coordinated approach for effectively translating genomic applications into clinical practice and health policy is still needed. In response to this need, CDC's Office of Genomics and Disease Prevention (OGDP) initiated the EGAPP Project in fall 2004. The ultimate goal of the project is to develop and evaluate a coordinated, systematic process for assessing genetic tests and other genomic applications in transition from research to clinical and public health practice. To support this goal, an independent, non-federal, multidisciplinary EGAPP Working Group was established in April, 2005. The roles of the Working Group are to prioritize and select genomic applications for evaluation, establish methods and processes, monitor progress of commissioned evidence reports, and develop conclusions and recommendations based on the evidence. The knowledge and experience gained through the project will be used to inform the development of a sustainable process for assessing the safety and efficacy of emerging genetic tests.

We are proposing an evaluation research activity to assess outcomes of the EGAPP Project. The study will be conducted in collaboration with outside consultants who will work with CDC to design the study, collect data for the study, conduct data analyses, and develop written reports of results.

The purpose of this evaluation research activity is to collect information on the value and impact of the EGAPP process and the products developed and disseminated (e.g., evidence reviews, published evidence summaries, published Working Group recommendations, informational messages) by surveying members of four key stakeholder groups identified for the EGAPP pilot project. The four key stakeholder groups selected are: Healthcare providers (e.g., physicians, mid-level practitioners, nurses), policy makers, healthcare payers (e.g., health plans, insurers) and purchasers (e.g., organizations purchasing healthcare), and consumers. Surveying of consumers will be targeted to advocacy and disease-specific support groups and OGDP Web site visitors.

Surveys will be administered during four survey periods staggered at intervals of six months. Feedback from healthcare providers and payers suggests that they are the most interested and ready to receive and use EGAPP products (e.g., evidence reports and Working Group recommendations). Therefore, they will be the subjects of *Survey 1* (about 6 months after release of products) and *Survey 3* (one year later). Consumers, policy makers, and healthcare purchasers are expected to receive and be impacted by information developed by EGAPP later. Therefore, these groups will be the subjects of *Survey 2* (6 months after Survey 1) and *Survey 4* (one year later).

The second mechanism for identifying participants will be through the EGAPP Web site. During specified periods of time, individuals accessing the Web site will be asked to participate. There is no cost to the respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Respondent	Form	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
Healthcare Providers:					
Primary Care Providers	Healthcare Provider Survey	385	1	10/60	64
Specialists		385	1	10/60	64
Genetic Counselors		200	1	10/60	33
Mid-level Practitioners		385	1	10/60	64
Nurses		385	1	10/60	64
Targeted Consumers	General Survey	770	1	10/60	128
Healthcare Payers	Policy/Payer Survey	100	1	10/60	17
Policy Makers	Policy Survey	50	1	10/60	8
Healthcare Purchasers	Purchase Survey	31	1	10/60	5
Total Burden					447

Dated: June 20, 2006.

Joan F. Karr,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–06–05CJ]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404–639–5960 and send comments to Seleda Perryman, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS–D74, Atlanta, GA 30333 or send an e-mail to *omb@cdc.gov*.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information

on respondents, including through the use of automated collection techniques or other forms of information technology. Written comments should be received within 60 days of this notice.

Proposed Project

Colorectal Cancer Screening Demonstration Program—New—Division of Cancer Prevention and Control (DCPC), National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The CDC, DCPC is requesting approval to collect individual patient-level screening, diagnostic, and treatment data in association with a new colorectal cancer screening demonstration program. DCPC is funding 5 cooperative agreements from fiscal year (FY) 2005–2008 for implementation of new colorectal cancer (CRC) demonstration programs. These 3-year demonstration programs are designed to increase population-based CRC screening among persons 50 years and older with low income and inadequate or no health insurance coverage in a geographically defined area.

Colorectal Cancer (CRC) is the second leading cause of cancer-related deaths in the United States, following lung cancer. Based on scientific evidence which indicates that regular screening is effective in reducing CRC incidence and mortality, regular CRC screening is now recommended for average-risk persons with one or a combination of the following tests: Fecal occult blood testing (FOBT), flexible sigmoidoscopy, colonoscopy, and/or double-contrast barium enema (DCBE). Fecal immunochemical testing (FIT) is considered an acceptable alternative to FOBT. In the absence of evidence indicating a single most effective test, selected programs will be able to choose which screening test(s) they will use from the above list of recommended tests.

All funded programs will be required to submit patient-level data on CRC screening and diagnostic services provided as part of this demonstration project. This information will be used to assess the quality and appropriateness of the services delivered.

Programs that receive CDC funding to provide screening and diagnostic services will collect individual patient-level data to capture demographic information, clinical services and outcomes, and submit these data to CDC on a quarterly basis. While CDC funds will not be used for treatment, programs will need to monitor treatment and document that patients are receiving appropriate treatment services. Submitted data must contain no patient identifiers.

All programs will additionally submit annual cost data to CDC to be used to monitor cost and cost-effectiveness over the 3-year program period.

The additional burden to these respondents will be small, since CDC will only select programs that are already performing some CRC screening, and will therefore already be collecting these types of data. Data collection for both patient-level and cost data will continue over the 3 years of the demonstration programs.

In the burden table below, two data collection forms will be used: Patient-level clinical data collection forms and cost data collection forms. The data will be collected from the 5 cooperative agreement recipients, i.e., the respondents. The estimated number of responses represents the number of patients receiving clinical services per recipient program, one report per patient per quarterly reporting period (estimated at 70 patients per program per quarter). This would result in an estimated annualized burden for the quarterly reports of 583 hours. Additionally, respondents will report annual cost data. For reporting the annual cost data, the respondents will submit only one report each for the entire year.

There is no cost to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Form type	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
Quarterly patient-level clinical data	5	280	25/60	583
Annual cost data	5	1	25/60	2
Total				585

Dated: June 20, 2006.

Joan F. Karr,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–06–06BJ]

Proposed Data Collections Submitted for Public Comment and Recommendations

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Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c)