Supporting Statement B for Request for Clearance:

Ambulatory Care Pretest: National Hospital Care Survey

OMB No. 0920-NEW

Contact Information:

Carol DeFrances, Ph.D.
Lead Statistician, Hospital Care Team
Ambulatory and Hospital Care Statistics Branch
Division of Health Care Statistics
National Center for Health Statistics/CDC
3311 Toledo Road, Room 3409
Hyattsville, MD 20782
301-458-4440
301-458-4032 (fax)
cdefrances@cdc.gov

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National Hospital Care Survey: Ambulatory Care Pretest

B. Collection of Information Employing Statistical Methods

1. Respondent Universe and Sampling Methods

The National Hospital Care Survey (NHCS) universe consists of all non-institutional, non-Federal hospitals in the 50 States and District of Columbia with six or more beds staffed for inpatient use. The sampling frame for 2012 consists of the universe of hospitals listed in the 2010 Spring release of the Hospital Market Profiling Solution database available from SDI (formerly known as Verispan and SMG). Freestanding ambulatory surgery centers (FSASCs) were selected from the 2005 Verispan Freestanding Outpatient Surgery Center Database and Medicare-certified facilities included in the CMS Provider-of-Services file.

Pretest Facilities

The 2012 ambulatory component pretest will take a convenience sample of 32 hospitals from the hospitals currently enrolled in NHCS. In order to be selected for inclusion in the pretest, the hospital must have one or more of the following: an emergency department (ED), outpatient department (OPD), and/or ambulatory surgery locations (ASLs). The NHCS hospital ambulatory pretest sample has a multi-stage design, with selected hospitals in the first stage, then clinics within OPDs (all emergency service areas within EDs and ASLs are selected with certainty), and finally visits selected within the ambulatory units. Within each selected hospital, OPDs, EDs, and ambulatory surgery locations are inducted into the survey. For each OPD, a sample of clinics is selected if more than 5 clinics exist. Clinics are in-scope if ambulatory medical care is provided under the supervision of a physician and under the auspices of the hospital. Clinics providing only ancillary services, such as diagnostic X-rays or radiation therapy, are out-of-scope. Services provided in dental or dental surgery clinics, pharmacies, or other settings in which physician services are not typically provided also are out-of-scope. In addition, freestanding medical clinics or physician groups that are physically located within a hospital, but not affiliated with the hospital (i.e., the hospital basically serves as landlord) are out-of-scope because they are included in the National Ambulatory Medical Care Survey (NAMCS). Emergency services contracted by the hospital under the "hospital as landlord" arrangement, however, are eligible for the ED component of the study.

In addition, a convenience sample of 15 FSASCs that are currently in the NHAMCS sample will be selected for the pretest. For FSASCs, the pretest sample consists of two stages, with selected FSASCs in the first stage and visits selected within the ambulatory units in the second stage. In-scope locations for both hospital-based and FSASC ambulatory surgery include all dedicated ambulatory surgery rooms, cystoscopy and endoscopy units, cardiac catheterization labs, laser procedure, and pain block rooms. Out-of-scope locations include those dedicated exclusively to dentistry, podiatry, abortion, births, family planning, and small procedures.

Visit sampling in all locations

Within sampling units patient visits will be systematically selected over an assigned reporting period. Sampling units are defined as an ambulatory care unit, such as an emergency service area, clinic, or ASL, from which patient visits are sampled. A visit is defined as a direct, personal exchange between an ambulatory patient and a physician, or a staff member acting under a physician's direction, for the purpose of seeking care and rendering health services. Visits solely for administrative purposes, such as payment of a bill, and visits in which no medical care is provided, such as visits to deliver a specimen, are out-of-scope.

The pretest will divide hospitals into three main categories for sampling purposes – (1) remote-reporting hospitals (i.e., hospitals with fully functioning electronic health records (EHRs), that is, all parts of the chart are stored electronically, thereby allowing the contractor to remotely access the medical records from their headquarters), (2) non-remote reporting hospitals with UB-04-based visit sampling, and (3) non-remote reporting hospitals with sign-in sheet based sampling. There is a fourth category discussed in Supporting Statement A1; however, no visit sampling will be performed. Attachment F shows how hospitals will be separated into each category.

(1) Remote-reporting hospitals (N=5).

Remote reporting hospitals are defined as those with fully electronic medical records, that is, all parts of the chart are stored electronically, thereby allowing the contractor to remotely access the medical records from their headquarters. Field managers will perform a 100% review of all ED visits occurring during a 3-month reporting period to identify ALL likely drug-related visits. The screener question "Did any substance(s) cause or contribute to this visit?" will be used to identify drug-related visits. It is estimated that this will be a review of 6,000 ED visits which should yield about 120 drug-related cases. In addition, contractor staff will perform a systematic random sample of 300 ED visits which may or may not be drug-related, 200 OPD clinic visits, and 100 ASL visits during the same time period. UB-04 billing data will be requested from these hospitals for comparison purposes.

(2) Non-remote reporting hospitals with UB-04 billing data-based sampling (N=15).

Two sampling methods will be used: 1) ICD-9-CM codes will be used to identify drug-related ED visits from UB-04 billing data with an expected yield of 90 cases during a 2-month reporting period; and 2) contractor staff will use all UB-04 billing data to select a systematic random sample of visits during the same period with an expected yield of 200 ED, 200 OPD, and 100 ASL cases. Sign-in sheets will also be requested from these hospitals. The two sampling frames will be examined to see how closely they compare with regard to identifying in-scope visits.

(3) Non-remote reporting hospitals with Sign-in sheet based sampling (N=10).

This sampling method will most closely mimic the traditional NHAMCS methodology, with the same reporting period (1 month) for each hospital. Both types of sampling frames will be requested from each of the hospitals, i.e., UB-04 billing data and sign-in sheets, but only the

sign-in sheets will be used for sampling. Systematic random samples of visits will be selected during the 1-month reporting period with an expected yield of 100 ED, 200 OPD, and 100 ASL cases. The two sampling frames will also be examined to see how closely they compare with regard to identifying in-scope visits.

The visit sampling procedures for FSASCs will be similar to those used in non-remote reporting hospitals. NCHS will request both UB-04 billing data and sign-in sheets from the facilities. Preference will be given to using UB-04 data for sampling, if feasible.

2. Procedures for the Collection of Information

Initial Contact

Introductory letters will be sent from NCHS (Attachments D and E) to the point of contact at each hospital and to the FSASC administrator. The letters describe the purpose of the survey, the authority for data collection, that participation is voluntary and that all collected information is confidential including the identity of the facility [308(d) confidentiality requirements and Confidential Information Protection and Statistical Efficiency Act (PL-107-347)]. It also covers requirements related to Health Insurance Portability and Accountability Act (HIPAA). At no time are the patients contacted to obtain information. Letters of endorsement by the American College of Emergency Physicians and the American Surgery Center Association will be obtained and included in the mailing.

Facility Induction

The introductory letter will be followed by a telephone call from the field manager to verify facility eligibility for the survey and to arrange for an appointment with the chief executive officer, directors of the ED, OPD, and ASLs and/or FSASCs, and whoever is designated as the coordinator for this survey. The telephone call is the first part of the facility Induction Interview (Attachments G and H). The rest of the Induction Interviews, including that of the ambulatory unit (Attachment I) will then be conducted in person to verify facility sampling frame information, induct the sample facilities, and obtain ED, OPD, and/or ASL data. During the meeting, the field manager will explain the purpose of the survey, describe the data collection methods and length of data collection, and obtain both general descriptive information about the organization of the ED, OPD, and ASLs and/or FSASC and specific information needed to sample clinics within OPDs and visits within ambulatory units.

Completion of Patient Record Forms

(1) Remote-reporting hospitals (N=5).

The sampled cases (120 ED drug-related, 300 ED, 200 OPD, and 100 ASL) identified in B1 will be abstracted onto a laptop PC-based data collection tool by field managers at the contractor's headquarters.

(2) Non-remote reporting hospitals with UB-04 billing data-based sampling (N=15).

The sampled cases (90 ED drug-related, 200 ED, 200 OPD, and 100 ASL) identified in B1 will be abstracted onto a laptop PC-based data collection tool by field managers at the hospital.

(3) Non-remote reporting hospitals with Sign-in sheet based sampling (N=10).

The sampled cases (100 ED, 200 OPD, and 100 ASL) identified in B1 will be abstracted onto a laptop PC-based data collection tool by field managers at the hospital.

(4) Hospitals with EHRs (N=2)

NCHS will submit a list of data elements based on items on the Patient Record form to the hospital. Hospitals will then extract these data elements from their EHRs and transmit a file to the contractor. This will include data from all visits that occurred during a 3-month reporting period. NCHS will then determine if these data can be used to complete the most important items on the Patient Record form. NCHS will also request UB-04 billing data from these hospitals.

For the 15 FSASCs, field managers will use a laptop PC-based data collection tool to retrospectively abstract data from medical records for each of the 100 sampled visits.

Field managers will complete all of the electronic Patient Record forms. Patient visit data will be entered for each sample visit using either the ED Patient Record form (PRF) (Attachment J), OPD PRF (Attachment K), or Ambulatory Surgery PRF (Attachment L). Instructions on completing the PRFs and definitions of terms will be provided in the computerized instrument through help screens.

The Patient Record forms will collect data on patient characteristics such as age, sex, race, and ethnicity, and visit characteristics such as date of visit, expected source(s) of payment reason for visit in patient's own words as recorded in the medical chart, provider diagnoses, medications provided or prescribed, and disposition.

Estimation Procedures/Sampling Errors

Pretest data will be analyzed for internal use only.

3. Methods to Maximize Response Rates and Deal with Non-response

The credibility of analyses based on the new survey and ultimately of the programs, policies, and decision-making based on those findings rests on achieving a high degree of cooperation among the sampled pretest facilities.

In terms of recruitment, hospitals will be mailed an introductory letter from Dr. Carol DeFrances, NHCS Team Leader, NHCS and FSASCs will be mailed an introductory letter from Dr. Edward J. Sondik, Director, CDC/NCHS. In addition, the NCHS Ethics Review Board approval letter (Attachment C) will be given to field managers to show the respondent upon request. If the respondent is reluctant to participate due to privacy concerns, frequently asked questions and

answers will be provided to inform sampled facilities that they may participate in the pretest and still be in compliance with HIPAA.

4. Tests of Procedures and Methods to Be Undertaken

The primary purpose of the ambulatory pretest is to test the feasibility of collecting ambulatory visit data through the National Hospital Care Survey. This pretest will also test new questions on drug- and mental illness-related ED visits. In addition, it will test new visit sampling procedures (e.g., collecting UB-04 billing data to use as a sampling frame, identifying drug-related ED visits by ICD-9-CM codes, increasing the reporting period) and abstraction methods (e.g., remote reporting). The results of the pretest will be used for the following purposes: to approve, modify or delete the new questions; to establish the sampling procedure(s) for selecting visits; to determine the method(s) of medical record abstraction for visits; to compare the drug-related ED visits identified by reviewing all cases via remote reporting with the drug-related ED visits identified by ICD-9-CM codes using the UB-04 outpatient billing data; to determine if UB-04 outpatient billing data can identify the eligibility of ambulatory units and visits and how much the sample size should be inflated to account for ineligible visits.

The pretest will also assess the feasibility of obtaining information on colorectal cancer screening during ambulatory surgery visits where a colonoscopy is performed and test new questions related to colorectal cancer screening at ambulatory surgery. The results will inform our federal partners as to the value of fielding a full-scale module that will produce estimates of annual colorectal screening rates as well as answer other research questions related to performing colonoscopies.

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

The statistician responsible for the pretest and the current NHAMCS and NHCS is:

Iris Shimizu, Ph.D.
Office of Research and Methodology
National Center for Health Statistics
(301) 458-4497
ishimizu@cdc.gov

The person responsible for the data collection aspects of the NHCS pretest is:

Kathy Chimes, BA
Project Director
Westat, Inc.
(301) 251-4302
chimesk1@westat.com

The person responsible for the analytic aspects of the NHCS is:

Carol DeFrances, Ph.D.
Lead Statistician, Hospital Care Team
Ambulatory and Hospital Care Statistics Branch
Division of Health Care Statistics
National Center for Health Statistics
(301) 458-4440
cdefrances@cdc.gov

ATTACHMENTS

A. Applicable Laws and Regulations

B. Federal Register 60-Day Notice

C. CDC #2009-21 IRB Approval for Continuation of Protocol

D. Introductory Letter to Hospital

E. Introductory Letter to Freestanding Ambulatory Surgery Center

F. Hospital Ambulatory Data Collection Flowchart

G. Hospital Induction Form

H. Freestanding Ambulatory Surgery Center Induction Form

I. Ambulatory Unit Induction Form

J. Emergency Department Patient Record form

K. Outpatient Department Patient Record form

L. Ambulatory Surgery Patient Record form

M. Pulling and Refiling Medical Records

N. Performance of Colonoscopy in the United States