and
- Age, ethnicity, level of education and annual household income of parents.

Information to be collect in the post-implementation survey will include the items in the pre-implementation survey and additional items listed below:

- Attendance of the "Learn the Signs. Act Early." campaign events;
- Exposure of the "Learn the Signs. Act Early." campaign materials; and
- Knowledge of the information in the "Learn the Signs. Act Early." campaign materials.

III. Identification of Website(s) and Website Content Directed at Children Under 13 Years of Age

No website content directed at children under 13 years of age is involved in this information collection request.

A.2. Purpose and Use of Information Collection

The goal of this data collection activity is to assess the reach of the intensive implementation of the "Learn the Signs. Act Early." campaign and to capture any change in awareness, knowledge, or behavior that may result among the intended audience. The information will be collected in a pre- and post-implementation survey format, which will help CDC to identify best practices for the implementation of the "Learn the Signs. Act Early." campaign. Without this information

collection activity, CDC's "Learn the Signs. Act Early." team will be hampered in its ability to successfully carry out its mission of providing high-quality programs and services to population served.

2.1 Privacy Impact Assessment Information

For the purpose of the evaluation, no individually identifiable information is being collected. Data collection, including the follow up survey, will be anonymous. The surveys will have no identifying information or any link to names or contact information. Therefore, the data collection is not anticipated to have any impact on the respondents' privacy. Descriptive summaries of the responses will be used to inform CDC of each grantee's ability to reach parents of young children with "Learn the Signs. Act Early." campaign messages. No contact information will be submitted to CDC.

A.3. Use of Improved Information Technology and Burden Reduction

This study will not employ automated, electronic, mechanical or other technological data collection techniques for these focus groups. Respondents' use of information technology is not applicable since all data will be collected through interpersonal interactions using pen-and-paper instruments.

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

Literature search, database searches, and consultation with other Public Health Service agencies indicate that this is a unique feasibility study and the proposed data collection efforts do not duplicate any other data collections conducted by CDC or other Federal agencies.

A.5. Impacts on Small Businesses or Other Small Entities

There is no burden on small businesses or other small entities. No small businesses will be involved in this activity. The surveys will be completed at the convenience of the participants and will not impact the participants' employers.

A.6. Consequences of Collecting the Information Less Frequently

This is a one-time request and only a pre-implementation survey and a post-implementation survey will be conducted. There is no frequency issue involved in the data collection process and the concept of collecting the information less frequently does not apply in this project. Without this information collection activity, CDC's "Learn the Signs. Act Early." team will be hampered in its ability to successfully carry out its mission of providing high-quality programs and services to the population served.

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

This request fully complies with the regulations regarding the guidelines of 5 CFR 1320.5. There are no special circumstances contained within this application.

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

A. A copy of the agency's 60-day Federal Register Notice is attached (*60-day Federal Register Notice* Attachment 2). The notice, as required by 5 CFR 1320.8 (d), was published on May 11, 2011 (volume 76, number 91, pages 27325-27326). No public comments were received in response to this notice.

B. The CDC team collaborated with Danya International staff (Contractor) on the development of the data collection instruments and thus represents consultation outside the agency. Danya staff are highly experienced in program evaluation. The following Danya International staff have participated in the development and review of the information collection procedures:

Danya International collaborators:

Jennifer Scherer, PhD, Vice President of Program Management and Evaluation, Danya International, Inc., 8737 Colesville Road, Suite 1100, Silver Spring, MD 20910; jscherer@danya.com

Baoyi Zheng, PhD, Senior Evaluation Specialist, Danya International, Inc., 9 Corporate Boulevard, Suite 100, Atlanta, GA 30329; bzheng@danya.com

Karen M. Gavin-Evans, PhD, Senior Director, Program Management & Evaluation, Danya International, Inc., 8737 Colesville Road, Suite 1100, Silver Spring, MD 20910; kgavin-evans@danya.com

CDC collaborators:

Katie Green, MPH, CHES, Health Communication Specialist, Learn the Signs Act Early Team, Prevention Research Branch, NCBDDD/CDC, 1600 Clifton Rd. Mail Stop E86, Atlanta, GA 30333; KKGreen@cdc.gov; 404-498-3872

Denise Levis, PhD, Health Communication Specialist, Learn the Signs Act Early Team, Prevention Research Branch, NCBDDD/CDC, 1600 Clifton Rd. Mail Stop E86, Atlanta, GA 30333; IGC1@cdc.gov; 404-498-0237

Rebecca Wolf, MS, Team Lead, Learn the Signs Act Early Team, Prevention Research Branch, NCBDDD/CDC, 1600 Clifton Rd. Mail Stop E86, Atlanta, GA 30333; RWolf@cdc.gov; 404-498-3951

Tom Bartenfeld, PhD, Behavioral Scientist, Office of the Director, NCBDDD/CDC, 1600 Clifton Rd. Mail Stop E87, Atlanta, GA 30333; 404-498-6766

A. 9. Explanation of Any Payment or Gift to Respondents

No incentive, remuneration, or gifts will be provided to participants of this data collection.

A.10. Assurance of Confidentiality Provided to Respondents

This information collection involves anonymous data collection. The types of information to be collected in the pre-implementation and post-implementation surveys include information about the respondents' demographics, such as age and race/ethnicity, and level of education. Information will also be collected on participants' exposure to and awareness of the "Learn the Signs. Act Early." campaign and knowledge and behavior regarding child development. CDC and Danya will take every precaution to secure the information collected. Contact information will be stored in a secure area and separate from the data. No individual identifying information will be collected, so no information participants provide will be linked to the respondents' identities.

IRB Approval
This information collection has been determined not to involve research.

10.1 Privacy Impact Assessment Information

A. This submission has been reviewed by the NCBDDD Privacy Officer, who determined that the Privacy Act does not apply.

B. No "Information in Identifiable Form" (IIF) will be collected. Moreover, Danya International, Inc. will ensure the highest level of privacy by using both electronic and physical means. Danya employs a stateful-inspection packet filtering firewall to protect their network perimeter and data contained within it from sources outside of the network. Internal security is controlled using Windows NT share and file level security, and Novell NetWare NDS security. All data are password protected and secured on file servers within a locked server room. Servers are protected from unauthorized physical access by separate key lock to the network room. The contractor backs up virtual data to its DLT (Digital Liner Tape) on a nightly basis, Monday-Friday.

C. The pre-survey screener asks parents about whether or not they would be willing to complete a brief survey, thus emphasizing that the survey is voluntary. Respondents may choose not to answer questions that they do not want to answer, and they may choose to leave the interview at any time for any reason.

A.11. Justification for Sensitive Questions

No sensitive data will be collected.

A. 12. Estimates of Annualized Burden Hours and Costs

The information will be collected from parents with young children age 0-60 months in four target areas. A pre- and post-implementation survey in pen-and-paper format will be conducted in the same four target areas as part of the effort to assess the reach and impact of the campaign. The surveys will be conducted in the following target areas:

- Washington: Yakima, Benton, Franklin, and Walla Walla counties
- Missouri: St. Louis City
- Utah: Salt Lake County
- Alaska: Cities of Anchorage, Palmer, Wasilla, Homer, and Kenai

The project aims to collect 250 completed parent surveys from each of the 4 sites prior to campaign implementation and after campaign implementation (for a total of 2,000 completed surveys). It is estimated that 2,400 respondents will have to be screened in order to recruit 2,000 total survey participants. Annualized burden hours are based on the estimated time it will take for potential participants to complete the surveys (Table 1). The total annual burden for this data collection activity is 454 hours. There is no cost to respondents other than their time.

Table 1: Estimated Annualized Burden Hours

TYPE OF RESPONDENT	FORM NAME	NUMBER OF RESPONDENTS	NUMBER OF RESPONSES PER RESPONDENT	AVERAGE BURDEN PER RESPONSE (in hours)	TOTAL ANNUAL BURDEN (in hours)
Parents with young children age 0-60 months	Screener	1200	1	3/60	60
Parents with young children age 0-60 months	Pre-implementation Survey	1000	1	10/60	167
Parents with young children age 0-60 months	Screener	1200	1	3/60	60
Parents with young children age 0-60 months	Post-implementation Survey	1000	1	10/60	167
Total	-	-	-	-	454

Estimates of annualized cost to respondents

Annualized cost estimates to potential respondents, presented in Table 2, are based on mean (average) hourly wage estimates obtained from the U.S. Department of Labor, Bureau of Labor Statistics at http://www.bls.gov/ocs/. The total number of burden hours for respondents to complete their responses is 454 hours. Thus, the total annual respondent cost is $9,488.

Table 2: Estimated Annualized Burden Costs

TYPE OF RESPONDENT	FORM NAME	NUMBER OF RESPONDENTS	NUMBER OF RESPONSES PER RESPONDENT	AVERAGE BURDEN PER RESPONSE (in hours)	TOTAL ANNUAL BURDEN (in hours)	AVERAGE HOURLY WAGE RATE*	TOTAL ANNUAL RESPONDENT COST
Parents with young children age 0-60 months	Screener	1200	1	3/60	60	$21.00	$1,260
Parents with young children age 0-60 months	Pre-implementation Survey	1000	1	10/60	167	$21.00	$3,507
Parents with young children age 0-60 months	Screener	1200	1	3/60	60	$21.00	$1,260
Parents with young children age 0-60 months	Post-implementation Survey	1000	1	10/60	167	$21.00	$3,507
Total		--	--	--	--	--	$9,534

* Source: The mean hourly wage rate ($20.90) is based on the latest government statistics from U.S. Department of Labor, Bureau of Labor Statistics (for all occupations), *May 2008 National Occupational Employment and Wage Estimates.* http://www.bls.gov/oes/current/oes_nat.htm We have revised it slightly and rounded this number to $21.00.

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

Respondents participate on a purely voluntary basis and, therefore, are subject to no direct costs other than their time to participate; there are no start-up or maintenance costs. The project does not require any additional record keeping.

A. 14. Annualized Cost to the Government

The average annualized cost to the Federal Government to collect this information is $18,267.30 for the 2011-2012 calendar years. The federal government personnel estimate is based on cost of the Federal Project Officer and two Co-Principal Investigators who are responsible for the management and oversight of the project (see Table A.14).

Contractor costs include direct labor, such as development of the screener and survey, data entry, data analysis, and final report preparation; and indirect costs such as fringe, overhead, general,

and administrative fees. The four grantees are responsible for administering the survey as part of their projects, which greatly reduces the administrative costs to the government and contractor.

Table 2: Governmental Costs

		Total ($)
Federal Government Personnel Costs	CDC Project Officer (GS-13 at 10% time)	$8,500
	CDC Co-Principal Investigator (GS-15 at 5% time)	$5,492.30
	CDC Co-Principal Investigator (GS-13 at 5% time)	$4,275
Contractor Direct Labor	Task 1-3	$35,000
	Task 4-6	$32,158
	Task 7-8	$40,000
Total Indirect Cost	Contractor fees	$77,928
Combined Costs	Government + Contractor	$203,353.30
Total Annualized Cost to Government		$18,267.30

A. 15. Explanation for Program Changes or Adjustments

This is a new data collection; therefore, program changes and adjustments do not apply.

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

This is a qualitative study using surveys. Statistical methods will not be used. This data will not be used for other than descriptive purposes and no identifying information will be collected or disclosed.

Moreover, data collected will only be used to inform NCBDDD for program planning purposes. This information is for internal use only and will not be published.

A data analysis plan for the data collection is described below:

Surveys

The data from the survey will be entered into an Excel or SPSS file for qualitative data analysis for the four grantees' and CDC's evaluation reports.

Project Time Schedule:

Action Step	**Target Completion Dates**
Contract's evaluation plan submitted to CDC	May 2011
Campaign implementation kickoff	July – October 2011 (depending on site)
Submit ICR package to OMB	September 2011
Grantees conduct pre-implementation survey	Immediately after OMB approval
Grantees conduct post-implementation survey	August 2012-November 2012
Contractor to analyze survey data	December 2012-January 2013
Contractor to prepare final report	February 2013- March 2013

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

No exemption is requested. The OMB expiration date will be displayed.

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

There are no exceptions to the certification.

References

Centers for Disease Control and Prevention. (2006). "How Many Children Have Autism? at http://www.cdc.gov/ncbddd/features/counting-autism.html, accessed on September 7, 2011.

Fombonne, et al. (1997). Autism and associated medical disorders in a French epidemiological survey. *Child and Adolescent Psychiatry* 36:1561-1569.

lshii,T. & Takahashi, O. (1983). The epidemiology of autistic children in Toyota, Japan: Prevalence. *Japanese Journal of Child and Adolescent Psychiatry* 24: 311-321.

Kadesjo B., Gillberg C., and Hagberg B. (1999). Autism and Asperger syndrome in sevenyear-old children: a total population study. *Journal of Autism and Developmental Disorders* 29: 327-331.

Pierce, K., Conant, D., Hazin, R., Stoner, R., Desmond, J. (2010). "Preference for Geometric Patterns Early in Life as a Risk Factor for Autism." *Archives of General Psychiatry* 68: 101-109.

Ritvo, E.R. et al. (1989). "The UCLA-University of Utah epidemiologic survey of autism: prevalence" *American Journal of Psychiatry* 146:194-199.