4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.

5. Assess information collection costs.

Proposed Project

National Hospital Ambulatory Medical Care Survey (NHAMCS) (OMB Control Number 0920–0278, Expiration Date 02/28/2018)—Revision—National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Section 306 of the Public Health Service (PHS) Act (42 U.S.C. 242k), as amended, authorizes that the Secretary of Health and Human Services (DHHS), acting through NCHS, shall collect statistics on ''utilization of health care'' in the United States. The National Hospital Ambulatory Medical Care Survey (NHAMCS) has conducted annually since 1992. NCHS is seeking OMB approval to extend this survey for an additional three years.

The target universe of the NHAMCS is in-person visits made to emergency departments (EDs) of non-Federal, short-stay hospitals (hospitals with an average length of stay of less than 30 days) that have at least six beds for inpatient use, and with a specialty of general (medical or surgical) or children's general.

NHAMCS was initiated to complement the National Ambulatory Medical Care Survey (NAMCS, OMB Control Number 0920–0234, Expiration Date 03/31/2019), which provides similar data concerning patient visits to physicians' offices. NAMCS and NHAMCS are the principal sources of data on ambulatory care provided in the United States.

NHAMCS provides a range of baseline data on the characteristics of the users and providers of hospital ambulatory medical care. Data collected include patients' demographic characteristics, reason(s) for visit, providers' diagnoses, diagnostic services, medications, and disposition. These data, together with trend data, may be used to monitor the effects of change in the health care system, for the planning of health services, improving medical education, determining health care work force needs, and assessing the health status of the population.

Starting 2018, CDC will implement the ED component of NHAMCS. However, between December 2017 and May 2018, the 2017 survey will run concurrently with the 2018 survey. This is typical with any data collection cycle: It begin in the last month of the preceding year and ends around the middle of the following year. For the 2017 data collection, CDC will collect information on all three settings (ED, OPD, and ASL). For this three-year request, CDC does not expect substantive changes or supplements for the survey.

Users of NHAMCS data include, but are not limited to, congressional offices, Federal agencies, state and local governments, schools of public health, colleges and Universities, private industry, nonprofit foundations, professional associations, clinicians, researchers, administrators, and health planners.

There are no costs to the respondents other than their time. The total estimated annualized burden hours are 1,806.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Hospital Chief Executive Officer	Hospital Induction 2017 Data Collection.	60	1	75/60	75
Hospital Chief Executive Officer	Hospital Induction 2018+ Data Collection.	340	1	75/60	425
Ancillary Service Executive	Ambulatory Unit Induction (ED, OPD and ASL).	810	1	15/60	203
Ancillary Service Executive	Ambulatory Unit Induction (ED only)	583	1	15/60	146
Medical Record Clerk	Retrieving Patient Records (ED, OPD and ASL).	396	144	1/60	950
Ancillary Service Executive—Reabstraction.	Reabstraction Telephone Call (ED, OPD and ASL).	29	1	5/60	2
Medical Record Clerk—Reabstraction.	Pulling and re-filing Patient Records (ED, OPD and ASL).	29	10	1/60	5
Total					1,806

Leroy A. Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–18–1190]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled ZEN Colombia Study: Zika in Pregnant Women and Children in Colombia to the Office of Management and Budget (OMB) for review and approval. CDC previously published a ''Proposed Data Collection Submitted for Public Comment and Recommendations'' notice on August 30, 2017 to obtain comments from the public and affected agencies. CDC did not receive comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570 or send an email to *omb@cdc.gov.* Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW., Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

Proposed Project

ZEN Colombia Study: Zika in Pregnant Women and Children in Colombia (OMB Control Number 0920–1190, expires 07/31/2019)—Revision—National Center on Birth Defects and Developmental Disabilities, Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Zika virus (ZIKV) infection is a mosquito-borne flavivirus transmitted by Aedes species mosquitoes, and also through sexual and mother-to-child transmission; laboratory-acquired infections have also been reported. Health officials observed sporadic evidence of human ZIKV infection in Africa and Asia prior to 2007, when an outbreak of ZIKV caused an estimated 5,000 infections in the State of Yap, Federated States of Micronesia. Since then, health officials have found evidence of ZIKV in 65 countries and territories, mostly in Central and South America. Common symptoms of ZIKV in humans include rash, fever, arthralgia, and nonpurulent conjunctivitis. The illness is usually mild and self-limited, with symptoms lasting for several days to a week; however, based on previous outbreaks, some infections are asymptomatic. The prevalence of asymptomatic infection in the current Central and South American epidemic is unknown.

Although the clinical presentation of ZIKV infection is typically mild, ZIKV infection in pregnancy can cause microcephaly and related brain abnormalities when fetuses are exposed in utero. Other adverse pregnancy outcomes related to ZIKV infection remain under study, and include pregnancy loss, other major birth defects, arthrogryposis, eye abnormalities, and neurologic abnormalities.

As the spectrum of adverse health outcomes potentially related to ZIKV infection continues to grow, large gaps remain in our understanding of ZIKV infection in pregnancy. These include the full spectrum of adverse health outcomes in pregnant women, fetuses, and infants associated with ZIKV infection; the relative contributions of sexual transmission and mosquito-borne transmission to occurrence of infections in pregnancy; and variability in the risk of adverse fetal outcomes by gestational week of maternal infection or symptoms of infection. There is an urgency to fill these large gaps in our understanding given the rapidity of the epidemic's spread and the severe health outcomes associated with ZIKV to date.

Colombia's Instituto Nacional de Salud (INS) began surveillance for ZIKV in 2015, reporting the first autochthonous transmission in October 2015 in the north of the country. As of December 2016, Colombia has reported over 106,000-suspected ZIKV cases, with over 19,000 of them among pregnant women. With a causal link established between ZIKV infection in pregnancy and microcephaly, there is an urgent need to understand: How to prevent ZIKV transmission; the full spectrum of adverse maternal, fetal, and infant health outcomes associated with ZIKV infection; and risk factors for occurrence of these outcomes. To answer these questions, INS and the CDC will follow 5,000 women enrolled in the first trimester of pregnancy, their male partners, and their infants, in various cities in Colombia where ZIKV transmission is currently ongoing.

The primary study objectives are to: (1) Describe the sociodemographic and clinical characteristics of the study population; (2) Identify risk factors for ZIKV infection in pregnant women and their infants. These include behaviors such as use of mosquito-bite prevention measures or condoms, and factors associated with maternal-to-child transmission; (3) Assess the risk for adverse maternal, fetal, and infant outcomes associated with ZIKV infection; (4) Assess modifiers of the risk for adverse outcomes among pregnant women and their infants following ZIKV infection. This includes investigating associations with gestational age at infection, presence of ZIKV symptoms, extended viremia, mode of transmission, prior infections or immunizations, and co-infections.

The project aims to enroll approximately 5,000 women, 1,250 male partners, 4,500 newborns, and a subset of 900 infants/children. Pregnant women will be recruited in the first trimester of pregnancy for study enrollment, followed by assessments during pregnancy (every other week until 32 weeks gestation and monthly thereafter), and within 10 days postpartum. At all visits, participants will complete visit-specific questionnaires. In addition to the questionnaires, at all pregnancy and delivery visits, participants will receive Colombian national recommended clinical care and provide samples for laboratory testing.

Researchers will recruit male partners around the time of the pregnant partners' study enrollment, followed by monthly visits until his pregnant partner reaches the third trimester (approximately 27 weeks gestation). If the male partner contracts ZIKV during this time, visits will occur every other week until the partner has two negative consecutive tests for ZIKV or the pregnancy ends. At all study visits, male partners will complete visit-specific questionnaires and provide samples for laboratory testing.

Researchers will follow all newborns of mothers participating in the study every other week from birth to 6 months of age. At all visits, infants will receive national recommended clinical care (at birth and follow-up visits at 1, 2, 3, and 6 months), provide samples for laboratory testing, and mothers will complete study-specific questionnaires about infant ZIKV symptoms and developmental milestones. During follow-up, infants will also have cranial ultrasounds, their head circumference measured, and hearing and vision tests. For mothers and their infants and as part of clinical care, researchers will abstract relevant information from medical records.

The revised information collection package includes the following changes.

During the data collection period, researchers will follow a subset of 900 infants until 2-years of age. A parent of each of these infants will answer a questionnaire at 6, 9, 12, 18, and 24 months, as well as have other clinical assessments performed to examine developmental delays.

CDC will use study results to guide recommendations made by both INS and CDC to prevent ZIKV infection; to improve counseling of patients about risks to themselves, their pregnancies, their partners, and their infants; and to help agencies prepare to provide services to affected children and families. Participation in this study is voluntary and there are no costs to participants other than their time.

The total burden hours are 14,210.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Pregnant Women	Pregnant Women Eligibility Questionnaire	600	1	5/60
	Pregnant Women Enrollment Questionnaire	500	1	35/60
	Adult Symptoms Questionnaire	500	15	10/60
	Pregnant Women Follow-up Questionnaire	500	8	15/60
	Infant Symptoms Questionnaire	2,250	14	10/60
	Parent-Child Eligibility Questionnaire	1,000	1	5/60
	Parent-Child Enrollment Questionnaire	900	1	20/60
	Parent-Child Follow-up Questionnaire	900	4	15/60
	Ages and Stages Questionnaire: 2 and 6 Month Visits.	2,250	2	15/60
	Ages and Stages Questionnaire: 12 and 24 Month Visits.	900	2	15/60
	Bayley Scales of Infant and Toddler Development.	900	3	30/60
	Strengths and Difficulties Questionnaire	900	1	5/60
	Peabody Developmental Motor Scales	900	1	30/60
	Parenting Stress Index IV	900	5	10/60
	Center for Epidemiologic Studies Depression Scale.	900	5	5/60
	Test of Nonverbal Intelligence	900	1	20/60
Male partners	Male Partner Eligibility Questionnaire	150	1	5/60
	Male Enrollment Questionnaire	125	1	25/60
	Adult Symptoms Questionnaire	125	7	10/60

Leroy A. Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Personal Responsibility Education Program (PREP) Multi-Component Evaluation Extension.

OMB No.: 0970–0398.

Description: The Family and Youth Services Bureau (FYSB) and the Office of Planning, Research, Evaluation (OPRE) in the Administration for Children and Families (ACF) are requesting an extension without change of a currently approved information collection (OMB No. 0970–0398). The purpose of the extension is to complete the ongoing follow-up data collection for the Personal Responsibility Education Program (PREP) Multi-Component Evaluation, which was designed to document how PREP programs are designed and implemented in the field, collect performance measure data for PREP programs, and assess the effectiveness of selected PREP-funded programs.

The PREP Multi-Component Evaluation contains three components: A Design and Implementation Study, a Performance Analysis Study, and an Impact and In-Depth Implementation Study. Data collection related to the Design and Implementation Study is complete; data collection related to the Performance Analysis Study will be complete in late summer 2017. This notice is specific to data collection activities for the Impact and In-Depth Implementation Study, which is being conducted in four sites. The proposed extension is necessary to complete ongoing follow-up data collection. The resulting data will be used in a rigorous program impact analysis to assess the effectiveness of each program in reducing teen sexual activity and associated risk behaviors.

Respondents: Youth participants who agreed to participate in the study upon enrollment in the four impact study sites.

ANNUAL BURDEN ESTIMATES

Instrument	Total/annual number of respondents	Number of responses per respondents	Average burden hours per response	Total/annual burden hours
Second follow-up survey	325	1	.75	244