



Medical Record Data Collection and Research Support Experience

Care Communications, Inc (*CARE*) has extensive experience in managing and implementing large-scale clinical data collection and coding efforts for health economics and outcomes research, clinical research, and litigation support projects. Objectivity characterizes *CARE*'s careful review of medical records, claims data, depositions, interrogatories, personnel records, insurance claims, and other relevant documentation. We perform clinical data collection and coding to meet specific project and study protocol requirements. *CARE*'s medical record abstraction and chart review services have been performed for drug safety studies, clinical trials, health outcomes and economics research, mass litigation cases, quality assurance studies, risk management claims analysis, insurance audits, cancer and other outcomes registries, and medical billing audits.

Care Communications, Inc., established in 1976, is a national Health Information Management (HIM) consulting and staffing company providing a full range of HIM services to over 200 healthcare facilities annually. The founders and staff of *CARE* were actively involved in the development and implementation of criteria-based quality measurement and improvement methods during the 1970's and 1980's. They developed and presented quality assurance training programs throughout the United States under the sponsorship of national and state healthcare organizations. Their publications and on-site consulting services served to launch many hospital quality assurance programs.

Since the implementation of DRGs in the United States in 1983, Care Communications has been at the forefront of improving data quality in hospitals. Through educational programs, publications, the development of software tools, and customized data quality review services, Care Communications provides the expertise needed to measure and improve the quality of coded clinical data.

The following case studies describe *CARE*'s clinical data collection and research support services and demonstrate our capabilities in support of a broad range of projects, from small to large in scope, and including customized clinical data abstraction and coding-related services.

ABSTRACTED AND CODED MEDICAL DATA PROJECTS

Client: Brown University, Center for Statistical Sciences and Biostatistics and Data Management Center for ACRIN (Sub-award between Brown and *CARE*)

Project Scope:

The National Cancer Institute (NCI) and the American College of Radiology Imaging Network (ACRIN) are sponsoring a nationwide study of Americans 55+ who have a history of long-time and/or heavy cigarette smoking. The study is called the National Lung Screening Trial (NLST). The purpose of the NLST is to compare two ways of detecting lung cancer: standard chest x-ray versus spiral CT (low radiation-dose computed tomography). Both chest x-rays and CT scans are used in an effort to find lung cancer early. So far, neither chest x-rays nor CT scans have been shown to reduce a person's chance of dying from lung cancer. This study will help determine which test is better at reducing a person's chance of dying from this disease. Twenty-three healthcare research sites are participating in this study.

CARE's medical record abstractors include certified coding specialists and certified tumor registrars. *CARE*'s activities from 2003 - 2010 include(d):

- Abstract medical records of 19,000 study participants.
- Work with the client to define data elements, refine data collection guidelines, data entry formats, training materials, document control, quality control and reporting and billing procedures.
- Develop procurement guidelines and train study sites on record procurement.
- Develop a policy and procedure manual to address the scope of work performed by *CARE*.
- Implement and enforce privacy and security of protected health information according to HIPAA business associate requirements.
- Develop and implement quality control procedures.
- Train and manage staff who collect and code data.
- Prepare detailed site reports that specify quantity and quality of work completed, productivity achieved by personnel, problems encountered and actions taken to correct them, and amendments and additions to policies and procedures as needed.
- Participate in weekly status meetings and attend annual meetings.

ABSTRACTED AND CODED MEDICAL DATA PROJECTS

Client: Confidential: Various clients working on health economics and outcomes research and drug safety initiatives on behalf of industry and the FDA

Scope of Work:

Collect medical (including pharmacy) data and code diagnoses and procedures using ICD-9, ICD-10, CPT-4, and ICD-0 classification systems. Many of these studies require CARE's certified coding staff to abstract details of medications and related medical diagnoses, including adverse events, and to assign or validate clinical diagnoses and/or procedure codes according to research protocol guidelines. CARE's experts are skilled at locating specific relevant documentation within paper and electronic medical records and gleaning appropriate data on prescribed drugs and clinical outcomes from real world documentation. As appropriate, clinical codes are applied to accurately and reliably capture or validate diagnoses and/or procedures to support research intent and study endpoints.

CARE supports a variety of blinded and non-blinded drug safety related research. CARE's clients evaluate safety concerns for approved drugs in the marketplace and/or evaluate the efficacy of diagnostic modalities or treatments for a wide range of medical diagnoses.

Medical chart review and clinical data abstraction play a vital role in these studies, in particular because claims data, upon which sample selections are based, may not be adequate to identify exposure, potential confounders and confirm clinical diagnostic outcomes. Claims data also does not capture the timing of drug administration or the indications for drug administration. Clinical data may also be abstracted to assist development of claims-based definitions (algorithms) to support further research in a diagnostic realm.

Care Communications staff provides the following expertise:

- Abstract and code medical record data from paper and electronic medical records according to research protocols and abstraction manuals developed by CARE research staff. Data collected from medical records is linked to pharmacy data and claims data.
- Abstraction and reporting of adverse event (including severe adverse event) data is included in study scope when deemed relevant by CARE's research clients.
- Assist in pilot studies to clarify study parameters, abstraction data elements and abstraction policies/guidelines.
- Translate study protocols into abstraction manuals that outline policies and procedures for CARE's abstractors. Test these guidelines to ensure reliability and validity of abstracted data.

- Create customized case report forms and data collection tools based on study protocol parameters, including consideration of data element constraints, database management and data analysis concerns, audit issues and reporting requirements
- Conduct technical data audits.
- Perform content audits using inter-rater reliability quality assurance method.
- Demonstrate in-depth knowledge and related application and implementation of HIPAA privacy and security practices. This comprehensive knowledge also helps research professionals navigate the complexities of HIPAA, ensuring that their research is not hampered in any way by misinformation in the industry as it relates to research and HIPAA regulations.
- Procure thousands of medical records from providers across the country. *CARE* has the highest procurement rate when compared to other firms, with an average procurement rate ranging from 75% to 85% of required study samples, depending on the study design. Drug safety studies in particular require a high procurement of claims-identified cases to support valid data analysis.
- Provide project management leadership, ensuring optimal productivity within defined quality parameters.
- Prepare and submit Internal Review Board (IRB) applications as a support service to researchers.

ABSTRACTED AND CODED MEDICAL DATA PROJECTS

Client: The Rand Corporation
1700 Main Street
Santa Monica, CA 90401

Project Scope:

Improving Chronic Illness Care Evaluation Project

The Improving Chronic Illness Care Evaluation project was a four-year study of two Institute for Healthcare Improvement Collaboratives targeted at improving care for people with chronic conditions. The evaluation of care compared before-and-after changes in the patient population targeted for early change (the pilot population) with changes in a control population whose care was not initially affected. The medical record abstraction data evaluated the process of care as documented in the patient's record both prior to and after the implementation of the Chronic Care Model. CARE participated in three of the initiatives: diabetes, congestive heart failure and asthma.

Chronic Diseases of the Eye

The Vision Care Study was an observational study to determine the impact of varying organizational and financing arrangements under managed care on the quality of eye care for working age patients with diabetic retinopathy or primary open-angle glaucoma, the two leading causes of blindness in the U.S. CARE abstracted initial visit data and all follow-up visit data within a designated time frame.

HCSUS

The HCSUS project examined costs of care, utilization of a wide array of services, access to care, quality of care, quality of life, unmet needs for medical and nonmedical services, social support, satisfaction with medical care, and knowledge of HIV therapies.

Care Communications staff:

- Worked with the client to develop data collection guidelines, data entry formats, quality control and reporting and billing procedures.
- Developed a policy and procedure manual that addressed all functions undertaken by CARE. Submitted clinical issues or related problems and suggested solutions to the Project Director when problems were not addressed by the policies and procedures. Updated the policies and procedures and distributed to staff as needed.
- Implemented and enforced security and confidentiality procedures.
- Coordinated with the client the assignment of coders/abstractors and travel arrangements.
- Coordinated training and managed staff who collected and coded data from medical records.
- Conducted weekly teleconferences with Project Director, Principal Investigator and Director of QA to review issues, progress, obstacles and suggested solutions.
- Implemented inter-rater reliability component to meet client specifications.

- Continuous QA throughout the life of the project.
- Downloaded data from individual coders' computers, compiled into site-specific batches and forwarded to client in ASCII format.
- Prepared detailed progress reports by site, by productivity. Additionally compiled QA reports and trends observed for further training or refining data collection instrument.

ABSTRACTED AND CODED MEDICAL DATA PROJECT

Client: St. Paul Fire and Marine Insurance Company
385 Washington Street
St. Paul, MN 55102

Project Scope:

CARE's medical record coders abstracted and coded data on approximately several thousand claims at 29 sites throughout the United States. Met project deadlines by completing all cases in 29 different cities within six months.

Care Communications staff:

- Worked with the client to define data elements, develop data collection guidelines, data entry formats, training materials, document control, quality control and reporting and billing procedures.
- Developed a policy and procedure manual that addressed all functions undertaken by CARE. Submitted problems and suggested solutions to the Account Manager when problems were not addressed by the policies and procedures. Updated the policies and procedures and distributed to staff as needed.
- Modified our automated encoder, CodeMaster, to permit collection and coding of data following specific guidelines developed for this project.
- Implemented and enforced security and confidentiality procedures.
- Coordinated with the client the assignment of coders and travel arrangements.
- Developed and implemented quality control procedures using The Validator software developed by Care Communications. Quality control was 100% validation of coding and data entry during a pilot study done on two hundred claims and a 10% validation for the remainder of the feasibility study. (The client found the data quality to be so high during the feasibility study that the number of quality control reviews done during the subsequent study was reduced even further at the client's request to random spot checks.)
- Trained and managed staff who collected and coded data from claim files which included claims data, interrogatories, and medical data and entered the coded data describing the medical history and injuries into lap top computers.
- Assigned ICD-9-CM codes to medical diagnostic and procedure data.
- Downloaded data from individual coders' computers, compiled into site-specific batches and forwarded to client in ASCII format.
- Prepared detailed, site reports that specified quantity and quality of work completed, productivity achieved by personnel, problems encountered and actions taken to correct them, and amendments and additions to policies and procedures as needed.

PRODUCT LIABILITY CLASS ACTION

Client: United States Bankruptcy Court

Project Scope:

Care Communications worked with attorneys and research firms representing both the plaintiffs and the defendants to abstract and code data from approximately 50,000 medical records of plaintiffs who claimed injury by the product of the defendant. The purpose of the study was to estimate the funds needed to be put into a trust fund to pay claims.

Care Communications staff:

- Worked with clients to define data elements, develop data collection guidelines, formats, ICD-9-CM coding guidelines, project-specific codes, training materials, document control system and procedures, quality control and reporting and billing procedures.
- Developed a policy and procedure manual that addressed all functions undertaken by *CARE* and the data entry subcontractor. Submitted problems and suggested solutions to the client's Project Officer when problems were not addressed by the policies and procedures. Updated the policies and procedures and distributed them to staff as needed.
- Implemented and enforced security and confidentiality procedures.
- Coordinated document control activities with a survey research firm in Baltimore whose responsibility was to obtain and photocopy medical records of plaintiffs and to arrange delivery of batches of records to *CARE's* office in Chicago.
- Developed quality control procedures for identifying and reconciling errors in the research firm's transmittal documents and/or the number of records sent to *CARE*.
- Developed document control procedures that not only tracked the progress of individual patient medical records through the abstracting, coding and data entry process, but ensured that additional records of plaintiffs that arrived at different times from different hospitals and medical care practitioners were abstracted, coded and combined with the original case file.
- Developed and implemented data quality control procedures that consisted of re-abstracting and recoding 10% of the source documents and reporting monthly error rates to project officers.
- Assisted in the development of logic edits to enable "deep cleaning" of the data tapes.
- Trained and managed data collection staff who assembled and reviewed patient records and completed detailed abstracts about the plaintiffs' medical history and injuries.
- Trained and managed medical record coders who assigned ICD-9-CM codes to abstracted data.
- Coordinated data entry with the data entry contractor.

- Prepared detailed, weekly reports that specified quantity and quality of work completed, productivity achieved by personnel, problems encountered and actions taken to correct them, and amendments and additions to policies and procedures.
- Tracked records of plaintiffs received to ensure that an individual plaintiff's records were reviewed by the same medical record professional.
- Met project deadlines established by order of the court.
- Trained additional staff when work flow increased, to ensure that deadlines were met.

In order to successfully complete this contract, *CARE* recruited and trained 5 document control personnel, approximately 75 medical record abstractors, 35 medical record coders, and 3 administrative personnel. Staff worked two shifts, six days per week. Additional workspace was obtained and secured in Chicago and Florida. The project was completed over an 18-month period.

DIOXIN CLASS ACTION

Client: Lewis, Rice and Fingersh
611 Olive Street
St. Louis, MO 63101

Project Scope:

Medical record coders on CARE's staff have reviewed and retrieved data from approximately 10,000 patient records of plaintiffs who claimed injury from association with sites contaminated with dioxin.

Care Communications staff:

- Worked with the client to develop data collection guidelines, formats, training materials, document control and reporting and billing procedures.
- Created an automated data collection form for recording information retrieved from plaintiff's medical records, which included hospital records, physicians' office records, emergency room records, nursing home records and home health records.
- Trained abstracting staff to review patient records to assemble a medical chronology and identify alternative causes of injury, such as work in a chemical plant or history of smoking two packs of cigarettes/day.
- Tracked records of plaintiffs to ensure that an individual plaintiff's records received at various times are reviewed by the same medical record professional.
- Up-dated plaintiff's master medical chronology file as new source documents were identified and received.
- Implemented quality control procedures that consisted of a review by the project administrator of every chronology report form for completeness.
- Met deadlines for completing chronologies of specified plaintiffs for scheduled depositions.
- Trained additional staff when work flow increased to ensure that deadlines were met.

ASBESTOS CLASS ACTION

Client: Resource Planning Associates on behalf of the Mannsville Trust
Resource Planning Corporation
1227 Twenty-fifth Street N.W.
Washington, DC 20037-1106

Project Scope:

Care Communications reviewed and collected data from several hundred medical records of plaintiffs claiming injury due to exposure to asbestos.

Care Communications staff:

- Worked with the client to define data elements, develop data collection guidelines, formats, training materials, document control procedures, quality control, reporting, and billing procedures,
- Prepared a policy and procedure manual addressing all of the functions undertaken by *CARE* and up-dated policies and procedures when unanticipated problems arose.
- Implemented and enforced confidentiality and security procedures.
- Developed document control procedures and system to track medical records received from and returned to client.
- Identified and resolved discrepancies in transmittal documents and number of records received.
- Developed and implemented quality control procedures that consisted of a 10% review of abstracted documents by project supervisors and monthly reporting of error rates.
- Trained and managed data collection staff who retrieved data from plaintiffs' medical records.
- Provided client with completed abstracts, quality and productivity reports, and management reports detailing project management problems identified and resolved each month.

QUALITY OF OUTPATIENT CARE IN MEDICARE HMOs

Client: Joint Commission on Accreditation of Healthcare Organizations
One Renaissance Boulevard
Oakbrook Terrace, IL. 60181

Project Scope:

As a subcontractor to the Joint Commission, *CARE*'s medical record coders abstracted and coded information from ambulatory records of several hundred patients at multiple sites in Ohio and Minnesota. Follow-up studies were conducted for two years following the initial contract year.

Care Communications staff:

- Worked with the client to define data elements, develop data collection guidelines, formats, training materials, and quality control procedures.
- Developed a policy and procedure manual that addressed all functions undertaken by *CARE*. Submitted problems and suggested solutions to the client's Project Director when problems were not addressed by the policies and procedures. Updated the policies and procedures and distributed to staff as needed.
- Trained and managed staff assigned to the project to review medical records for presence or absence of study criteria and to record findings on the data collection instrument.
- Coordinated travel arrangements with the client to be able to visit facilities at the same time as the clinician reviewers to minimize disruption to the staff at the HMOs.

QUALITY OF CARE IN FEDERAL PRISONS

Client: Federal Bureau of Prisons
Health Services Division
320 First Street N.W.
Washington, D.C. 20534

Project Scope:

The U.S. Senate demanded a study of the quality of healthcare for inmates in Federal prisons. Care Communications was selected for the contract. We reviewed 344 patient records from Federal prisons, abstracted the data, assigned ICD-9-CM codes, and transmitted data in ASCII format to client.

Care Communications staff:

- Helped client with study design.
- Developed policies and procedures for document control, data collection, quality of care determinations and ICD-9-CM coding.
- Developed forms for document control and data collection.
- Logged records in and out and tracked through the project.
- Trained nurses to abstract data from original records; a physician to make quality of care determinations and a medical record coder to assign ICD-9-CM codes.
- Developed a data entry program using dBase, entered the data and transmitted it to client in ASCII format.
- Managed project.

This project had to be completed within strict timeframes. *CARE* had 15 days in which to collect and code data and return data discs to the client, in time for them to analyze the data and issue a preliminary report. The information from this study was used in several professional articles prepared by staff at the Federal Bureau of Prisons.

FRAUD AND ABUSE CASES

Client: Confidential

Project Scope:

While performing coding quality reviews for two hospital clients, *CARE* consultants identified fraud and abuse patterns. These patterns were discussed with the hospital client. At *CARE*'s recommendation in each case the client communicated the fraud and abuse patterns to the hospital attorney.

CARE subsequently entered into a contractual relationship with the hospital attorney group making all audit findings privileged information. *CARE* continued to work with the attorneys until all evidence of fraud and abuse patterns had been appropriately managed.

Care Communications staff:

- Provided evidence to hospital attorneys of fraudulent activities.
- Participated in a compliance rebilling project by auditing and recording over 1000 records.
- Provided education to coding staff.
- Assisted in redesigning coding processes.
- Provided guidance on developing medical staff documentation guidelines.
- Provided guidance on the compliance program requirements.
- Provided guidance on self-reporting.

REOPERATION RISK ASSOCIATED WITH HEART VALVES

Client: Eugene Blackstone, MD
University of Alabama
Department of Surgery
790 LHR
Birmingham, AL 35294

Project Scope:

The Department of Surgery at the University of Alabama participated in a study of the risks of reoperation to patients receiving heart valves in the original operation. This was a data abstraction project for which the data collection instrument and data retrieval instructions had been refined through previous data collection efforts. Over 800 cases were reviewed.

Care Communications staff:

- Abstracted data related to both the original operation and reoperation. Data was located in several data sources, including patient medical records, research notes, heart pump logs, etc. Many cases were on microfilm.
- Ensured that data from multiple data sources related to one patient were coordinated, and information from one source that would affect the interpretation/gathering of data in another source was used appropriately. .