REQUEST FOR OMB REVIEW AND
REINSTATEMENT WITH CHANGES

ESTIMATING THE CAPACITY FOR NATIONAL AND STATE-LEVEL COLORECTAL CANCER SCREENING THROUGH A SURVEY OF ENDOSCOPIC CAPACITY (SECAP II)

Previous Title: "National Survey of Endoscopic Capacity"

OMB No. 0920-0539

SUPPORTING STATEMENT

PART B: COLLECTIONS OF INFORMATION
EMPLOYING STATISTICAL METHODS

May 2010

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List of Attachments

B.1. Respondent Universe and Sampling Methods

The respondent universe and sampling methods for the proposed SECAP II study are similar to those used in the previous *National Survey of Endoscopic Capacity* (OMB No. 0920-0539, exp. 3/31/2003) and *State Survey of Endoscopic Capacity* (OMB No. 0920-0590, exp. 6/30/2006). As was done for the previous national and state SECAP studies, in the proposed SECAP II national study a random sample of facilities will be surveyed and in the proposed SECAP II state study the universe of facilities will be surveyed in up to 18 selected states.

Respondent Universe

The respondent universe for the proposed national and state SECAP II surveys is all facilities that use lower GI flexible endoscopic equipment for the detection of colorectal cancer in adults. This will include single-specialty and multi-specialty physician practices, single-specialty and multi-specialty ambulatory endoscopy/surgery centers, hospitals, medical clinics, and managed care organizations. Medical facilities that screen for colorectal cancer only using non-endoscopic methods (e.g., FOBT, barium enema, computed tomographic colonography) will not be included in the study. In addition, the following facilities will be excluded from the study:

- Facilities located outside of the United States or its territories
- Facilities that no longer perform colorectal cancer screening
- Facilities that perform lower endoscopic procedures only for other purposes (e.g. staging of other cancers)
- Pediatric practices and other practices that do not screen adults
- Veterinarians

National survey. Based on the results of the previous national SECAP study, we estimate that approximately 11,005 facilities in the U.S. perform lower GI endoscopy to screen for colorectal cancer in adults. The estimated size of the respondent universe, by region and urban/rural practice location, is shown in Table B.1-1.

B.1-1. Estimated Size of Respondent Universe, by Region and Urban/Rural Location

	Urban	Rural	Total
Region			
Northeast	1,698	364	2,062
Midwest	1,743	911	2,654
South	2,842	1,147	3,989
West	1,778	522	2,300
Total	8,061	2,944	11,005

State surveys. The size of the respondent universe will vary by state—with an average of approximately 130 facilities per state that were not previously sampled in the national survey. See Attachment L, Preliminary List of Participants in the State Survey.

Sampling Frame

Three manufacturers—Olympus America Inc., Pentax Precision Instrument Corporation, and Fujinon Inc.—currently distribute lower GI endoscopic equipment (sigmoidoscopes and colonoscopes) in the United States. These manufacturers collectively represent >95% of the endoscopic market share. All three companies participated in the previous national and state SECAP studies by providing the names and addresses of facilities that purchased or leased lower GI endoscopic equipment from 1996-2000, and from 2001-2003. For the SECAP II study, we will request sales and lease data from 2004-2009. The purchaser lists from the three manufacturers will be merged and duplicate addresses removed. The merged list will represent the universe of practices that own lower endoscopic equipment used for the detection of colorectal cancer.

Sampling Plan

National survey. For the national capacity survey, a random sample of health care facilities will be selected to ensure that all regions, as well as both urban/rural practice locations, are represented proportionately in the sample. Region will be defined by the four Census regions (e.g., Northwest, Midwest, South, West). To define urban/rural practice location, facilities will be classified using a zip code version of the rural-urban commuting area (RUCA) coding scheme developed by the Health Resources and Service Administration's Federal Office of Rural Health Policy, the Department of Agriculture's Economic Research Service, and the WWAMI (Washington, Wyoming, Alaska, Montana, Idaho) Rural Health Research Center at the University of Washington. RUCA codes are based on standard U.S. Census Bureau definitions of urban areas and urban places, definitions which take into account both population density and population work commuting patterns. The coding scheme is based on Census tracts rather than on geographically less specific county-based definitions that tend to under- and over-bound the actual boundaries of cities and towns. As we did in the previous SECAP studies, the tract-based coding scheme will be applied to the facility zip codes using a previously defined algorithm described in detail on the Internet (http://www.fammed.washington.edu/wwamirhrc/rucas/rucas.html). To yield a rural-urban dichotomy, codes 4 (large town census tract) to 10 (isolated small rural census tract) will be considered to be rural, and codes 1 (urban core census tract) to 3 (census tract weakly tied to urban core) will be considered to be urban.

Once the facilities in the sampling frame have been classified by U.S. Census region and rural/urban location, we will select an equal proportion of facilities from each of the eight cells. Since 27% of the facilities in the universe are likely to be located in rural areas, we will not need to oversample facilities in rural areas to ensure that rural facilities are adequately represented in the sample.

A total of 2,100 facilities will be selected for the national capacity survey. Screening calls will be made to determine whether or not the facilities are eligible for inclusion in the study. Based on data from the previous national and state capacity studies, we estimate that approximately 15% of the facilities selected will not be able to be located or will be ineligible because they do not perform lower GI endoscopic procedures in adults. Therefore, of the 2,100 facilities that are

screened, we expect that approximately 1,800 facilities will be eligible for inclusion in the national survey. An estimate of sample size for the national capacity survey, by region and urban/rural practice location, is presented in Table B.1-2.

B.1-2 Estimated Sample Size for the National SECAP II Survey, by Region and Urban/Rural Location

	Urban	Rural	Total
Region			
Northeast	278	60	337
Midwest	285	149	434
South	465	188	652
West	291	85	376
Total	1,318	482	1,800

State surveys. The sampling frame to be used in the national capacity survey will also be used to identify the facilities to be surveyed in the state capacity surveys. The list of facilities will be sorted by state to identify the facilities that are eligible for inclusion in the state surveys. In conducting the previous state capacity surveys, we found that states were interested in receiving capacity estimates for different regions of the state, in addition to capacity estimates for the entire state. To provide these estimates, we will work with the selected states to identify sub-state regions (based on state health planning regions). The number of regions will vary depending on the size and population of the state. Each facility will be assigned a regional identifier for use in reporting the results of the data analysis.

Response Rate

To minimize possible bias from nonresponse and to maximize statistical power, the study aims to achieve a response rate of at least 80%. The response rate in the previous national SECAP study was 75%. In the previous state SECAP study, the overall response rate in the 15 state surveys averaged 82%. Details of methods that will be used to maximize response rates are described in Section B.3 (Methods to Maximize Response Rates and Deal with Nonresponse).

Sample Size and Statistical Power

National survey. As described above, a random sample of health care facilities will be selected for inclusion in the SECAP II study. The sample size for the national survey has been determined to insure precision of the key statistics (e.g., mean number of colonoscopies and flexible sigmoidoscopies performed per facility per week). This sample size will also result in precise estimates of health provider and practice characteristics. To approximate the precision of the mean numbers of procedures performed, we utilize data from the previous national capacity survey that was conducted in 2002.

It is anticipated that approximately 1,440 of the 1,800 facilities (80%) that are mailed surveys

will return completed questionnaires. However, some facilities will only perform flexible sigmoidoscopy, while other facilities will only perform colonoscopy. Among facilities that perform lower endoscopies, about 76% of these will perform colonoscopies. Furthermore, it is also expected that about 19.3%, 22.8% and 57.9% of the facilities will be physician practices, ambulatory surgery centers and hospitals, respectively. Among facilities surveyed in the previous national SECAP study, the mean unused capacity per week was about 28.7 (standard deviation = 40.6). Given the same variation in the estimated unused capacity found in the previous national SECAP study, 1,440 respondents will be sufficient to identify statistically significant differences in unused capacity between physician practices and ambulatory surgery centers when the difference is at least at least 5.3% of the mean with 80% power and a confidence level of 95%. Similarly, this sample size is expected to identify statistically significant differences between ambulatory surgery centers and hospitals or between hospitals and physician practices when the difference is at least 4.2 or 4.4% of the mean, respectively.

State surveys. The target population for the survey will include all facilities where lower GI endoscopy is used to detect colorectal cancer. If a sample of facilities were surveyed in each state, the variability associated with key parameters (e.g., the mean numbers of flexible sigmoidoscopies and colonoscopies performed in each facility) would be unacceptably large. Given the relatively small number of facilities that perform lower GI endoscopic procedures in each state, the variability in the total number of procedures performed by facility, and the need to provide states with estimates by sub-state region, it will be necessary to survey the universe—rather than a sample—of facilities in each state.

B.2. Procedures for the Collection of Information

Development of the SECAP II Survey Instrument

The SECAP II survey instrument is a slightly modified version of the survey instruments that were used in the previous national and state SECAP studies. Copies of the survey instruments to be used in the national and state SECAP II surveys are included as Attachments E1 and F1, respectively. In developing the SECAP II questionnaire, we sought input from health care providers who perform lower GI endoscopies and who represent different physician specialties (gastroenterologists, primary care physicians, surgeons, non-physician endoscopists). These consultants were also selected because they are well-known as research experts in the field of colorectal cancer screening, and could provide valuable input on both the contribution of the data to the field, as well as the appropriateness of the survey questions. In light of the changing environment in which lower GI endoscopy is being performed, the consultants recommended adding some questions, deleting some questions, and making minor wording and/or formatting changes to improve the readability of the questions. Experienced Battelle survey operations staff formatted the survey questionnaire for ease of completion, as well as to facilitate coding and data entry. In addition, as described in Section B.4 (Tests of Procedures or Methods to be Undertaken), the SECAP II survey questionnaire was pre-tested at nine facilities.

Data Collection Procedures

The data collection methods for the proposed SECAP II study are similar to those used in the

previous national and state SECAP studies. As was done for the previous national SECAP study, a random sample of facilities will be surveyed. As was done for the previous state SECAP study, the universe of facilities will be surveyed in up to 18 selected states. The survey will be administered by the Battelle Centers for Public Health Research and Evaluation. The SECAP II study will utilize the same data collection procedures that were used in the previous national and state SECAP studies.

- ***Screening telephone call.*** Once the sample of facilities has been selected, a screening telephone call will be made (1) to confirm that the facility is eligible for inclusion in the study and (2) obtain the name and address of the individual who is most knowledgeable about the use of the endoscopic equipment. Copies of the screening telephone call script to be used in the national and state SECAP II surveys are included as Attachments E2 and F2, respectively.

- ***Administration of the mail survey.*** Following the telephone screening call, a survey packet will be sent by Federal Express to the individual identified during the screening call. The packet will include: (1) the survey questionnaire with a pre-printed ID number; (2) a personal cover letter emphasizing the importance of the study; (3) a stamped, self-addressed return envelope; and (4) a reimbursement of $40 for the individual's time and effort given to the study. The cover letter, which will stress the importance of the study, will be signed by Laura Seeff MD, Acting Branch Chief, Comprehensive Cancer Control Branch, Division of Cancer Prevention and Control, CDC. The letter will ask respondents to return the completed survey in the postage-paid, return envelope. The survey cover letter will provide the name and toll-free telephone number of a staff member to call with questions about the study. It will also include the name and telephone number of a person to call with questions regarding Human Subjects protection. Copies of the cover letter that will accompany the national and state SECAP II surveys are included as Attachments E3 and F3, respectively.

- ***Thank you/reminder postcard.*** Within two weeks of the initial mailing, a thank-you/reminder postcard will be sent to each respondent to encourage survey completion. The postcard will include a toll-free number that can be called if the respondent has any questions about completing the survey or needs to have another copy of the survey mailed. A copy of the reminder postcard is included as Attachment G1.

- ***Telephone follow-up with non-respondents.*** A survey tracking database will be used to track all returned surveys. Two weeks after the postcard reminder is mailed, a telephone call will be placed to respondents who have not returned a completed questionnaire. This call will serve as a reminder, and allow the opportunity to answer any questions that may be delaying survey completion. A second telephone call will be made if a completed survey is not received within two weeks following the first follow-up telephone call. A third (and final) telephone call will be made if a completed survey is not received within two weeks following the second call. The script for the reminder telephone calls is included as Attachment G2.

State-specific versions of the script for the telephone screening call (Attachment F2), survey

cover letter (Attachment F3), and mail survey (Attachment F1) will be prepared. Each version of the survey will be printed with a different color cover. The questions to be asked in the screening telephone call and in the mail survey for the state capacity surveys are identical to the questions that will be asked in the national capacity survey. The reminder postcard (Attachment G1) and script for the reminder telephone call (Attachment G2) for the state survey will be the identical to those used in the national survey.

Each respondent will be assigned a unique study identification number. Surveys mailed to respondents, as well as the electronic data files containing the survey data, will be identified only by study identification number. Neither the mail surveys nor the electronic files of the survey data will contain names, addresses or telephone numbers of facilities or respondents.

Training Battelle Data Collection Staff

Before data collection begins, we will train all Battelle data collection staff. This will include the telephone interviewers who will make the screening and follow-up telephone calls, staff who will mail the facility surveys, and data entry staff who will handle the completed questionnaires. Staff will be trained to understand the purpose, sponsorship, background, objectives, and importance of the project, as well as their specific role and activities on the study. In training staff, we will emphasize the steps that will be taken to safeguard the data that are collected. Telephone interviewers also will receive training in the use of the screening script and the specific procedures for the study.

Quality Control Procedures

Beginning with study initiation and continuing through all phases of data collection and analysis, steps will be taken to ensure that the data collected are of the highest quality possible. Editors who have been trained specifically for this project will manually edit each questionnaire for completeness, accuracy and consistency. The editors will check for skip pattern errors and inconsistent or illogical answers; logs of inconsistencies and their resolution will be maintained. After the survey responses are edited and coded, the questionnaires will be key-entered and an electronic data file will be produced. Battelle programmers will develop data entry programs that minimize data entry errors by screen clarity. All data entry will be 100 percent verified by someone other than the original keyer, and all errors will be checked and corrected. Completed surveys will be stored in locked file cabinets. All electronic databases and survey data files will be password protected and access to the files will be limited to authorized project staff.

Monitoring the progress of data collection activities. A management information system, developed for the previous national and state SECAP studies will be tailored to monitor data collection activities on the SECAP II surveys. The database will store all background data known about each respondent. In addition, the database will contain the dates of screening and follow-up telephone calls, the dates that questionnaires and other survey materials are mailed, and the dates that completed surveys are received. Mailing labels and personalized letters will be generated from this system. Follow-up mailing dates will then be computed by the tracking system to ensure timely mailing of necessary and appropriate follow-up materials. The management information system will also be used to generate weekly reports summarizing the

status of the data collection activity throughout the data collection period.

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

Health care providers who spend most of their time on direct patient care are a particularly difficult group to survey. Nevertheless, Battelle has developed methods that have been successful in achieving response rates to surveys of health care providers in excess of 80%. The response rate achieved in the previous national SECAP study was 75% and the overall response rate to the 15 state surveys that were conducted in the previous state SECAP study was 82%. The same procedures that were successful in achieving high response rates to health care provider surveys, including the previous national and state SECAP surveys, will be used for the SECAP II study. In particular, the following steps will be taken to achieve an 80% response rate in the SECAP II surveys: (1) using a screening call to identify the most knowledgeable person to complete the survey; (2) sending a personally addressed cover letter emphasizing the importance of the study; (3) providing the name and telephone number of the Battelle Project Leader to call with questions regarding the survey; (4) sending survey materials by Federal Express to insure fast delivery of the survey; (5) including a postage-paid envelope for returning the completed survey; (6) providing a $40 incentive; (7) sending the incentive with the survey, rather than upon receipt of a completed questionnaire; and (8) sending a thank you/reminder postcard and making up to three telephone reminder phone calls. Since the name and address of the individual will be confirmed before the questionnaire is sent, we do not expect many questionnaires to be returned because of incorrect addresses.

Once data collection has been completed, we will conduct a non-response analysis and adjust for non-response in our calculation of sampling weights. The base weight for each survey respondent will be the inverse of the respondent's probability of selection. To adjust for non-response we will use sample weighting class adjustments. The variables that are the best candidates for the formation of weighting classes are those variables that are: (1) available for respondents as well as non-respondents; (2) highly correlated with the survey variables; and (3) highly correlated with the likelihood of non-response. Variables available for the non-response analysis will be limited to region and urban/rural location, and those variables obtained during the screening telephone interview (e.g., type of facility). Weighting class adjustment does remove the component of bias that is due to the variability of the response rates across the weighting classes; however, it does not eliminate the bias component that is due to the differences of survey statistics of respondents and non-respondents within the weighting classes.

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

The telephone screening script and the survey instrument that were used successfully in the previous *National Survey of Endoscopic Capacity* (OMB No. 0920-0539, exp. 3/31/2003) and *State Survey of Endoscopic Capacity* (OMB No. 0920-0590, exp. 6/30/2006) were modified slightly for the proposed SECAP II study. In the previous national and state SECAP studies, a telephone screening call was shown to be a successful way of identifying the appropriate respondent for the mail survey, even in large hospital settings. Survey questionnaires were then sent by Federal Express to the respondents identified during the telephone screening calls. A postcard reminder and up to 3 follow-up telephone calls were used to follow-up with non-

respondents. Utilizing these survey procedures, the response rates achieved in the previous national and state capacity surveys were 75% and 82%, respectively. A summary of the response rate achieved in the Years 2 and 3 of the previous state SECAP study after each stage of survey administration is presented in Table B.4-1.

B.4-1 Response Rate Achieved by Stage of Survey Administration

	Response Rate	**Cumulative Response Rate**
Initial mailing	41%	41%
Postcard reminder	21%	62%
First follow-up call	10%	72%
Second follow-up call	5%	77%
Third follow-up call	6%	83%

The SECAP II telephone screening script and the mail survey were pretested at six facilities that perform lower GI endoscopy. Of the six facilities, three were urban hospitals (including one VA hospital and one Indian Health Center), one was a rural hospital, one was a gastroenterology ASC and one was a surgery ASC. The purpose of the pretest was to obtain an estimate of respondent burden, as well as to obtain comments and advice about the format, appropriateness and relevance of survey questions. Respondents were paid $70 each for completing the survey and a 30-minute phone call for debriefing. Four of the respondents were nurse managers at their facility, one respondent was a nurse endoscopist, and one respondent was a gastroenterologist.

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

Laura Seeff, M.D., of the Division of Cancer Prevention and Control, is the Principal Investigator and Technical Monitor for the study, and has overall responsibility for overseeing the design, conduct, and analysis of the study. She will also approve and receive all contract deliverables. Telephone: 770-488-3223. E-mail address: lvs3@cdc.gov.

The survey instrument, sampling and data collection procedures, and analysis plan were designed in collaboration with researchers at Battelle Centers for Public Health Research and Evaluation (CPHRE) under contract No. 200-2008-27956; Task Order 02 with the Centers for Disease Control and Prevention. Battelle will conduct data collection and will perform data analysis, in consultation with the CDC investigators.

Diane L. Manninen, Ph.D., has overall technical and financial responsibility for the study at Battelle and led the Battelle effort to design this protocol. She will direct the overall data collection and analysis effort. She will also be responsible for writing the project reports. Telephone: 206-528-3140. E-mail address: manninen@battelle.org.

Other CDC and Battelle personnel involved in designing the study protocol, development of the data collection instruments, data collection, and analysis include:

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