QUALITY CONTROL

FOR

CANCER REGISTRIES

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To
Tom Dundon
Friend, colleague, and loyal public servant

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PREFACE

The authors write as representatives of the Centralized Cancer Patient Data System (CCPDS). This organization, a registry system for the Comprehensive Cancer Centers of the United States, was developed by intense cooperative group effort. In five years of data collection, this system yielded registration and follow-up information on about 250,000 cancer cases. From its inception in 1977, CCPDS practiced scientific control of data, building on the experience and cooperation of the national Surveillance, Epidemiology, and End Results (SEER) Program and the Commission on Cancer of the American College of Surgeons.

The authors represent the Quality Control and Training Subcommittee of the CCPDS Technical Advisory Committee. This subcommittee, under the successive leadership of Janet Cherry, University of Pennsylvania, and Warren Lane, Roswell Park Memorial Institute, together with the staff of the Statistical Analysis and Quality Control Center (SAQC), has been responsible for all aspects of quality control of the data system. This document springs from their experience. While the members of the Quality Control and Training Subcommittee are too numerous to list as authors, the contents of this manual reflect the valuable contributions of all of them.

This manual is directed to several audiences. First, it is intended for the participants of CCPDS, as a consolidation and summary of ideas and techniques we have developed and as a reference compilation of dispersed documents. Second, the manual is directed to those responsible for new and established cancer registries. Both as monitors of quality control for a large, central registry system and as observers of a variety of institution-based and centralized registries, we have advice to offer. Finally, although this manual is directed to cancer registries, its techniques can be adapted to other medical data systems, such as cooperative clinical trials or registration systems for other diseases.

It is our intent to present the basic ideas of quality control and practical aids to their implementation. We intend to show the adaptability of the methods we describe to all kinds of registries — new and established, single- and multi-institutional, incidence-based and institution-based, manual and computerized. This is not a manual on how to set up and manage a tumor registry. We assume the reader is familiar with those methods. It is a manual on how to set up and manage a *data quality-control program*.

Use of this Document

Major topics are listed in the Table of Contents. The first two chapters introduce the topic of quality control and stress the importance of written definitions and procedures, building on the axiom that "if it isn't documented, it isn't done." The chapters on completeness, timeliness, and accuracy—Chapters Three, Four, and Five—cover basic methods, as well as more sophisticated ones. The final two chapters address specialized topics in quality control (Chapter Six), discuss some of the costs and benefits, and offer recommendations for a basic program (Chapter Seven). Details are found in the appendices, which include sample forms and protocols that can be tailored to individual circumstances, and training documents that we have developed. Additional training documents and copies of the CCPDS Data Acquisition Manual, which contain all the procedures, definitions, and edit checks for that system, are available from SAQC.*

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LIST OF ABBREVIATIONS

CCPDS   Centralized Cancer Patient Data System
IARC   International Agency for Research in Cancer,
        Lyons, France
ICD-O   International Classification of Diseases for
        Oncology
NCI   National Cancer Institute
NED   No evidence of disease
NIH   National Institutes of Health
SAQC   Statistical Analysis and Quality Control
SEER   Surveillance, Epidemiology, and End Results
WHO   World Health Organization

CHAPTER ONE
PRINCIPLES OF QUALITY CONTROL

Modern quality control, with its emphasis on sampling, written specifications and statistical techniques, is relatively recent, but the purpose of quality control has always been "to provide a quality of product or service that meets the needs of the users."[1] There is a direct analogy between data-gathering and manufacturing. Tumor registry data can be viewed as a product and users of the data as consumers. Without an adequate level of quality and some way of assuring that this level will be maintained, there will be no consumers. This is what quality control is all about. The needs of the users balanced against available resources (time, money, and personnel) determine the level of quality to be maintained.

Quality of registry data is considered by many, including the authors, to be one of the most important elements in the establishment and maintenance of a registry. As Brooke [2] states, "Every year an enormous quantity of medical statistics is compiled and published, and very little is known about the quality of the data on which these statistics are based." Goldberg, *et al*, identify two key concerns in the evaluation of registry data quality: *completeness* and *validity* (accuracy), and point out the disastrously incorrect conclusions that can be drawn by failing to appreciate sufficiently the importance of data quality. (Appendix 1).

To be most effective, quality control should deal with every aspect of production, from acquisition of raw material (in our case, medical records) to distribution of the final product. The term "quality-control program" refers to the implementation and routine use of various quality-control methods in an organized, planned manner. It implies a comprehensive approach to maintenance of quality. The maxims that follow are the philosophic essence of a good quality-control program and apply to any system, including tumor registries or other medical data systems.

- Build quality into the system from the beginning.
- Set useful standards.
- Make everyone an inspector.
- Close the quality-control loop.

Built-in Quality

If we want to build a good radio, we should start with good parts. The word "good" implies a certain degree of reliability, life-expectancy, and performance within specified criteria. The same applies to data gathering. Building in quality means starting with good raw materials, namely medical records and other source documents. These prerequisites are discussed in Chapter Two. It means having well defined data items, well designed forms, and well trained personnel. It means that the data system has been purposely designed to reduce sources of error and maximize reliability.

Perhaps the single most important aspect of building in quality is the development of a properly written procedure manual which contains a description of how the data are to be collected and a definition of every data item (see Chapter
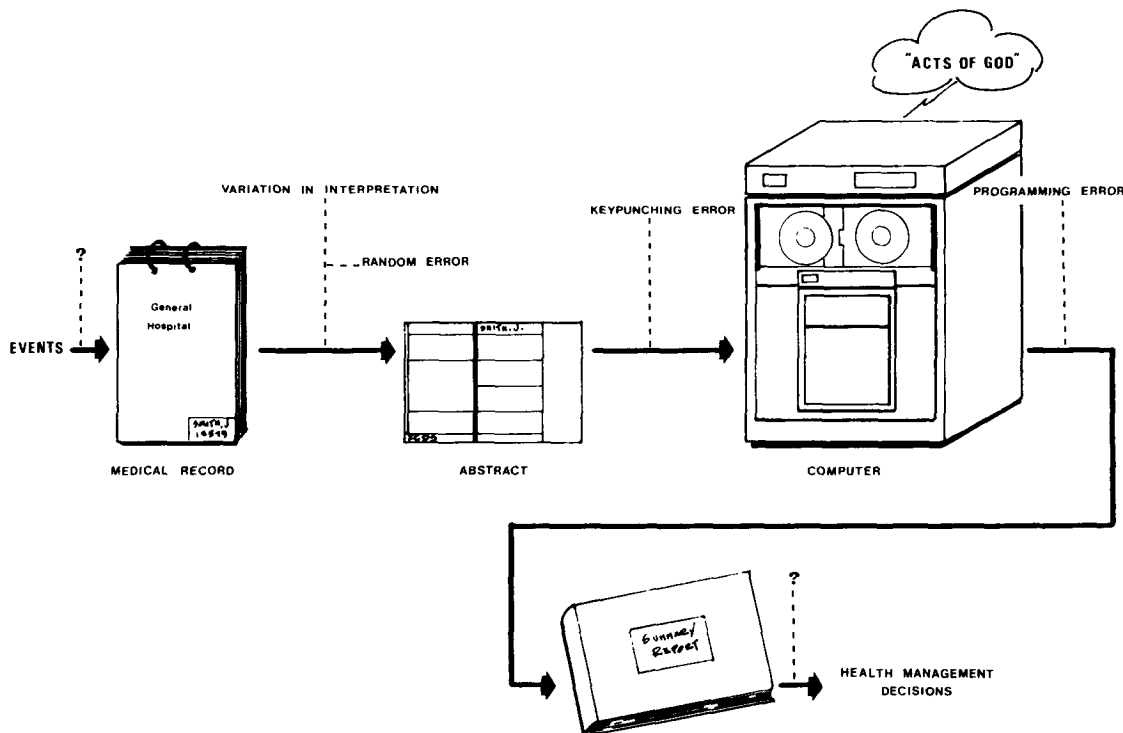
Sources of errors in Tumor Registry Data

Two). This is akin to having architectural blueprints for the construction of a building. Clarity is exceedingly important if the end product is to resemble what the designer intended. Similarly, proper design and format of data collection forms can substantially improve data quality by minimizing missing data and permitting direct computer entry.

Training of data-collection personnel is an essential ingredient in building and maintaining a high quality data system. Training should include workshops and special topic programs, as well as periodic discussion of problem cases within the registry. Training should be designed both to improve cancer knowledge and registry skills and to ensure uniform interpretation of data items. The written data-acquisition manual is invaluable in this regard and should be a constant reference. Participation in regional and national continuing-education programs will help reduce institutional peculiarities in the use of data items that are common to many institutions.

In contrast to a "one-time" data quality evaluation, an ongoing quality-control program takes a prospective, rather than a retrospective view. From this perspective, completeness is critical. It has two components. At any point in time, the completeness of the registry's data files depends on both the completeness of case-finding and the timeliness with which cases are entered into the files. As a result, we have identified three key components of data quality: (1) *completeness*, (2) *timeliness*, and (3) *accuracy*. Each of these components is the subject of a separate chapter—Chapters Three, Four, and Five.

As a final remark on building in quality, we note that the tumor registry rarely controls the quality of its raw materials (medical record and other source documents). Nonetheless, a good working relationship with the medical records department and interested medical personnel can result in better data quality in all areas. The tumor registry and medical records departments may be able to perform useful quality-control checks for each other.

Standards

The very act of writing a data definition or designing a form to complete implies a standard. Any deviation from that standard could be viewed as an "out-of-control" condition. In reality, however, this perspective is neither practical nor even useful. The term "standard" usually implies some minimum level of quality or adherence to specification, below which the data are unacceptable. The standard may be very simple, such as "for all patients, recorded birth date must precede recorded date of diagnosis," (that is, patients must be born before they can be diagnosed). Any cases not fitting the standard are unacceptable. Computerized registries usually have many such standards. Other standards might be maintaining 90 percent follow-up, or having no more than five percent errors on reabstracting. Examples of these standards will be discussed in more detail in Chapters Five

and Six. The standard helps to identify when the system is running smoothly and when corrective action must be taken. A standard should be set only after careful consideration of the capabilities of the system to meet that standard and of users' needs for data of a certain quality.

Error Detection

Having done all we can to insure the collection of high quality data, we must consider how to identify and correct errors which inevitably occur. The most effective place to identify problems is at the source. The sooner errors are detected, the easier they are to fix and the fewer the additional problems that will result. "Inspection," or checking for errors, can be done at every stage of registry operation, from case-finding to final report preparation. Inspection can be as simple as re-reading one's own abstract/code sheet before filing, or as complicated as automated, computer edit checks. Some types of inspection can be done on every record (e.g., computer edit checks), while others are only practical to do on a sample of records.

Formal techniques, such as case-finding studies, edit-checking (manual and computer), and reabstracting studies, are discussed in Chapters Three and Five. The following is a list of additional error-detecting techniques which have proven effective in many registries:

- Duplicate coding

- Duplicate data entry (verification)

- Exchange of abstracts between abstractors for review

- Review of abstracts by the registry's medical advisor

- Periodic comparative audit of paper and computer files

- Patient care audits with simultaneous review of registry data

Not every technique is applicable to every registry system. Each registry's inspection program should be designed to suit its particular needs. A good program monitors a variety of points in the data collection and management process and makes effective use of existing procedures and personnel.

It is important that everyone involved in the system participate actively in quality control. Pride of workmanship and a sense of personal involvement are very important in establishing a positive, quality-control attitude, which in turn results in higher-quality data.

The universe, so far as known to us, is so constituted that whatever is true in any one case,
is true in all cases of a certain description; the only difficulty is to find what description.

Closing The Loop

It is not enough simply to detect errors. Quality control must function as a closed loop in order to exercise control over quality. Information about errors should be fed back into the system, so that the same problems do not continue to occur. Orderly error correction is one of the end products of a quality-control program. Problems resulting from ambiguous data definitions or a poor choice of data items should be used as incentives to revise the data set and/or guidelines. Problems in interpretation should be used to target additional training. Errors should be "charged back" to their source, with tumor registry personnel viewing error detection as a learning experience and as an opportunity to improve performance. Personnel at all levels should be encouraged to express their ideas for eliminating sources of difficulty and improving productivity.

A maxim in the study of cancer is that early detection *and* early treatment are our best chance for cure. Similarly, in tumor registries a well-thought-out, closed-loop, quality-control program, which detects and treats the problem early, is a way for the registry system to maintain a high level of quality. In turn, such a control program must constantly adapt to fit the changing needs of the data system.

No quality-control system is foolproof: there will always be errors and inconsistencies which cannot be detected or eliminated, no matter how much effort is expended. As suggested at the beginning of this discussion, proper quality control balances what is desired, what is really needed, and what is available. A well designed quality-control program will result in more reliable reports, greater data utilization, a more smoothly-running registry, and greater job satisfaction for registry personnel.

CHAPTER TWO
PREREQUISITES TO QUALITY CONTROL

As suggested in Chapter One in the section "Built-in-Quality," active control of data quality is built upon a foundation of registry structure and organization. The present chapter reviews the following seven constituents of that foundation: (1) definitions, of cases and data items; (2) data collection forms; (3) the data manual, compiled from definitions and procedures into a written document; (4) manual maintenance; (5) special cases, and provisions for their interpretation; (6) training; and (7) response to problems, in an orderly and consistent manner. The most expensive quality-control system is doomed to failure without adequate attention to these fundamentals.

Definitions

The purpose of any registry is to collect a uniform set of data on all reportable cases; hence the tumor registry is concerned with two kinds of definitions, *cases* and *data items*. The *uniformity of data definitions across cases and the clear distinction between "cases,"* which are in the registry, and non-cases, which are not, are what make registries useful. Fuzzy or imprecise definitions, no matter how expertly applied, significantly impair the utility of a registry.

Case Definitions
The definition of a "case" varies depending upon the purpose of the registry, and should be specified with this in mind. There is an important conceptual difference between incidence registries and institutional registries. Incidence, or population-based, registries are not simply large hospital registries. They are designed to capture all cases in a particular geographic area, regardless of hospital affiliation. By contrast, institutional registries are limited to cases within a particular hospital, or group of hospitals, and may be further bound by the requirements of various regulating and accrediting bodies. Even within these guidelines, however, there is a wide range of options.

Two basic questions are contained in the issue of case definition. The first, and simpler, question is: "Exactly which diseases are included in the registry?" Most cancer registries include all frank malignancies (ICD-O behavior codes of 2 or 3), with the exception of basal and squamous cell carcinoma of the skin [3]. (In this category, it is important to specify which sites qualify as "skin.") The decision of whether to include benign tumors, or diseases of "uncertain" malignancy, such as villous adenoma or polycythemia vera, should be made according to the purpose of the registry and the needs of the users. A complete list of reportable diseases is essential.

The relationship of the patient to the institution is a more difficult question. For the incidence registry, any case diagnosed within the population of interest is registered, with little regard to the formal relationship of the patient to a hospital. For the institution-based registry, the main concern is to record patients for whom the institution takes some measure of responsibility regarding medical management. The Commission on Cancer of the American College of Surgeons states that "all cancer cases diagnosed or treated within the hospital . . . must be included."[4] This simple definition, however, leaves many problems unresolved. For example, what does "within the hospital" mean? Is there a distinction between an outpatient and an inpatient? Some hospitals do not consider outpatients to be hospital patients at all, but rather private patients of the attending physicians. Patients served by a screening clinic often bear a different relationship to the hospital than do regular patients. CCPDS dealt with the case-definition problem by stipulating that all

patients who receive a hospital number are considered hospital patients; others are not. Each registry must make its own determination on this question. Similarly, the Commission on Cancer states that "consult-only" and "history-only" patients should be excluded. However, different institutions may distinguish these cases differently. The following discussion summarizes our experience with these problems and may provide some guidelines for making such decisions.(Table 1)

Table 1
Problems to be Considered
in Determining Reportability

Reportable	Problems
Hospital Number Assigned	Outpatients Included?
Face-to-Face Encounter with Patient	History Only? Consult only?
One or More of the Following:	
a) First Diagnosis of Cancer	Equivocal Diagnosis? Diagnosed at Autopsy?
b) Cancer-Directed Treatment Given	Adjuvant Treatment? Courtesy Treatment?
c) Management of Residual Disease	

Most registries require a face-to-face encounter with a patient for that patient to be included in the registry. Re-reading slides or X-rays does not constitute a reportable encounter. Registries generally record all cases in which the first diagnosis was made at their institution. The definition of a "diagnosis," however, is not always easy to determine, particularly for "clinical" diagnoses. Each registry needs a set of rules to determine whether or not a diagnosis has been made. The CCPDS has adopted guidelines for uniformly interpreting such equivocal phrases as "consistent with," "probable," and "rule out," when they appear in the medical record (Appendix 2). Those clinical assessments confirmed by a pathological diagnosis pose less of a problem. A policy regarding inclusion of patients diagnosed only at autopsy should be adopted as well.

The majority of registries also include all cases which receive treatment at their institution. Exceptions to this rule might include a case in which a partial course of chemotherapy was given as a courtesy to a patient who was in the area temporarily, but whose treatment was under an unaffiliated physician's direction. Another exception might

be a case of prophylactic therapy given well after the primary therapy was administered at another institution. Such exceptions should be very carefully described.

Data Item Definitions

When designing a new data-collection system, data items should be selected only after carefully considering feasibility of collection and planned utilization. Data items included as an afterthought, or simply because "it would be nice to know," should be avoided. Use of data items and data definitions from other well-established cancer data systems, such as Surveillance, Epidemiology, and End Results (SEER), the American College of Surgeons Commission on Cancer, CCPDS, the World Health Organization, the International Association for Research in Cancer, and various state and central registries, can be very helpful [4,5,6,7,8, and Appendix 3]. Why re-invent the wheel when a perfectly good one has already been designed, tested, revised, re-tested, and used on the road for 500,000 miles, especially when it's free? Use of standard data definitions promotes consistency and opens the door for sharing data with other registries. Data items developed from scratch should be pre-tested to identify ambiguities and problems in collection before the items become permanent additions to the data base. Experience accumulated from CCPDS, SEER, and other large and small cancer data systems indicates that a small set of well-chosen data items provides more useful information than a large, but poorly-designed data set. A well-defined data item is unambiguous, applies to every situation, and corresponds logically to the other data items in the data set, as well as to related data sets.

Selecting a coding scheme is an integral part of the definition process. Even small manual registries adopt standard words and abbreviations to record data. For example, some registries record "race" using the standard words "BLACK," "WHITE," "OTHER," and "UNKNOWN," while others use different words, letters, or numbers. All of these are really codes.

Good coding schemes, no matter what form they take, are constructed so that each case fits into one, and only one, category. For example, a good definition for "race" will include rules for handling cases of mixed parentage. Codes for "sex" must provide for cases of sex-change, or hermaphrodites. It is clear that even such relatively simple data items as "Race" and "Sex" may require considerable thought in order to construct unambiguous definitions and non-overlapping categories. More complicated data items, such as "date of treatment" or "date of diagnosis," are often very difficult to define rigorously. For example, to which treatment does "date of treatment" refer? Some patients are treated many times; others are never treated. How is "date of treatment" to be coded for each? What is meant by "date of diagnosis?" Is it the date of the biopsy, or the date of the first positive chest X-ray, or some other date? What constitutes a diagnosis? Appendices 4 and 5 contain examples of several good data definitions that have stood the test of time.

The Problem of Unknowns

At first glance, it would seem easy to code most items with a set of codes like "YES," "NO," and "UNKNOWN." However, when the record from which the data are drawn fails to mention the items at all, or has conflicting information, it may be important to document the situation more precisely. The absence of information in the record will mean different things in different contexts. For example, if the question is whether or not the patient received acupuncture therapy, lack of mention (silence) in the record can be comfortably taken to mean "NO." On the other hand, if the question is whether or not the patient possesses two arms, a silent record can be taken to mean "YES." In less obvious situations, it may be desirable to create a special category, such as "NOT STATED," for situations in which the record is silent.

When specifics about test or therapy outcome are included in the codes, it may be necessary to create codes with varying degrees of uncertainty (Table 2). The purpose of the item will determine how these possibilities are combined into the final codes. When distinguishing among several "unknowns," however, it is important to spell out distinctions clearly and to avoid labelling any code simply "unknown."

Data Collection Forms

When designed and formatted properly, data collection forms can minimize missing data and permit direct computer entry. This can lead to a substantial improvement in data

Table 2
Degrees of Uncertainty in Coded Data

Test?	Results?	Outcome?
Test Not Done		
	No Results—Specimen Inadequate	Negative *
Test Done	Results Known	Positive *
		Equivocal
	Results Unknown	
Unknown If Test Done		
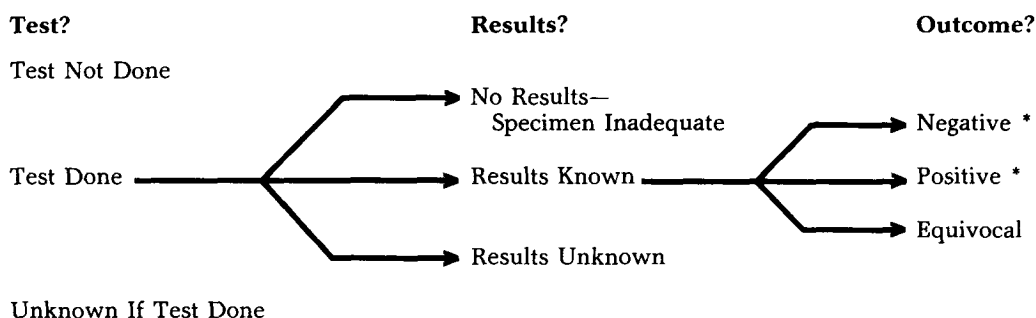
* Specific values may also be recorded.

quality. Forms should be structured so that logically-related data items and items from the same source document are grouped together. The most important people to ask about the usefulness of a new from are those who will use it. Graphic techniques, such as color, shading and outlining to set off separate parts of the form, can significantly improve readability. Simple things, like filling out black and white forms with blue or green ink, can make a big difference. Data items with relatively few codes to choose from can be "self-coding," using check-off boxes. Transcription of data from one form to another, or from one location to another on the same form, should be avoided.

Data Manual

Experience has taught us that: "if it isn't documented, it isn't done." Even long-established registries benefit from formal written definitions and procedures. Thus, perhaps the single most important quality-control task is to establish a written data-acquisition manual, which at least contains the following three categories: (1) definition of reportable cases, (2) description of case-finding and data-collection procedures, and (3) explicit definitions of every data item.

In addition, the manual should contain policies and procedures for data processing (for computerized registries), file management, registry organization, data utilization and quality control. Exhaustively prepared, the manual "defines" the registry data base and represents a complete compilation of all material relevant to the function of the registry. Although it is primarily designed for use by tumor registrars for collecting and managing data, a properly prepared manual is a useful tool for data users as well. The remainder of this discussion will focus on the "data" portion of the manual.

Each data item should receive a separate name to ensure unambiguous references to that piece of information throughout the manual. For each data item, the manual should include: (1) a clearly worded, unambiguous description of the data item, (2) a list of all codes with definitions of each (or a reference to the comprehensive list and definitions, e.g.,—ICD-O [3]), and (3) lists or descriptions of special cases or exceptions (Appendices 4,5).

In addition to detailed information on each item, the manual should contain a summary list of all data items. The items should be arranged in the order in which they appear on the data-collection forms. Supporting definitions, geocodes for residence and birthplace, lists of reportable diseases, chemotherapy agents, and staging guidelines should be included as appendices whenever possible. The more information that can be included directly in the manual, the more certain it is to be used. Copies of the manual and any support materials which are published separately, such as the American Joint Commission Staging Manual [9], or the ICD-O, must be readily available at every registry workstation.

A well-designed and well-maintained manual is like the Bible, it is a constant source of inspiration and has something to offer for virtually every data problem. The manual provides the foundation on which all other quality-control activities are built.

Manual Maintenance

Once written, the data manual must be updated as the system is modified. By assigning each data-item definition a separate page, the manual's authors can use a standard format for each definition. This practice insures that all necessary specifics are included. Definitions can be revised by replacing individual pages, rather than by re-issuing the entire manual. Each page in the manual, and all the various data-collection forms, should be dated to indicate the last time they were revised.

Changes in definitions, as opposed to clarifications of existing definitions, may constitute a new "version" of the data set. Consideration must be given to how such a change will affect the interpretation of other related items in the set. New versions should be kept to a minimum and be very carefully planned. The date of change to the new version should be documented, to avoid problems when combining data from different "versions." For example, it must be specified whether the changeover date refers to abstract completion or to patient contact.

When the new version is introduced, careful planning is also needed to modify cases already in the data base. In a computerized registry codes for new data items may be set to "unknown" for old cases, or retrospectively abstracted and added to the system. Where feasible, new codes should be compatible with old codes, or old codes convertible into the new ones, so that the data base can be used in its entirety. Items or codes that have changed in meaning must be carefully evaluated to ensure proper conversion. Such changes may require review of individual cases. Automated registries may demand considerable effort to convert from one "version" to another, and the data-processing staff should be consulted prior to the making of any changes. A complete set of case and data definitions, as well as a description of all conversion procedures, must be maintained on all prior versions of the data base.

Special Cases

The written manual serves as a set of rules or guidelines. Sometimes the rules must be interpreted to permit the handling of a particular case. Such interpretations or decisions should be written down so that similar cases will be handled accordingly in the future. SEER and CCPDS have developed a formal method for documenting such situations. Called the Inquiry Reporting System (IRS, Appendix 6), the method has been useful for maintaining consistency across all registries contributing to these data systems. Building an "unusual case" file does not have to be complicated. It is also a good way to maintain consistency among abstractors within the same registry. As time passes, fewer cases will be "unusual," because guidelines for handling them will already exist. These cases can be used as well for training and discussion with the consulting physician(s).

Blessed are they who were not satisfied to let well enough alone.
All progress the world has made, we owe to them.

Training

Practically every aspect of quality control can be useful for training. Informal training occurs every time an unusual case is discussed or an error report is returned. The success of such training depends largely upon the attitude of the participants. Physician involvement in registry operations is an important quality-control element. It helps engender an atmosphere of professionalism and the exchange of information. Most of the formal quality-control activities discussed in this manual (edit checks, reabstracting studies, reliability studies, etc.) can serve a training function (see also Chapter Five). As such, they have been well-received and effective in improving performance at the institutions participating in the CCPDS.

There are now many national, state and local professional tumor registrars' organizations which provide formal, external training opportunities. Participants in central registries often have their own workshops and training programs. These continuing education activities are strongly recommended, not only for the information and skills gained, but also for professional contact and mutual exchange of information.

Response to Problems

It is hard to over-emphasize the importance of problem-handling and error correction. They make the difference between passive quality assessment and active, prospective quality control. Even the simplest registry is made up of several files which cross-reference each other. Corrections made in one place must be carried across to all related files. As with making conversions, maintaining a record or "audit-trail" of corrections is important. Cases may require several "rounds" of corrections before they are clean enough to be included in the data base. Sometimes reconstructing the sequence of corrections to a case is necessary so as to understand and correct a problem. The data manual should discuss procedures for accomplishing such corrections, and methods for keeping track of when and by whom the corrections were made.

As we have seen, a quality-control program cannot exist without clearly specifying what quality is. This means carefully-thought-out case and data definitions, a written manual, a training program, and procedures for handling the inevitable changes and errors.

CHAPTER THREE
COMPLETENESS

Completeness of case-finding, is one of the three essential components, along with timeliness and accuracy, of quality in registry data. Completeness should be monitored as part of the total quality-control program. Demonstrating that the registry actually contains the cases it is supposed to contain—and does not contain other "cases"—is an important part of any study based on registry data. Failure to recognize incomplete reporting can result in false conclusions, especially if certain types of cases tend to be omitted more often than others (e.g., certain primary sites or cases from certain services). Likewise, over-reporting can be an important issue in medical reporting. For diseases like cancer, however, where the vast majority of cases are histologically confirmed, over-reporting is less of a problem than in other diseases.

Evaluating Case Definitions

As we have seen in Chapter Two, the problem of case definition is not a trivial one. CCPDS began with what was thought to be a straightforward definition of the reportable patient population. When we began to look at completeness of case-finding, we discovered that different centers were interpreting the definition in different ways. A case which one center included would be excluded by another. Differences in interpretation make case-finding assessments imprecise and comparisons between institutions vague. The problem is particularly acute for multi-institutional registries, such as CCPDS, but it also arises in single-institution registries. Unless definitions are carefully specified in writing—and constantly reviewed—the patient population will be ambiguous and practices variable.

As a means of examining the problem of divergent case definitions in CCPDS, we performed a study (Inclusion Study, Appendix 7) to determine which factors were involved in decisions to include or exclude cases. A set of 40 hypothetical cases were constructed, representing difficult reporting decisions. These were sent to all centers to determine whether the institution would or would not include each case in its registry and/or report the case to CCPDS. Many of the generalizations which can be drawn from this study are summarized in Chapter Two's section "Case Definitions."

Our experience showed that the most difficult cases to define are patients who are neither first diagnosed nor treated at the institution. It is in these cases that the definition of "consult-only" becomes critical. In the Inclusion Study, the purpose of the patient's visit to the institution was the single most important factor in determining which cases were included. Patients seen for diagnosis of a suspected malignancy and patients seen for medical management of a proven malignancy were most often included. Next came patients seen for consultation about treatment. Patients seen only for confirmation of a previous diagnosis were rarely included.

The problem with "purpose" or "intent" as a criterion for inclusion is its subjectiveness. Often the purpose of the patient's admission is not clearly stated. In addition, intent may change during the patient's contact with the hospital. Rules for inclusion need to specify which of the institution's actions signify the taking of responsibility for the patient's disease. Actual treatment of the patient is such an action. Some registries regard recommendations for treatment as an indication of responsibility, particularly if a change in treatment plan is recommended. In the Inclusion Study, the making of recommendations seemed to be more important than whether or not the recommendations were followed.

Definitions of cases to be included will vary depending on the registry's purpose and self-definition. In the Inclusion Study, some centers would have included only three of the 40 test cases in their registries, while at least one center said it would register all 40. Precisely because these criteria vary so much, it is important for each registry to monitor its own usage periodically so that inclusion criteria will not vary unintentionally over time.

Case-Finding

Most tumor registries engage in several routine case-finding procedures, such as review of the hospital disease-index, pathology reports, and radiation therapy logs. The Commission on Cancer, recognizing the importance of completeness in case-finding, recommends the establishment of a "suspense file" of all cases potentially eligible for entry into the registry. The commission also strongly recommends that several overlapping case-finding sources be used.

Case-finding procedures can become static. They should be evaluated from time to time and amended as hospital procedures or services change. For example, methods of diagnosis have changed with the development of more sophisticated radiologic techniques. New technology and more stringent reimbursement policies have shifted many diagnostic and treatment procedures from the operating room to the clinic or physician's office. Consequently, case-finding procedures are more complicated and traditional sources may be inadequate.

The experience of two large medical centers, prior to the reorganization of their cancer registries, illustrates these points. At Duke University, Laszlo estimated that 50-60 percent of cancer patients were not included in the registry [10]. Most of the missed cases were outpatients, for whom no accrual system had been established. After retrospectively checking operative and pathology reports, tissue registry records, cystoscopy and cytology reports and the Medical Diagnostic Index files, the Mayo Cancer Patient Data System found that a significant number of cases (approximately 15-20 percent) had been missed (H. Golenzer, unpubl. data).

As an experiment in case-finding evaluation, the Quality Control and Training Subcommittee of the CCPDS designed a protocol to assess the completeness of one hospital registry using two methods (Appendix 8). In the first part of the study, a random sample of all patients "seen" by the institution during a certain time period was selected and the medical records were reviewed for reportable malignancies. Although simple in concept, this method was expensive and difficult

There are moments when everything turns out right. Don't let it alarm you; they pass.

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to implement. It is probably not feasible for the average registry.

Primary source review, the second method in the study, was a more traditional approach which can be applied successfully to most registries. According to this method, samples representing specific time periods for each of the major-case finding sources (e.g., disease-index, outpatient appointment logs, pathology reports) are independently re-evaluated. The "missed case" rate is calculated by comparing lists of cases from each source with those in the registry. For example, if a registry reviewed oncology clinic appointment logs for the month of January and found 100 patients eligible for registration, 96 of which had actually been entered into the registry or were awaiting abstracting, then the missed case rate for this case-finding source would be four percent. If this was considered too high for such an important source of cases, steps could be taken to tighten up procedures. The problem could then be re-examined to see if there had been an improvement. Results from re-evaluation of several case-finding sources can be combined to estimate overall completeness. For example, if review of the four most important sources yielded a total of 125 reportable patients, 118 of which were known to the registry, overall completeness would be 94 percent.

We do not believe that any registry can achieve 100 percent complete case-finding. There will always be omissions. A registry should set an achievable goal and then strive to reach and maintain it.

Missing Data

Completeness can refer not only to a body of cases, but to data within a case as well. In any registry there will be items of information which are unobtainable, and therefore recorded as "unknown." (See also Chapter Two in the subsection "The Problem of Unknowns.") However, using "unknown" can also become a way to avoid the extra effort required to obtain information that is not immediately available. Consequently, the frequency rate for "unknown" codes should be monitored as part of the quality-control program.

In order to use frequencies of "unknown" to monitor quality, some thought must be given to what rates are acceptable and unacceptable. Many demographic items can almost always be coded precisely. "Sex," "race," "birthdate,"

and "date of admission" are nearly always recorded in the medical record and should be available to the registry. In CCPDS some centers have been able to achieve item completeness rates of more than 99.5 percent for "birthdate," "birth place," "race," "sex," "state or country of residence," and "zip code." Multi-institutional registries may be unable to achieve such rates. Certain data items regarding the disease can also almost always be recorded in detail. Centers have achieved perfect or near-perfect rates for data items such as "histology," "method of diagnostic confirmation," "type" and "date of therapy," and "date of last contact." In addition, over 95 percent item-completeness was often reached for "date of diagnosis," "primary site," and "laterality." Completeness rates for items concerning the vital status of the patient at last contact are highly dependent on the resources devoted to follow-up. Rates exceeding 99 percent have been achieved. Most registries aim for 90 percent or better. Follow-up completeness is discussed in more detail in Chapter Six.

Some data items are more difficult to obtain and may have low rates of completeness. "Extent of disease" is a particular problem. Determining disease stage is one of the most difficult tasks an abstractor faces. Unfortunately, "stage of disease" is also one of the most important variables in studying disease end-results. A majority of CCPDS centers achieve staging rates of 90 percent or more (fewer than 10 percent of cases unstaged), with some centers reaching above 95 percent. Such rates can be attained if the registry puts sufficient resources into the task. When a registry is unable to achieve a reasonable rate of completeness for a particular data item (e.g., greater than 70 percent), serious consideration should be given to revising the data item or dropping it from the data set.

The utility of a tumor registry depends on its completeness in two senses. First, the registry must contain all pertinent cases, but no others. Second, the records of cases should contain complete information for key data items. When completeness rates fall below 80-90%, the possibility of unknown selection bias compromises the integrity of the registry's data base. The registry quality-control program thus needs to include at a minimum: 1) systematic monitoring of case-finding and, 2) critical review of any data item that is missing or unknown for more than 10-20 percent of cases.

CHAPTER FOUR
TIMELINESS

Timeliness is the second indispensable component of registry data quality. In order to be effective and useful, data collection must be conducted according to schedule. Falling seriously behind schedule reduces the usefulness of registry reports. Getting ahead of schedule may compel the omission of important information from the data base, when cases are abstracted before complete information is available. This discussion concerns the timeliness of original data capture (see Chapter Six for timeliness of follow-up).

Standards

Setting standards for timeliness is an important task and should be done by the individual registry to suit its purpose. Although some systems are designed for rapid reporting, to ensure that source records are complete, most registries incorporate a significant delay between the patient's first contact and abstraction. If a registry records up to four months of "initial therapy," and if nearly all cases begin treatment within a month of first admission, then allowing an additional month to complete the medical record means the vast majority of cases can be abstracted within six months of first admission. Similarly, with the exception of early deaths, no cases should be abstracted less than four months after admission.

Establishing reasonable time frames for data entry and incorporation into the computer data base requires knowledge of the registry's data-processing procedures. Some registries enter data into the computer as they are collected, while others enter them only once a week or once a month. Central registries which receive data by mail, and process records in batches, may have even longer delays. As there will always be some problem cases in the registry, standards of timeliness should be based on a percentage of cases. For example, 95 percent of all cases should be abstracted and entered on the computer within seven months of first contact. Timeliness standards also may be set for various points in the data-collection process, e.g., identification, abstraction, and computer entry.

There are two relatively simple approaches to monitoring registry timeliness:

1. Monitoring the overall accumulation of cases (Accrual Method). This approach can be used in any registry. It is designed to keep track of broad trends in accrual over months or years.

2. Monitoring the length of time between critical events in the data acquisition process (Process-Monitoring Method). This approach may require computer support. It is most useful in controlling routine operations and identifying short-term problems.

Accrual Method

Timeliness can be displayed by plotting the total number of cases present in the registry for certain time periods on the same graph as the number of cases expected for each of those periods. The time lag between patient admission and completion of registry data should be allowed for in the expected curve. For example, cases admitted in January are expected to be entered in July. Established registries can draw upon their past experience in estimating the number of cases expected. The number of cases added to the registry will remain relatively constant unless there is a significant change in the services provided by the hospital, such as adding a radiation therapy department or a new screening clinic. Such changes will alter the slope of the expected line. New registries without previous experience can estimate expected cases from the hospital's bed size. A survey of 137 hospital registries approved by the Commission on Cancer, representing a broad spectrum of hospital sizes and types, found accession rates ranging from 1.0 to 2.3 cancer cases per bed per year, with an average of 1.7 cases (Appendix 9).

The following hypothetical example will illustrate the method. Suppose a hospital added an average of 400 new cases per year. If we start counting in 1983, with cases admitted in January anticipated to be in the registry by July, then the "expected line" would look like the lines with dots (•) in Figures 1-3. If the registry actually contained 225 cases in January, 1984; 375 cases in July, 1984; 625 cases in January, 1985; and 850 cases in July, 1985; then the graph would resemble Figure 1.

Assuming our estimate of the expected number of cases is accurate, the "actual" points should hover closely around the "expected" line (Figure 1). If the "actual" points tend to run parallel to the expected line but are below it (Figure 2), the registry is accruing the expected number of cases, but is running behind schedule by a constant number of months. If the "actual" points diverge and fall below the "expected" line (Figure 3), the registry is falling further and further behind and serious action is required.

Figure 1

EXAMPLE OF EXPECTED AND ACTUAL PLOTS
WHEN ACCRUAL IS ON TARGET

EXPECTED   ACTUAL

CASES IN THE REGISTRY
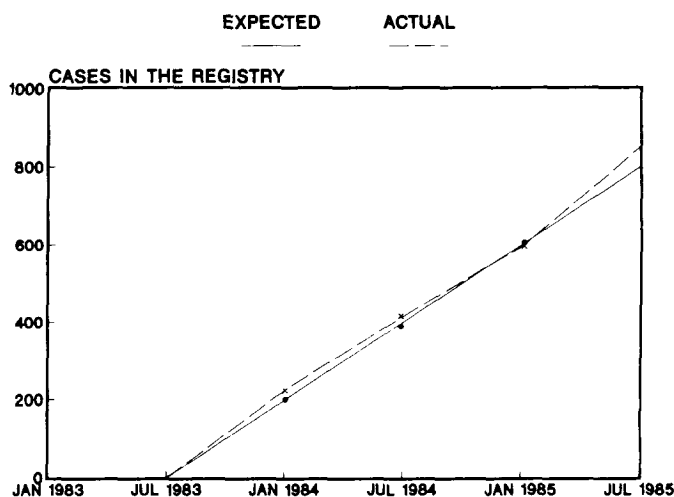
Figure 2

**EXAMPLE OF EXPECTED AND ACTUAL PLOTS
WHEN REGISTRY IS CONSISTENTLY BEHIND SCHEDULE**

EXPECTED   ACTUAL

CASES IN THE REGISTRY
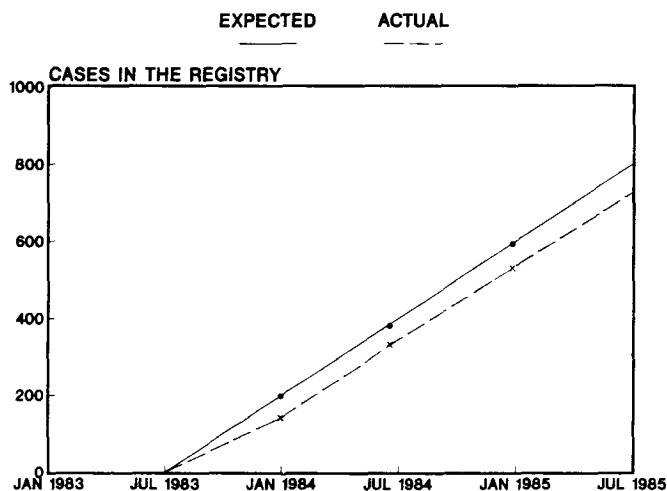
Figure 3

**EXAMPLE OF EXPECTED AND ACTUAL PLOTS
WHEN REGISTRY IS INCREASINGLY BEHIND SCHEDULE**

EXPECTED   ACTUAL

CASES IN THE REGISTRY
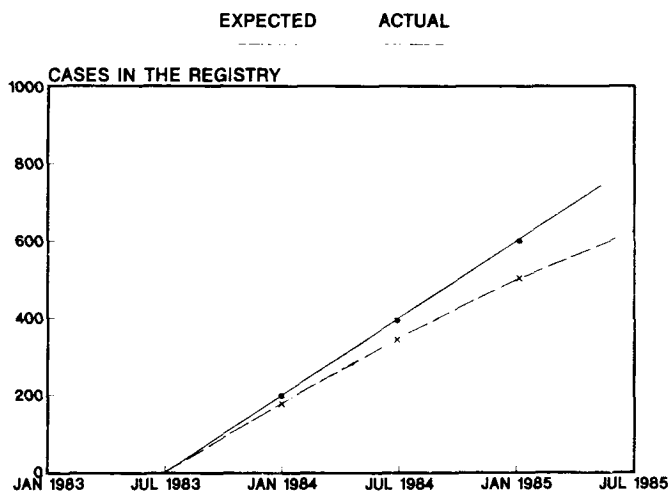
Process-Monitoring Method

The second method of checking on timeliness involves monitoring the process of data accumulation as it advances. The dates in a patient's life experience follow a familiar sequence of critical events:

Birth→Onset of Disease Process→Diagnosis→(Therapy)→Death

The survival time from treatment to death for a group of patients can be plotted and used to monitor the success of treatment. There is a similar sequence of critical events in a record's progress in the registry:

Identification→Abstraction→(Computer Entry)→Reporting

The time intervals between these dates may be used to monitor the data- acquisition process. It is not as difficult as it might seem to record the dates on which these events take place for each record. The "date of first admission" or "first contact" should always be a part of the registry data set. To monitor work flow, many registries also include the date the abstract was completed. The abstractor's initials can also be entered. Computerized registries can be designed to add critical dates to records automatically (e.g., entry, edit, and addition to data base.)

Individual time intervals, such as the time between admission and abstraction or computer entry, can be plotted just like survival data to provide pictures of the data-acquisition process. In the absence of computer support, the simplest way of using dates to monitor the timeliness of registry acquisition is to measure how long it takes, from the end of a given year, for all of the cases admitted in that year to be entered into the registry. (Some cases tend to drag out. Thus periodically calculating the percent of cases entered into the registry within six months of admission would be more informative.)

In manufacturing, an important aspect of quality control is the selection and monitoring of an appropriate production schedule. This can be applied to registries as well, most of which already contain the information necessary to perform this function. Properly reported and displayed, this "management information" can be used to identify potential problems and to initiate quick remedial action. Although useful, computers are not essential; simple tabulations and graphs, periodically updated, can portray the same information.

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CHAPTER FIVE
ACCURACY

Accuracy is the third critical component of quality in registry data. The word accurate, from a Latin word for "prepared with care," means "in conformity to truth or to a standard or rule."[11] In most cases it is not possible to know what "truth" is, but we can guarantee that the data are at least within the realm of possibility (e.g., internally consistent), and that repeated data collection essentially will generate information of the same standard of accuracy.

Consistency Checks

Although the ultimate test of registry data accuracy involves comparison with the original source documents, accuracy can also be checked by determining whether the data are plausible and internally consistent. Some of these checks can be performed without the use of a computer. Abstractors should review their own abstracts to see that required items have not been left blank, that the codes match the text (e.g., pathology information, treatment summaries), and that the "story" of the abstract makes sense. Alternatively, abstractors can review each other's abstracts. Errors caught at this early stage can be corrected directly, while the original documents are still available. Such visual checks are an essential step in comprehensive data-quality control, but should be kept relatively simple and quick.

In computerized systems, a variety of additional checks— usually called "edit checks"—should be performed. Computers are not a substitute for visual review, but can execute a large number of additional checks which could not be done by hand. Unlike registries where reports are compiled manually, in which the registrar works very closely with the original data and can often find previously undetected errors, computerized registries may not offer this advantage. The point at which computer edit checks are performed will depend on the registry's data-processing procedures. No matter when the checks are done, only "clean" data should be added to the data base.

The simplest edit checks verify the use of valid codes for individual items. For example, not all of the numbers between 140.0 and 199.9 represent ICD-O topography codes; thus certain numbers would be suspect if used to designate topography. More elaborate checks look for logical consistency between data items. For example, male patients should not be listed as having uterine cancer, or females prostate cancer. Living patients do not have autopsies. Many combinations of "site" and "histology," or "stage" and "site/histology," are impossible (e.g., in situ leukemia, leukemia not primary in bone marrow, hepatocellular carcinoma not primary in the liver). Similarly, given a particular state of residence, only certain zip codes are allowable. Lists of allowable combinations can be used to check these variables.

Dates on the abstract should follow an orderly progression. For example, dates of birth, diagnosis, treatment, and last contact should always appear in that order. Other more intricate relationships involving dates can be constructed and checked using information in other variables.

Some data combinations are not altogether impossible, but are so unlikely that it is worthwhile to flag them for a double check. For example, indication of a long period between initial diagnosis and first treatment may call for a second look. As reviewing implausible codes often requires reference to the original source documents, it may be advisable to perform this kind of edit check periodically on the entire file, rather than individually on each record at entry time. Other checks which may be conducted in a batch are cross-checks for multiple tumors in the same patient. Unless data are maintained in a complex, data-base system, there will usually be separate computer records for each primary tumor. These should be cross-checked to see that such items as "name," "sex," "race," and "birthdate" agree. Other mismatches, such as "residence" or "marital status," should be treated as improbabilities rather than as errors and a review of the records done to establish which information is correct.

The CCPDS Data Acquisition Manual contains a complete list of edit checks which are performed on the CCPDS data (Appendix 10). Also available from SAQC is a catalog of probable "site/histology" combinations. Permissible "state"/"zip code" combinations can be constructed by consulting an up-to-date zip code directory. Many participating registries found the CCPDS material to be a useful basis for developing their own set of edit checks.

Reabstracting

In the context of this manual, accuracy is the degree to which tumor registry data represent data recorded in the source documents (medical records). Consequently, the best method of checking the accuracy of registry data items is to compare them with the original medical records. This can be done informally, by reviewing both documents—in a number of registries the supervisor does this routinely—or formally, by conducting a reabstracting study. In reabstracting, the entire abstract (or some selection from it) is completely redone without reference to the original abstract, preferably by someone other than the original registrar. In contrast to edit-checking, in reabstracting usually only a small sample of cases is scrutinized, so the procedure cannot be expected to glean a large number of errors. Instead the intent of such a study is: (1) to standardize interpretation and abstracting of the medical record, (2) to estimate rates of agreement, and (3) to identify problems in data collection and interpretation. Thus, reabstracting is primarily an assessment and training tool.

After recognizing the need for this type of quality control, the Quality Control and Training Subcommittee of the CCPDS developed a formal plan for its Reabstracting Study, which was conducted periodically by the SAQC staff. Uniformly-trained registrars were sent to each comprehensive cancer center to reabstract 25, randomly-selected cases. The abstracts were returned to SAQC, where the data were coded, edited, and the codes compared with those data submitted originally. Each registry received a listing of the disagreements, and had the opportunity to discuss the cases and make corrections. The results of these studies are reported in Appendix 11.

In order to adapt this approach for an individual institution, we have developed a plan which combines

workshop training and formal reabstracting, using local personnel (Appendix 12). The protocol is versatile and can be adapted to the circumstances of the individual institution. To avoid overburdening registry personnel, the study can be carried out over an extended period (e.g., six months or a year). To be most useful, all registrars must participate, including the lead registrar or supervisor, and everyone should reabstract the complete set of cases in the sample.

Once a group of cases has been reabstracted, a workshop is held during which each reabstracted case is compared among registrars. Differences are discussed and a consensus abstract is developed. Often the input of a pathologist or surgeon is required to accomplish this. The consensus abstracts are then compared to the originals in the registry's file. Differences are tabulated and necessary corrections made. The important benefits of this process are: (1) correction of the individual cases, (2) establishment of a set of "model cases," for future reference, (3) identification of ambiguity or inadequacy of existing rules and definitions, (4) development of up-to-date guidelines, and (5) identification of areas where additional training may be necessary. Many such workshops were held as part of SAQC's reabstracting visits for the CCPDS. Participants found them to be the most beneficial feature of the visits. The opportunity to discuss the fine points of data interpretation and to obtain immediate feedback on reabstracted cases were deemed very important.

In order to interpret the results of a reabstracting study, it is necessary to set standards for acceptable and unacceptable rates of disagreement. One hundred percent agreement on all items is not a reasonable standard. Each registry should establish its own standards, based on a data item's relative importance and the system's ability to collect it accurately.

In setting standards for CCPDS, we began by defining two types of disagreements — major and minor — based on the degree to which differences would alter the results of studies using the data. For example, ICD-O primary site of 174.1, versus 174.3, was considered a minor disagreement, because both codes would be included in any analysis of breast cancer. Using the agreement levels achieved in previous reabstracting studies as a guide, standards for rates of major and minor disagreement were set, based on the degree of judgment involved in collecting the data item. In general, items requiring little or no interpretation by the registrar were allowed no major disagreements. The standards for more difficult data items were set at a four-to-eight-percent range of major disagreement, allowing one or two disagreements in a sample of 25 cases (Appendix 13).

Upon completion of a reabstracting study, results should be summarized. Accuracy — that is, agreement between the original abstracts and "truth," as determined by the workshop discussions — can be measured for each data item and for groups of related data items. The results should be compared with the standards. Findings should also be compared with previous years' results to demonstrate improvement (or lack thereof). A brief description of the outcome of the study can be part of the registry's annual report. The following fictitious example illustrates what such a report might include.

Example of a Hypothetical Reabstracting Study

Suppose 50 cases were chosen with 15 data items reabstracted for each case, for a total of 750 (50 x 15) data items. Looking at the "consensus abstracts," 699 data items

were found to be in agreement with the original data, representing a 93 percent overall agreement rate. Agreement rates for the 15 individual data items could also be reported and might have ranged from 100 percent for birthdate to 70 percent for stage (Table 3).

In addition, cluster agreement rates would also be useful in describing the relative reliability of the data. For example, CCPDS defined a Tumor Descriptor Cluster, composed of "primary site," "histology" and "stage." (See Appendix 13, section 1.6). The agreement standard for the cluster required 76 percent of abstracts to have no major disagreements in any of the items. Returning to our example, suppose 46 of 50 cases agreed on "primary site," and of those, 44 agreed on "histology." If 30 of the 44 agreed on "stage," then the cluster agreement rate would be 60 percent (30 out of 50). This is well below the standard we set and suggests the need for additional training, particularly on staging.

Use of Test Cases

Reabstracting studies provide a measure of accuracy, but it is also desirable to have a measure of how closely abstractors would agree if they abstracted the same case. A simple way to check the agreement between several coders is to ask each abstractor to code the same set of charts or abstracts. A special set of "test charts" can be prepared for this purpose. Agreement rates are then based on how often and how closely the different coders agree on each data item. This method is analogous to giving the same set of chemical materials to different technicians for analysis, and comparing the results. Within a registry the use of test cases can be helpful in training new personnel and in monitoring the consistency of experienced coders. Centralized registries can study uniformity of coding among registries using the same mechanism.

The concept of reproducibility/reliability emphasizes agreement among several coders (raters, observers, recorders). It is possible, but unusual, for a group of coders to have high reproducibility on a wrong (inaccurate) code. The notion of accuracy requires a "correct" or known "right" answer. In formal reproducibility studies of central registries, the "correct" codes are determined by panels of experts. In single-institutional registries, the "correct" code may be determined by the supervisor in consultation with medical advisors.

Example of a Formal Test-Case Study

The following section describes a formal reliablity study based on a set of test cases. The methods are applicable to any centralized registry. Application of the same ideas and techniques in an institutional registry can be useful both for training and for monitoring coding accuracy. In monitoring accuracy we recommend that records be maintained on the performance of each coder over time.

To determine consistency of reporting among institutions participating in CCPDS, 25 standardized medical charts were presented to coders at 18 centers. The 25 standardized test charts were prepared from actual charts, chosen from the most common anatomic sites and thought to be typical of cancer cases admitted to the 18 centers.* Although 34 data items were coded, interest focused on 10 key items: "site," "morphology," "stage," "vital status," "initial therapy" (three items), and three patient dates. The "correct" code for each case was defined to be the one most commonly used

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Table 3
Results of Hypothetical Reabstracting Study

Data Items	Number Reabstracted	Number in Agreement	Percent Agreement
Date of Birth	50	50	100
(1) Date of Admission	50	48	96
(1) Date of Diagnosis	50	43	86*
Date of Treatment	50	45	90*
Date of Last Contact	50	48	96
Vital Status at Last Contact	50	49	98
Sex	50	50	100
Race	50	50	100
(2) Primary Site	50	46	92*
(2) Histology	50	46	92*
(2) Stage	50	33	66*
Treatment			
Surgery	50	48	96
Radiation Therapy	50	47	94*
Chemo-Endocrine Therapy	50	46	92*
Other Therapy	50	50	100
TOTALS	750	699	93.2%
Clusters			
(1)-Patient Contact Dates	50	43	86%
(2)-Tumor Descriptor Cluster	50	30	60%*

*Below Standard

by the 18 centers. This "most common" code agreed almost unanimously with an independent expert judgment. Disagreements with the correct code were defined as major or minor (see previous section and Appendix 13). For each data item there were 450 pairs of codes (18 x 25) for comparison. The percentages of codes (out of 450) in exact, minor, and major disagreement were reported for each item. "Stage" had a 14 percent major disagreement rate, "date of diagnosis" eight percent, and each of the other key items less than five percent. Appendices 14-16 present the methodology, a test case similar to those used in the study, and the results.

While the idea of a reliability study is simple, implementation requires careful planning. The number and type (real or hypothetical) of cases must be determined and the standardized charts prepared. Each chart must contain all the necessary information. Correct codes have to be determined and major/minor disagreement specified. Finally, a report comparing the agreement rates with institutional standards must be prepared and distributed to participants, appropriate physicians, and administrators.

* These test cases, as well as similar cases prepared for workshop and training purposes, are available on request from the SAQC Center (see Appendix 15).

Comparison of Reabstracting and Test-Case Methods

In addition to editing procedures, we have presented two methods for checking data abstracting/coding quality: the reabstracting study and the use of test cases. Clearly the two approaches can be combined, as when a registry supervisor pulls charts for cases already entered in the registry and asks several employees to independently re-code them.

The reabstracting method provides direct descriptive information on data quality in a registration system, provided the sample size is large enough. In contrast, the test-case method measures the quality of the abstracting/coding process under special circumstances. Only to the extent that test cases are "like" those in the registry, is anything learned about registry data quality.

One significant advantage of the reabstracting method is that quality is evaluated for data submitted under routine conditions. That is, the cases to be reabstracted are chosen from among those already in the system, eliminating the opportunity for special care to be lavished by the abstracters/coders. Also, in the reabstracting study, measures of data quality from different centers can be compared as to anatomic site and time period. Other subgroups of cases can be compared by changing the sampling plan.

Two primary advantages of using test cases are: (1) the ease of comparing individual coders or groups of coders to some standard, as everyone is looking at the same material; and, (2) the relative simplicity and adaptability of the approach. A reliability study like the one sketched earlier can provide formal estimates for the reproducibility of abstracting/coding under controlled circumstances. However, the other major uses for the set of test cases may be more important. These include training and monitoring the work of individual coders. In many settings it is helpful for coders

to have periodic conferences to compare their coding of test charts. This is particularly important when new codes or modules are introduced, or when a new employee begins working with a supervisor. It is also possible to have the same person code the same charts on different occasions, to provide some information on intra-coder variability.

The test-case approach has the disadvantage that it is hard to know what the selected cases represent. They may be easier (or harder) than the average case and they will undoubtedly be abstracted with special care. If there are particular concerns about a difficult variable, such as stage or certain anatomic sites, a "test-case" study based on a sample of actual cases from that registry may combine the best features of both the reliability and reabstracting approaches.

This discussion has dealt with measuring accuracy, the third key element of registry data quality. However, it is not enough simply to measure accuracy after a large quantity of data has been accumulated. Quality control implies monitoring and exercising control over accuracy as the data accumulate.

CHAPTER SIX
SPECIAL TOPICS IN QUALITY CONTROL

Special problems require special handling. Just as "problem-oriented," hospital quality-assurance programs use specifically designed audits and screening systems to deal with specific problems, some registry quality-control questions may require special study or analysis. Assessment studies, data collection instruments, and training materials can be designed to focus on individual data items or groups of items. Similarly, a variety of methods can be used to monitor quality of follow-up.

Data from External Sources

Data items which derive from information obtained outside the institution (i.e., physician offices, other hospitals, nursing homes, or government agencies) are particularly troublesome for the registry. Data quality may depend on circumstances over which the registry has little or no control. Coding the first course of therapy when some or all of the therapy is given "outside" is one such situation. CCPDS ran into this problem when it attempted to study the use of adjuvant therapy in breast carcinoma. Marked differences in reported data between centers led to the suspicion that information about adjuvant therapy given outside the center was not finding its way back into the medical record or the registry abstract.

A study (Appendix 17) was devised to measure the extent of under-reporting. We had planned to obtain complete data on a small sample of cases and then extrapolate the results to the entire group. The severity of the problem could then be assessed and, as necessary, steps taken to solve it. Although time limitations prevented CCPDS from conducting this study, individual registries could easily adapt it for their own use. Similar methods can be used for other items in which there is a suspicion of incomplete reporting.

In a recent study of "Patterns of Care," coordinated by SAQC for the NCI, obtaining complete treatment data was given a high priority. Special questionnaires were designed (Appendix 18) to obtain the data. The questionnaires were sent directly to the physicians for completion, with a cover letter emphasizing the importance of the data and the care that had gone into selecting the requested data items. When such item-specific or project-specific data collection involves effort by outside personnel, it should be short-term and should focus on specific questions. It is costly in money, time and goodwill to impose on physicians' offices too often.

Items of Special Difficulty

Certain data items in the registry data set are critically important, yet are difficult to collect accurately (see also Chapter Three, Missing Data). "Stage" and "date of diagnosis" are two examples. Methods similar to those described for data from external sources could be used to improve the capture and monitor the accuracy of these data items. Some hospital registries use special "staging forms" which are placed in the medical record and completed by the attending physician as part of the staging work-up. A sample of cases drawn from the registry could be pulled and only the items of critical interest abstracted. Comparison with institutional standards (discussed in detail in Chapter Five) can be used for measuring accuracy. Training exercises focusing on these items can be very effective in sharpening abstracting skills and are relatively easy to do (Appendix 19).

Follow-up

Lifetime follow-up of the cancer patient is one of the prime directives of the hospital tumor registry. This may also be one of the registry's most challenging tasks. Established registries must often obtain annual follow-up data on four times as many patients as they accession each year. As life expectancy of the cancer patient increases, so will the follow-up patient load. Highly mobile populations and increasing reliance on outside sources of information compound the problem and reduce our certainty regarding all but the simplest data items.

Depending on the registry, a variety of data items may be collected at follow-up. The most essential items, however, are "date of last contact" and "vital status" on that date. Items such as "recurrence," "treatment," etc. share the same quality-control problems as corresponding data items in the abstract, but tend to decrease in accuracy as more and more of the information is obtained from outside sources.

Let's assume that all the usual quality control measures have been applied, to insure that registry files are updated with accurate information (edit checks, audits of files, etc.). Follow-up quality can then be assessed in two ways: (1) by measuring the volume of delinquent cases (completeness), and (2) by gauging the lag between date due for follow-up and most recent date of contact (timeliness). By defining cases as delinquent after a certain period of time, completeness and timeliness can be combined into an overall measure of follow-up success.

It is not possible to maintain up-to-the-minute, follow-up information on every patient in the registry all the time. Therefore, a minimum-acceptable level of follow-up success must be defined. This definition should include a period beyond which cases are marked delinquent. The defined level should specify the percent of cases which must be current (non-delinquent). The Commission on Cancer declares a case to be delinquent if there has been no patient contact in the last 15 months. Computerized registries and central registries, which often experience a significant lag between data collection and final update of computer files with "clean data," should take the delay into account when defining their own delinquency period. The Commission on Cancer requires a 90 percent or better follow-up rate (less than 10 percent of cases delinquent). The SEER program sets various target rates depending on the year of diagnosis (90 percent of patients diagnosed two years previously must have current follow-up, while only 80 percent of all patients diagnosed more than five years previously must have current follow-up (Appendix 20).

Part of the problem in evaluating performance against these standards is that there are several ways of calculating follow-up rates, depending on the definitions of the numerators and denominators. The simplest way is to calculate the total follow-up rate. This method is used by the

Table 4
Several Methods of Calculating Follow-up Rates

$$\text{Total Follow-up Rate (\%)} = \frac{\text{Number Non-delinquent Patients}}{\text{Number Registered Patients}} \times 100$$

Standards: 90% CCPDS and Commission on Cancer
80-90% SEER

$$\text{Active Follow-up Rate (\%)} = \frac{\text{Number Patients Successfully Followed}}{\text{Number of Patients Due for Follow-up}} \times 100$$
(excludes "dead", includes "lost")

Standard:†   75–85%

$$\text{Modified Active Follow-up Rate (\%)} = \frac{\text{Number of Current Patients Followed‡}}{\text{Number of Current Patients Due for Follow-up}} \times 100$$
(excludes "dead" and "lost")

Standard:†   80–90%

* SEER sets standards for groups of patients by year of diagnosis (admission).
† Suggested Standards, based on SEER experience.
‡ The term "current patient" means patients last known alive within some specified time period (e.g., less than 5 years ago).

Commission on Cancer. The numerator is the number of non-delinquent patients (excluding in-situ cervix) and the denominator is the total number of patients in the registry (excluding in-situ cervix). This ratio can be modified easily to compute follow-up rates for sub-groups of patients, for example, by year of diagnosis or year of admission. The total follow-up rate, however, may not accurately reflect quality of follow-up activity. In very old registries, the majority of cases may already be dead and the standard of 90 percent total follow-up can be met with little or no effort.

In addition to total follow-up rate, we suggest looking at other measures of follow-up activity which use different numerators and denominators (see Table 4). Total follow-up reflects the proportion of the registry data base that is up-to-date. Active follow-up reflects the proportion of cases updated, during some time period, out of all the cases on which follow-up should have been sought. Total follow-up rates tend to favor older registries, while active follow-up rates tend to favor young registries, where "lost-to-follow-up" patients have not yet accumulated. Although "lost" patients should never be written off, a modified statistic is proposed which more closely reflects recent follow-up success. In Table 1 of Appendix 20, columns 7 and 8 correspond closely to what we have called "active follow-up." Columns 9 and 10 correspond to what we have called "modified active follow-up." "Total follow-up" is reported in columns 11 and 12. All three rates can be used to give a total picture of a registry's follow-up activity.

Manual registries may compile follow-up rate statistics once a year, while computerized registries can easily compute these rates more often. The SEER approach of computing separate rates for groups of patients, and following these from one year to the next, can be very useful in monitoring performance and identifying problem areas requiring intervention or increased effort.

This section has dealt with quality control of data items that may not be available from the patient record. The most important of these is the follow-up information on patient survival. Since follow-up is the *raison d'etre* of most tumor registries the importance of quality control for this critical variable cannot be overemphasized.

CHAPTER SEVEN
SUMMARY

Assuming that the decision to implement an integrated quality-control program has been made, the quality-control plan must take into account all aspects of the registry's scope of work. New registries should build quality-control procedures into their data-collection activities from the beginning, avoiding duplication of effort and maximizing efficiency. Established registries should add quality-control programs as a part of a general review of the registry operation.

Components of the Integrated Quality-Control Program

We have discussed a number of tumor registry quality-control methods and techniques which are summarized in the following table (Table 5). We regard some of these as "essential" for adequate data quality in any registry, new or old, large or small, central or institution-based. Other methods in the table are classified as "very desirable." These techniques are valuable in maintaining a high quality registry, but are not necessarily "essential." The remaining methods are considered "desirable," and relate to the fine tuning of a quality-control program.

Benefits of Quality Control

Everyone agrees that quality control is a good thing. The problem is that the costs are clearly evident, while the benefits lie hidden beneath the surface. The last thing that overworked registry personnel want to hear is that they are supposed to take time from their regular tasks to do something extra. Checking cases already abstracted is somewhat like eating yesterday's pancakes. The world of industry and commerce, however, has discovered that quality-assurance programs more than pay for themselves in the long run. Widget manufacturers know that making a widget right the first time costs less than fixing or replacing it. They have discovered that should they skimp on quality control, the public will soon catch on that the shop down the street makes widgets that don't fall apart. Consumers often are willing to pay a little more for quality.

The analogy to registry data systems is close. If substantial inaccuracies or omissions are discovered in a study which uses registry data, the cost of correcting these deficiencies will far exceed the extra cost of good quality control. If inaccuracies are not discovered, the study may fail to reach the conclusions it should have, or worse, may reach conclusions which are wrong.

While the tumor registry may not appear to be selling its goods in a competitive environment, the analogy still holds. If investigators cannot get good data from the registry, they may arrange to get it some other way—e.g., by having a graduate student or an intern ferret it out. Or, investigators may give up the quest altogether. While the registry does not usual-

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Table 5
Components of a Quality-Control Program

OBJECTIVE	METHOD	IMPORTANCE
Standardize and Define Reportable Cases	• Written documentation of definitions	ESSENTIAL
	• Review of questionable records	ESSENTIAL
	• Use of test cases	Desirable
Define Data Items	• Data acquisition manual	ESSENTIAL
	• Periodic review of items	Desirable
Assess Completeness of Case-Finding	• List of sources	ESSENTIAL
	• Documentation of case-finding procedures	ESSENTIAL
	• Active check on outside sources	Very Desirable
	• Formal case-finding study	Desirable
Assess Completeness of Data Capture	• Monitoring of "Unknowns"	Very Desirable
	• Monitoring capture of therapy information	Very Desirable
Control Timeliness	• Monitoring of number of cases "on time"	ESSENTIAL
	• Standards for registration and follow-up rates	Very Desirable
Assess Accuracy	• Edit checks—manual/computerized	ESSENTIAL
	• Review of abstract/coding by supervisor	ESSENTIAL
	• Systematic reabstracting of routine cases	Very Desirable
	• Systematic reabstracting of special cases	Desirable
Provide Training	• Orderly training of new staff members	ESSENTIAL
	• Intra-institutional workshops	Very Desirable
	• Written documentation of unusual cases	Very Desirable
	• Formal Continuing Education	Desirable

ly get paid directly for its services, it does compete with other parts of the institution for increasingly scarce funds. A registry, after all, represents a significant ongoing investment on the part of the hospital. A large registry often costs $60 per case; a small one as much as $100 (Appendix 9). A useful registry costs only a fraction more.

A registry will generally receive funds to the extent to which it is perceived to be useful or indispensible by the decision-makers of the institution. Part of that perceived utility can be built up by appropriate advertising of what the registry has to offer. Part is provided by making registry output "user friendly." But providing a good product—in this case accurate and complete data—is also essential. The question is not, "Can we afford quality control?" Rather, it is "Can we afford *not* to have quality control?"

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APPENDIX 1

Registry Evaluation Methods: A Review and Case Study

By
Goldberg, J., Gelfand, H.M., Levy, P.S.

Methods of registry evaluation are reviewed with emphasis on achieving completeness and validity. Reproduced by permission of the publisher, The John Hopkins University School of Hygiene and Public Health.

REGISTRY EVALUATION METHODS: A REVIEW AND CASE STUDY[1]

JACK GOLDBERG, HENRY M. GELFAND AND PAUL S. LEVY

The great proliferation of disease registers is a relatively recent phenomenon. During the 18th century and the first half of the 19th century there were few disease registers; the early leprosy registry in Norway (1) and several tuberculosis registries (2, 3) are notable. An increase in the number of disease registries began in the 1950's as a result of two interrelated factors: 1) the increasing concern with chronic disease, and 2) the failure of the traditional methods of infectious disease epidemiology to provide an adequate framework for the study of chronic disease. The increasingly widespread establishment and use of disease registries is most pronounced in the field of cancer epidemiology. For example, the third volume of *Cancer Incidence in Five Continents* (4) presents data drawn from 78 population-based cancer registries. Other conditions, such as blindness (5), mental illness (6), rheumatic fever (7), burns (8), heart disease (9), child abuse (10), and trauma (11), have all been subjected recently to the registry approach. The widespread availability of computer resources has contributed to this trend.

While registries provide an excellent mechanism for studying the distribution and pattern of disease, their usefulness is governed by the quality (as well as the quantity) of data they contain. To date, no systematic analysis of the methods which would be useful in evaluating the quality of registry data has been offered. This review has four objectives: 1) to describe disease registries in terms of definitions, types, uses and problems, 2) to outline a framework for the evaluation of registry data, 3) to critically review and classify studies which describe registry data systems or utilize registry data, and 4) to present a case study evaluating the quality of data in the Illinois Trauma Registry.

THE CONCEPT OF DISEASE REGISTRIES

Definitions

A number of definitions have been suggested for the word "registry." One dictionary (12) defines the verb "to register" as meaning: "to set down (facts, names, etc.) formally in writing; to enter or record in a precise manner." Bellows (13), in her classic paper on case registers, defines registries as "a system of recording frequently used in the general field of public health which serves as a device for the administration of programs concerned with the longterm care, follow-up or observation of individual cases . . . (with their single distinguishing feature being) that changes in status of cases are recorded over a period of time." Brooke (14) in a recent monograph for the World Health Organization defines a register as "a file of documents containing uniform information about individual persons, collected in a systematic and comprehensive way, in order to serve a predetermined purpose." The main difference between

the latter two definitions is that Bellows emphasizes the use of registers for program administration and patient follow-up, while Brooke focuses on the uniformity and comprehensiveness of data collection.

Types

Several registry typologies have been proposed based on the uses to be made of the data. Weddell (15) classifies all registries (not just those for diseases) into seven types: registers used in preventive medicine, disease-specific registers, treatment registers, aftercare registers, at risk registers, registers for prospective studies, and specific information registers. Amsel (16) suggests that registries can be categorized as either clinical or research, the key distinction being that research registers anticipate no clinical intervention and therefore "case reporting then reflects the natural history of a condition." While both Weddell's and Amsel's classification systems are useful, they are limited because they fail to recognize that potential registry uses are related to the sources of registry data.

Pedersen (17), rather than approaching registry classification by use, attempted to classify registries by their sources of data. He proposed three types of registries (specifically for cancer): local hospital registries, central registries, and population-based registries. The characteristics of each of these types are as follows:

1) The *local hospital registry* serves just one hospital and is a file of all patients seen at that hospital with a particular disease. Its function is to ensure complete and accurate data on diagnosis and treatment and its primary use would be in preparing a detailed statistical profile for cases of a specific disease.

2) The *central registry* is analogous to the local hospital registry, but it includes a selected group of hospitals in a region. Its chief function is to supply data on diagnosis and treatment for the hospitals involved. The combining of several local hospital registries provides a sufficient number of cases for a more detailed breakdown of data into subgroups for analysis; central registries are particularly valuable for comparing end results among different therapeutic regimens.

3) The *population-based registry* represents an attempt to collect detailed information about all new cases of a disease in a population of known size and composition. Its essential feature is the effort to account for all diagnosed cases of a specific disease, whether in hospital or not, and its specific use is to determine the risk of disease in a population.

Uses

Registry data have been used for a wide variety of purposes. Brooke (14) has surveyed many of the registers currently functioning and has identified eight major purposes:

1) *Identification of individuals*—to provide the physician with access to a large number of individuals with a particular condition.

2) *Immediate protection of the individual*—to make readily available information on cases which can be vital in the event of an emergency.

3) *Surveillance*—to help ensure that medication is received and taken for conditions which require long-term treatment.

4) *Epidemiology*—to provide a basis for estimating incidence and prevalence rates for a defined population.

5) *Planning, operation and evaluation of service*—to make it possible to calculate estimates of need for services and to evaluate program efficiency and effectiveness.

6) *Evaluation of treatment*—to provide the basis for calculating the efficacy of various therapeutic techniques.

7) *Research*—to permit the natural history of a condition to be followed and to attempt to identify etiology.

8) *Education*—to assist in educating

physicians by sharpening their diagnostic skills in identifying cases.

Problems

While registries may serve a wide variety of uses, there are many problems associated with their establishment and maintenance. Foremost among these is the *expense of operating a registry*. As early as 1956, Haenszel and Hon (18) noted that the primary concern in establishing a central cancer registry should be cost: "Follow-up of surviving patients at annual intervals contributes to the total cost, but maintenance of central files for elimination of duplicates, follow-back for incomplete or missing data, resolution of contradictory information, revision of coded data to meet changing concepts, and tabulations for routine, periodic reports all entail sizable expenditures."

A second major problem is *organization and staffing*. For central registries, and even more so for population-based registries, major impediments include the difficulties encountered in developing cooperative agreements, defining goals and objectives, identifying staff and funding sources, and specifying the computer resources available. The staffing problem is especially important; most registries will, at the very least, require three types of personnel: research support staff, computer specialists, and data ascertainment staff. The research support staff are those individuals (biostatisticians, epidemiologists, clinicians, health planners) who determine the variables to be collected and the analyses which will be conducted. Computer specialists design the system for data entry, storage and retrieval; recurrent concerns for registry computer specialists are that the data bank be secure, that the computer system be flexible enough to handle a large quantity of follow-up information, and that the data can be interfaced with a statistical analysis system. Data ascertainment personnel are those who identify, code and

enter cases. The need to adequately train and maintain this level of staff is basic for the smooth functioning of a registry.

The third problem with which all registries must deal is the *quality of registry data*. Several authors (19–22) have noted that insufficient attention has been given to the quality of the information which registries collect. The need for stringent methods to assure data quality has been underscored by Brooke (14): "Every year an enormous quantity of medical statistics is compiled and published, and very little is known about the quality of the data on which these statistics are based. However, since many theories and even expensive research projects are established on the basis of statistical findings, it is important that their quality should be as high as possible."

EVALUATION OF REGISTRY DATA

Two fundamental concerns should govern the evaluation of registry data: completeness and validity. The *completeness* of data is defined as the proportion of all cases in the target population which appear in the registry database. If a registry is population-based then all diagnosed cases of a disease for a defined population theoretically appear in it. For local and central registries, all cases of the disease seen at the reporting source should be included. If completeness is not guaranteed (and it rarely can be), it is necessary to identify those factors which are related to the selectivity of case inclusion. The result of systematic bias in case reporting is the calculation of misleading rates of disease. For example, if a registry is 60 per cent complete and the data which are missing come from a random group of cases, the extent of disease will be underestimated, but the underestimation will be the same for all patient subgroups. However, if the missing data are concentrated on one case characteristic (for instance, the least severe cases), the error in the calculation of rates would be com-

pounded; the extent of the disease would be underestimated as before, but, in addition, the relative frequency of severe cases would be overestimated.

Validity is the second essential component in assessing the quality of registry data. In this context validity may be defined as the percentage of cases in the registry with a given characteristic (e.g., age, sex, disease type) which "truly" has this attribute. In practice, it is the percentage of agreement between registry data and an independent source objectively measuring the same variable. The need for registry data with a high degree of validity is obvious; case ascertainment may be nearly complete, but the registry may contain a high percentage of information which is incorrect. Once again, the importance of differentiating between random errors and systematic errors must be stressed.

The following is an attempt to classify registry data evaluation methods in terms of completeness and validity. This review is not exhaustive; our approach is selective, to present a representative sample for a wide variety of disease registries.

Completeness

The completeness of case ascertainment has been measured by four distinct methods:

Death certificate method. In this approach, completeness is defined as the proportion of registered cases which have not been first identified by death certificate. The rationale is that if cases are found by death certificate, they have eluded prior registration and represent incomplete reporting. This method is commonly applied to cancer registries (4, 23, 24) and recently has been used for a stroke (25) and a myocardial infarction (26) registry.

The death certificate method is relatively inexpensive because independent data collection for the specific purpose of registry evaluation is not necessary. However, the method is not sensitive in the instance of diseases which have low case fatality rates. Even for cancer, the method would fail to identify many cases in diagnostic categories which are not uniformly fatal.

Independent case ascertainment method. By comparing the number of cases found in the registry with that ascertained in an independent survey, a measure of completeness can be derived. Registries for cancer (27), myocardial infarction (26), blindness (5), and rheumatic fever (28) have been evaluated in this fashion. A variant of this technique is the intensive survey of a single hospital or small area, the development of completeness estimates for this sample, and then the extrapolation of the results to the total registry.

Independent case ascertainment is perhaps the most definitive method for determining registry completeness. The value of this method is greatly enhanced if an attempt is made to link cases identified in the survey with cases appearing in the registry; the subsequent examination of case selection bias is then easily accomplished. However, the expense of this approach often prevents its use for large registry systems. Even for small registries the intensity and care with which the survey is conducted will directly affect both the results and the costs.

Historic data method. In this method a comparison is made of an "expected" number of cases with that observed in the registry. The expected number is calculated by applying a known incidence or prevalence rate (derived from a demographically similar population) to the registry population. The difference between the expected and observed rates is a rough measure of registry completeness. This approach has been used by Saxén et al. (29) on a registry of congenital malformations and by Brennan and Knox (30) on a blindness registry.

The historic data method, while rapid and inexpensive, is a relatively crude technique for developing estimates of registry completeness. At a conceptual level, it is flawed because the expected rates (which form the basis for estimating completeness) are not independently derived from the study population. This method permits the possibility that a truly low incidence rate will be mistaken for a low degree of registry completeness. Also, this method does not permit examination of the possible biasing factors in case selection.

Simulation method. This approach does not measure completeness directly. Instead, it takes the registry database and simulates patterns of incomplete reporting to examine the possible effect upon a specific dependent variable. Schork et al. (31) have used this technique on a burn registry to examine the effects of 24 patterns of simulated underreporting on burn mortality.

The simulation method is a powerful tool for determining the impact of case selection bias on a particular dependent variable, such as mortality. It does not, however, give any indication of the actual completeness of reporting. Serious difficulties could be encountered in interpreting simulated reporting patterns unless the actual completeness of reporting to the registry is known.

Validity

Three basic methods have been utilized to assess the validity of registry data:

Diagnostic criteria method. This method determines the proportion of registry cases which meet stringent diagnostic criteria. Cancer registry evaluators typically judge the validity of data by the proportion of cases with histologic confirmation (4). An analogous measure for stroke is the proportion of cases confirmed by lumbar puncture, angiography, or brain pathology at autopsy (32). For myocardial infarction it would be the pro-

portion with elevated enzyme levels or unequivocal serial electrocardiograph changes (33).

The diagnostic criteria method is subject to two main difficulties. First, the meaning of a test or measurement instrument used to ascertain diagnostic validity may be open to differing interpretation by medical specialists. For example, studies of cancer registry data have identified substantial interobserver and intraobserver variability among pathologists in classifying the histopathology of neoplasms (34, 35). Second, the diagnostic criteria method has a limited focus. Because the technique is solely designed to determine if a case is diagnosed correctly, it does not permit the assessment of the validity of other variables (e.g., sex, age, marital status). The principal advantage of this method is that independent data collection is not required; the type of diagnostic test used to confirm the final diagnosis is often routinely recorded during case ascertainment.

Reabstracted record method. In this approach, records appearing in the registry are reabstracted at the ascertainment source and then compared to the registry records. Because the reabstraction process is more thorough, the reabstracted record is assumed to be correct. The extent of agreement between the reabstracted records and the registry is the measure of validity. This method has been employed to evaluate several cancer registries (36, 37).

The reabstracted record method is an excellent means to appraise the validity of registry data. Because the same variables are contained in both the registry and the reabstracted record, detailed analysis of the validity of particular case characteristics can be conducted. The cost of identifying and reabstracting records is the primary limiting factor in using this method. Strict control needs to be placed on the process of reabstracting data, since the determination of registry validity is

wholly dependent upon the accuracy of the reabstracted data.

Internal consistency method. In this method, records are examined (usually by use of the computer) to check the registry database for legitimate codes (e.g., sex can only be male or female). Because of its simplicity this method has been used by cancer (38), psychiatric (39), burn (8), and trauma (40) registries.

The usefulness of the internal consistency method for assessing registry validity is limited. Only cases which are outside the boundaries of the prescribed logic are identified as invalid. For example, a specific case characteristic (such as sex) may be consistently coded wrong (e.g., all males are coded as females) and never be identified. While increasingly sophisticated algorithms are being developed to test internal consistency, this does not change the basic problem; illogical cases can be identified but incorrect logical cases cannot. The most attractive aspect of this method is its low cost. No independent data are collected and the checks for internal consistency are conducted by computer programs.

EVALUATION OF THE ILLINOIS TRAUMA REGISTRY: A CASE STUDY

Background and method

In 1971 the first statewide registry for traumatic injuries in the United States was initiated in Illinois. The Illinois Trauma Registry (ITR) was designed as the principal evaluative tool for the comprehensive set of medical programs known as the Illinois Trauma System (41). The ITR is a central registry that was designed to record all hospitalized patients with traumatic injuries treated at 50 hospitals designated as Trauma Centers in Illinois. The stated objectives included those related to the improvement of patient care, descriptive and analytic epidemiology, and program management and evaluation (40).

As part of a critical examination of the Illinois Trauma System, an evaluation of the utility of the ITR was conducted. Specifically, the evaluation focused on three characteristics which determine the "quality" of registry data: 1) the completeness of case reporting from hospital records to the register, 2) overreporting, i.e., fraudulent cases in the register not found in the hospital records, and 3) the validity of the items of information attributed to registry cases, as compared with the same data found in hospital records.

To accomplish these objectives two independent samples were selected for a one-year period: a Hospital Sample and a Registry Sample. (Because the overall objective of our research focused on "downstate" Illinois, 17 Trauma Centers in the Chicago metropolitan area were excluded from both these samples.) The Hospital Sample required a search of the diagnostic index at the Trauma Centers to compile a list of all patients with 20 selected trauma diagnoses ("tracers"), specified according to the *International Classification of Diseases* (42). A 10 per cent systematic random sample of these cases was then retrieved and transcribed onto a standard coding form. An attempt was then made to match those tracer cases found in the hospital records with those contained within the ITR. The Registry Sample was a 10 per cent systematic random sample of cases with tracer diagnoses in the ITR. Where possible, these cases were matched to the corresponding hospital records.

In the ITR evaluation, the completeness of case reporting was defined as the proportion of cases in the Hospital Sample which were also found in the ITR. Overreporting is the converse, and was defined as the proportion of cases recorded in the Registry Sample which were not found in hospital records. The validity of ITR data was determined by the concordance of specific variables in the matched cases—

those individuals whose records were found both in the ITR and in the hospital record rooms. Two sets of matched cases were available in this study—Hospital Sample cases which were located in the ITR, and the Registry Sample cases which were found in hospital records. Either would serve the purpose, and the latter set was utilized.

For the validity assessment the *predictive value* of positive and negative ITR data (the converse of measures of sensitivity and specificity) was calculated for each item recorded on the ITR record (43). The predictive value was used because the orientation of the overall study was to determine the utility of the ITR for epidemiologic research. The "predictive value of ITR positive data" was defined as the percentage of ITR records with a given attribute which had that attribute in the matched hospital records. The "predictive value of ITR negative data" was the percentage of ITR records without a given attribute which also lacked that attribute in the matched hospital records. For example, if the ITR classified 200 individuals as having a fractured clavicle and the hospital record identified 160 of these as having a fractured clavicle, the predictive value of ITR positive data would be 160/200 or 80 per cent. Conversely, if the ITR classified 500 individuals as not having a fractured clavicle and the hospital record identified 450 of these as not having a fractured clavicle, the predictive value of ITR negative data would be 450/500 or 90 per cent.

It should be noted that the completeness of case reporting can only be measured if a Hospital Sample is available for use, and that overreporting can be measured only if a Registry Sample is available. Matches based on either sample can be used for assessing the concordance of case characteristics.

Four groups of variables which may influence the completeness and validity of ITR data were examined:

1) demographic—age, sex, race, marital status;

2) accident—mechanism of injury, means of transportation, time and day of admission;

3) clinical—specific tracer diagnoses, severity of injury; and

4) outcome—mortality, length of hospital stay, admission to an intensive care unit, patient transfer from one hospital to another.

The analysis of ITR completeness and validity for each of the listed variables has been presented elsewhere (44, 45). For the purposes of this review, detailed results are presented for only one variable—injury severity.

Severity of injury: An illustrative example

Since severity of injury would be an important primary or adjustment characteristic in almost any epidemiologic use of the ITR, it was selected to illustrate our approach to registry evaluation. The estimated survival probability (ESP) index (46) was used as the method to establish retrospectively the severity of a traumatic injury. The ESP takes into account the nature of the injury and the effect of multiple injuries in assigning numerical severity scores; these scores reflect the probability of survival from combinations of traumatic injuries. Thus, the lower the ESP score the more severe the injury.

Table 1 shows that there was a monotonic decrease in the completeness of reporting to the ITR as severity of injury decreased, from 42.3 per cent for ESP values of 0.90 or less to 33.3 per cent for ESP of 1.00. This table also shows the validity of ITR records as measured by the predictive value of positive and negative results. The predictive values for positive results vary in a linear fashion with injury severity; the lowest predictive value is observed for cases with severe injuries and the highest predictive value for cases with minor injuries. Specifically, this

TABLE 1

*Completeness and validity of the Illinois Trauma Registry (ITR)
records for injury severity, July 1973–June 1974*

| Severity level | Completeness of reporting | | | Validity of reporting | |
| | No. of cases in the Hospital Sample* | No. of cases found in the ITR | % completeness | Predictive value of | |
				Positive results	Negative results
ESP ≤0.90	52	22	42.3	60.9% (23)†	94.4% [161]‡
ESP 0.91–0.99	237	90	38.0	92.3% (104)	90.0% [80]
ESP = 1.00	147	49	33.3	94.7% (57)	97.6% [127]

* Twenty cases are excluded from the total Hospital Sample because they could not be identified by using the specified tracer diagnostic conditions, although they appeared in the ITR.

† Numbers in parentheses represent positive case classification according to the Registry Sample (i.e., cases having that estimated survival probability (ESP) level). The adjacent percentage is that of Registry Sample positive cases in agreement with the hospital medical record.

‡ Numbers in brackets represent negative case classification according to the Registry Sample (i.e., cases not having that ESP level). The adjacent percentage is that of Registry Sample negative cases in agreement with the hospital medical record.

means that of all cases in the Registry Sample which were classified as having ESP scores of 0.90 or less (N = 23), only 60.9 per cent were similarly classified by the matched hospital record; and of all cases in the Registry Sample with ESP scores of 1.00 (N = 57), 94.7 per cent were in agreement with the matched hospital record. The predictive values for ITR negative data do not vary directly with injury severity. The poorest concordance for negative results was for ESP scores of 0.91–0.99; the predictive value of the ITR for those cases classified as having other than ESP scores of 0.91–0.99 (N = 80) was 90.0 per cent. This would imply that 10.0 per cent of the ITR cases which were classified as not having intermediate severity do in fact possess intermediate severity, according to the information contained in the hospital records.

Table 2 was prepared to illustrate the misleading conclusions that would have resulted from the uncritical use of the ITR to estimate the proportion of patients hospitalized with tracer conditions who were treated at Trauma Centers, overall and by level of case severity. It is based on the Trauma Center case samples referred to above, plus a sample of tracer cases

admitted to hospitals not designated as Trauma Centers (Non-System Hospitals) and not otherwise discussed in this review (47).

In table 2, column (a), the number of cases in the 10 per cent Registry Sample are listed by ESP severity level, and in column (e) the estimated number of cases treated at Non-System Hospitals are similarly displayed. If the ITR had been accepted without evaluation, the proportion of each severity level (and of all cases) treated in the Trauma System would have been as indicated in column (g).

We may accept the 10 per cent Hospital Sample as demonstrating the true ESP distribution and total number of cases treated in Trauma Centers, as shown in column (d), and the proportions as shown in column (f). A comparison of columns (f) and (g) shows that the ITR greatly underestimated the role of the Trauma System.

In this instance, attempts at partial adjustment of the ITR (i.e., the Registry Sample) fail to correct its deficiencies. Correction for ITR overreporting as made in column (b) results in little change in the estimated proportions (column (h)). Correcting for both overreporting and misclassification of ESP level results in

TABLE 2

Effect of incomplete and invalid registry data on calculations of the proportion of cases treated in the Illinois Trauma System, by level of severity, July 1973 –June 1974

Severity level	Cases in Trauma Centers			
	No. of cases in Registry Sample	No. of cases in Registry Sample corrected for overreporting*	No. of cases from (b) corrected for misclassification†	No. of cases in Hospital Sample
	(a)	(b)	(c)	(d)
ESP ≤0.90	26	23	23	54
ESP 0.91–0.99	108	104	104	251
ESP = 1.00	59	57	57	151
Total	193	184	184	456

no changes in numbers (column (c)) or proportions (column (i)). Although misclassification did occur for individual cases (as demonstrated in the analysis of the predictive values of positive and negative ITR data), the net effect on the distribution of injury severity was negligible. This implies that systematic biasing did not occur and that the misclassification errors tended to cancel each other out in the overall distribution of injury severity. Since the principal error in the ITR was underreporting, only the Hospital Sample (column (d)) gives the true number and distribution of cases seen at Trauma Centers.

These results are instructive. If we had accepted *prima facie* that the ITR was correct, our conclusions would have been disastrously incorrect. Our experience with the ITR indicates that researchers using registry data should not rely solely on a single validity or completeness assessment, but must subject their data to a more thorough evaluation.

SUMMARY AND CONCLUSIONS

Registry data systems provide powerful tools for researchers in a variety of health related disciplines. In particular, extensive use of disease-specific registries is made by epidemiologists conducting studies of disease etiology. The use of registries for such investigations offers

many advantages: a relatively large number of cases, uniform data collection, and the potential for longitudinal observation. However, for a register to be used as a valid tool in etiologic studies, it is essential that it contain data of high quality. As outlined in the review of registry evaluation methods in this paper, there are a wide variety of techniques whereby the completeness and validity of registry data may be assessed, each having advantages and disadvantages in its application. The internal consistency method for validity evaluation, for example, is inexpensive and rapid, but it is not definitive, whereas the reabstracted record method is definitive but is often prohibitively expensive. Nevertheless, since valid inferences can only be derived from studies based on valid and unbiased data, the difficulty and expense of registry evaluation must be accepted as a necessary cost of registry operation.

One peculiar aspect of registry evaluation is the lack of an interdisciplinary perspective. The problems of registry completeness and validity are ubiquitous and are not limited to specific diseases or conditions. The parochial development of disease-specific registries may actually hinder their successful operation. For example, many of the problems of the ITR might have been anticipated from previous experience with cancer and heart dis-

TABLE 2—*Continued*

Severity level	Cases in Non-System Hospitals	Estimated proportion of cases treated at Trauma Centers			
		From Hospital Sample $10a \div (10d + e)$	From Registry Sample		
			Uncorrected $10a \div (10a + e)$	Corrected for over-reporting $10b \div (10b + e)$	Corrected for over-reporting and misclassification $10c \div (10c + e)$
	(e)	(f)	(g)	(h)	(i)
ESP ≤0.90	460	0.54	0.36	0.33	0.33
ESP 0.91–0.99	3091	0.45	0.26	0.25	0.25
ESP = 1.00	1940	0.44	0.23	0.23	0.23
Total	5465	0.46	0.26	0.25	0.25

* Correction for overreporting is accomplished by excluding nine cases not admitted to Trauma Centers, but which appeared in the Illinois Trauma Registry.

† Correction for misclassification is based on the estimated survival probability (ESP) distribution according to the hospital medical record.

ease registries. Communication among researchers developing or using registries deserves to be encouraged.

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APPENDIX 2

CCPDS Guidelines For Interpretation of Equivocal Diagnostic Terminology

The following lists are provided for use by abstractors and coders. Common ambiguous descriptors are classified as either indicative of tumor involvement or indicative of non-involvement.

Guidelines for Interpretation of Equivocal Diagnostic Terminology

A number of ambiguous terms may be used by clinicians and pathologists to indicate tumor involvement or non-involvement. It is sometimes extremely difficult to determine the precise meaning intended when these terms are encountered. To promote uniformity, SAQC has arbitrarily classified some of these terms as involvement or non-involvement. The priority for coding is pathologic, operative and clinical information, in descending order.

Involvement	Non-Involvement
apparently	adherent to
compatible with	attachment to
consistent with	equivocal
encroaching	extending up along
extension or invasion "to", "onto",	extension over
"out onto", "into"	extension to without
favor	perforation
induration	impending perforation of
intrudes	impinge
most likely	impose
obliterating	infringe
presumed	overstep
probable	possible
suspect	questionable
suspicious	rule-out
violates	suggests

NOTE: If there are questions concerning terminology, consultation with a physician or pathologist is suggested.

APPENDIX 3

List of CCPDS Data Items

From the CCPDS Data Acquisition Manual, Version 2, June 1981.

SECTION III - MINIMAL PATIENT DATASET

A. LIST OF DATA ITEMS

INITIAL REGISTRATION ITEMS

Initial Registration Items (Cont'd)

FOLLOW-UP ITEMS

B. LIST OF DATASET ITEMS AND CODES

	Character	
Items/Codes	Number	Position

****
Administrative Items
****

Version Number   1   1

"2"   Second Version of Initial
        Registration/Follow-up Record

Record Type   1   2

"A"   Initial Registration
"F"   Follow-up

Operation Code   1   3

1 - New case
2 - Correction
3 - Deletion

****
Basic Identification Items
****

1. Institution Number   4   4-7

    01 - Comprehensive Cancer Center University of Alabama
         in Birmingham
    02 - Colorado Regional Cancer Center, Inc.
    03 - Comprehensive Cancer Center Duke University Medical
         Center
    04 - Fox Chase/University of Pennsylvania Comprehensive
         Cancer Center
    05 - Fred Hutchinson Cancer Research Center
    06 - Georgetown University Comprehensive Cancer Center
    07 - Howard University Comprehensive Cancer Center
    08 - Illinois Cancer Council
    09 - Johns Hopkins Oncology Center
    10 - Kenneth Norris, Jr. Cancer Research Institute and the
         University of Southern California Comprehensive
         Cancer Center
    11 - Mayo Comprehensive Cancer Center
    12 - Comprehensive Cancer Center for the State of Florida
    13 - University of Texas Health System Cancer Center,
         M.D. Anderson Hospital and Tumor Institute
    14 - Ohio State University Comprehensive Cancer Center
    15 - Roswell Park Memorial Institute
    16 - Sidney Farber Cancer Institute
    17 - Memorial Sloan-Kettering Cancer Center

	Character
Items/Codes	Number Position

```
****************************************************************************
      Basic Identification Items (Cont'd)
****************************************************************************
      18 - UCLA Jonsson Comprehensive Cancer Center
      19 - University of Wisconsin Clinical Cancer Center
      20 - Yale University Comprehensive Cancer Center
      21 - Comprehensive Cancer Center of Metropolitan Detroit
      22 - Columbia University Cancer Research Center

      Last 2 digits (C.P. 6-7) for center use; "00" if not used.
```

Items/Codes	Number	Position
2. Patient Identification Number	9	8-16
3. File Number	1	17

```
         1-9
```

```
****************************************************************************
      Verification Items
****************************************************************************
```

4. Birthdate	8	18-25

```
      MMDDYYYY
```

```
****************************************************************************
      Demographic Items
****************************************************************************
```

5. Birthplace	3	26-28

```
      Source: SEER Geocode in Appendix C
```

6. Race/Ethnicity	2	29-30

```
      10 - Caucasian, NOS
      11 - Caucasian, Spanish
      12 - Caucasian, Non-Spanish
      20 - Black
      30 - Other
      99 - Unknown/not stated
```

7. Sex	1	31

```
      1 - Male
      2 - Female
      3 - Other
      9 - Unknown/not stated
```

8. Geocode of Residence at Time of Admission	3	32-34

```
      Source: SEER Geocode in Appendix C
```

Character

Items/Codes	Number	Position

```
************************************************************************************
```
     Demographic Items (Cont'd)
```
************************************************************************************
```

9. **Zip Code of Residence at Time of Admission**   3   35-39

     Source: for the 50 states, Zip Code Directory
     00000 - Non-United States
             Country unknown
             Zip Code unknown

     (Blank)   4   40-43

```
************************************************************************************
```
     Diagnosis Items
```
************************************************************************************
```

10. **Date of First Admission to Center for This Tumor**   4   44-47

     MMYY (July 1977 and later)

11. **Sequence**   1   48

     0   - One primary
     1   - 1st of multiple primaries
     2-8 - 2nd-8th of multiple primaries
     9   - Unknown/unspecified sequence number

12. **Date of Initial Diagnosis**   4   49-52

     MMYY

13. **Primary Site**   4   53-56

     Source: ICD-O Manual

14. **Laterality**   1   57

     0 - Not a paired organ, not applicable
     1 - Right origin of primary
     2 - Left origin of primary
     3 - Only one side involved, right or left origin unspecified
     4 - Bilateral involvement, lateral origin unknown, stated to be
         single primary
     9 - Paired site, but no information concerning laterality

15. **Histology and Behavior**   5   58-62

     Source: ICD-O Manual

     Behavior Code: /2 - Carcinoma in-situ
                         Intraepithelial
                         Non-infiltrating
                         Non-invasive
                    /3 - Malignant

Character

Items/Codes	Number	Position

****
      Diagnosis Items (Cont'd)
****

16. <u>Histologic Grade</u>   1   63

    1 - Grade I   - Well differentiated
    2 - Grade II   - Moderately well differentiated
    3 - Grade III - Poorly differentiated
    4 - Grade IV - Undifferentiated
    9 - Not determined/not stated/not applicable

17. <u>Diagnostic Confirmation</u>   1   64

    1 - Microscopic confirmation
    2 - Specific immunologic/biochemical tests
    3 - Other clinical diagnosis
    9 - Method of confirmation unknown

18. <u>Stage of Disease at Time of First Admission</u>   1   65
    <u>to Center</u>

    <u>Solid Tumors</u>   <u>Lymphomas (Ann Arbor)</u>
                           (See Staging Guide,
    0 - In-situ   Page E-9, 5.)
    1 - Localized   1 - Stage I
    2 - Regional, direct extension
    3 - Regional, nodes only
    4 - Regional, direct extension
        and nodes
    5 - Regional, NOS   5 - Stage II
    6 - Non-localized, NOS
    7 - Distant   7 - Stage III
    9 - Unstaged/unknown   8 - Stage IV
                           9 - Unstaged/unknown

****
      Cancer Directed Therapy Prior to Admission Items
****

19.	<u>Surgery</u>	1	66
20.	<u>Radiation Therapy</u>	1	67
21.	<u>Chemotherapy</u>	1	68
22.	<u>Endocrine Therapy</u>	1	69
23.	<u>Immunotherapy</u>	1	70
24.	<u>Other Cancer Therapy</u>	1	71

    0 - None
    1 - Yes
    9 - Unknown, not stated

Character

****
      Initial Course of Therapy After Admission to Center Items
****

25. Date of Initial Course of Therapy   4   72-75
     After Admission to Center

     MMYY

26. Surgery   1   76
27. Radiation Therapy   1   77
28. Chemotherapy   1   78
29. Endocrine Therapy   1   79
30. Immunotherapy   1   80
31. Other Cancer Therapy   1   81

     0 - None
     1 - Yes
     9 - Unknown, not stated

****
      Patient Status Items
****

32. Date of Last Contact or Death   4   82-85

     MMYY

33. Vital Status of Patient at Last Contact   1   86

     0 - Alive
     1 - Dead

34. Tumor Status at Death   1   87

     0 - Patient alive
     1 - Dead, no evidence of cancer
     2 - Dead, this cancer present (with or without another
         cancer)
     3 - Dead, no evidence of this cancer, but another
         cancer present
     4 - Dead, cancer present, but it cannot be established
         whether it was this or another cancer
     9 - Dead, cancer status unknown

35. Tumor-Specific Cause of Death   1   88

     0 - Patient alive
     1 - Death unrelated to this tumor
     2 - This tumor, its spread, or treatment are an
         underlying or contributing cause of death
     9 - Relationship between this tumor and patient's
         death cannot be determined

55

****
        Patient Status Items (Cont'd)
****

36. Autopsy   1   89

        0 - Patient alive, no autopsy
        1 - Yes (gross and microscopic)
        9 - Unknown if autopsy performed

```
+-----------------------------------------+
|                                         |
|  FIFTH LAW OF UNRELIABILITY:            |
|                                         |
|  TO ERR IS HUMAN, BUT TO REALLY         |
|  FOUL THINGS UP REQUIRES A              |
|  COMPUTER.                              |
|                                         |
+-----------------------------------------+
```

APPENDIX 4

Selected CCPDS Data Item Definitions

Sex
Primary Site
Histology and Behavior

Copies of the entire CCPDS Data Acquisition Manual, Version 2, can be obtained from SAQC, Fred Hutchinson Cancer Research Center, 1124 Columbia St., Seattle, Washington, 98104.

<u>SEX</u>

ITEM 7

Initial Registration
Character Position 31

<u>Ref.</u>

1.   Code: 1 - Male
                  2 - Female
                  3 - Other
                  9 - Unknown/not stated

2.   Description:

            Code "3 - Other", includes hermaphrodites and instances of defin-
            itive sex change. Primary site/sex edits are not performed for these
            cases.

PRIMARY SITE

ITEM 13

Initial Registration
Character Positions 53-56

Ref.

1.	Code:

CCPDS uses the 4-digit topography code of the <u>International Classi-fication of Diseases for Oncology</u> (ICD-O), 1976. The decimal point between the third and fourth digits is not coded.

2. Description:

2.1 Definition:

2.1.1 This item identifies the site of <u>origin</u> of a tumor. When the record is not clear, it is suggested that a physician be consulted to determine the most definitive code that can be used.

2.1.2 If the precise site of origin cannot be determined, it may be possible to use the "NOS" category of an organ system or the ill-defined site codes, T-195.0 - T-195.8. (Site-specific histologies are in Subsection 3.4 below.)

2.1.3 If the only available information on the malignancy pertains to metastatic involvement and the pathologist or clinician cannot further define the origin of the primary, it is proper to code to an "Unknown primary site", T-199.9.

2.2 Scope:

This item should be corrected when better information becomes available during the course of the patient's disease. If a definitive determination of primary site is made, for example, at autopsy, this information should be reported through an initial registration correction record (A2).

The natural history of certain malignancies may show a progression from one histology and primary site to another histology and associated site. This is particularly true for lymphomas and leukemias. As a general guideline, such cases should be coded to the site/histology sign-out diagnosis at the time of initial diagnosis and should not be changed because of conversion to another histologic type.

(Cont'd)

PRIMARY SITE (Cont'd)

ITEM 13

Initial Registration
Character Positions 53-56

Ref.

2.3   Reportability of skin carcinomas:

2.3.1   Basal and squamous cell carcinomas of non-genital skin sites
                    are not reportable to CCPDS. (Pages II-2, 3.3 and B-1, 1.1.1-
                    1.1.2)

2.3.2   Basal and squamous cell carcinomas of certain genital sites
                    are reportable. These include

                        T-184.1, T-184.2   Skin of labia
                        T-184.3   Skin of clitoris
                        T-184.4   Skin of vulva
                        T-187.1   Skin of prepuce
                        T-187.4   Skin of penis
                        T-187.7   Skin of scrotum

3.   Specifics:

3.1   Reference:

                The Introduction to the ICD-O (Pages v-xxiii) contains detailed
                instructions for coding primary site. Some specific aspects and
                references are covered here.

3.2   Use of ".8" codes:

3.2.1   "A tumor that overlaps the boundaries of two or more subcate-
                    gories of a 3-digit rubric and whose point of origin cannot be
                    assigned to one of the 4-digit subcategories within that rubic
                    should be assigned to ".8" (ICD-O, Page xix, #5).

3.2.2   T-196.8, "Lymph nodes of multiple regions", is provided for cod-
                    ing the topography of lymphomas when multiple nodes are involved
                    and no 4-digit subsite can be assigned as the primary site
                    (ICD-O, Page xix, #3).

3.3   Multiple tumors within a site (adapted from SEER Code Manual,
                1976):

3.3.1   Section VI, "Summary of Data Procedures for Multiple Primary
                    Malignancies" should be consulted.

                                                                    (Cont'd)

PRIMARY SITE (Cont'd)

ITEM 13

Initial Registration
Character Positions 53-56

Ref.

3.3.2   Generally, if multiple tumors of the same histology are diagnosed in subsites within a 3-digit site rubric, the topography is coded to the rubric that includes them all. For example, multiple tumors of the same histology of different subsites of the bladder would be coded to T-188.9 "Bladder, NOS".

3.3.3   For the larger systems of colon, (T-153.0 to T-153.7), rectum (T-154.0 to T-154.1), bone (T-170.0 to T-170.8), connective tissue (T-171.0 to T-171.7) and skin (T-173.0 to T-173.7), each subcategory is considered a separate site.

3.3.4   Each side of a paired site is considered a separate site unless stated to be metastatic. An exception to this rule is made for ovarian primaries in which there is bilateral involvement of the ovaries and for which only a single histology is reported. Such involvement is considered a single primary unless there is medical documentation of multiple tumors.

3.4   Site-specific histologies:

3.4.1   A number of histologies listed in the ICD-O are associated with specific sites. These sites are given in parentheses with the appropriate histologic code (ICD-O, Page xvii). In general, if the patient has a histology associated with a specific topography in the ICD-O, it is helpful to use this site code when no specific site is mentioned in the patient's record, or if only a metastatic site is given. The abstracter/coder should verify that there is no contradictory evidence to the use of the site. Thus, a patient diagnosed with "metastatic hypernephroma" with no mention of primary site is coded to site T-189.0 "Kidney, NOS".

3.4.2   In cases where no specific primary can be assigned clinically, the pathologist's appraisal of the tumor may enable coding to an organ system such as "Gastrointestinal tract, NOS" T-159.9, or "Connective tissue, NOS" T-171.9.

3.4.3   Although lymphoma histologies are not always assigned to lymph node or lymph-bearing sites, a lymphoma should be coded to an extranodal site only when there is no nodal involvement of any kind or if there is a medical statement that the site of origin was extranodal.

3.4.4   Leukemias are coded to T-169.1 "Bone Marrow".

     (Cont'd)

PRIMARY SITE (Cont'd)

ITEM 13

Initial Registration
Character Position 53-56

Ref.

3.4.5   Mesotheliomas arise in mesothelial tissue such as the pleura
               (T-163._), the peritoneum (T-158.8 to T-158.9), or rarely, in
               the pericardium (T-164.1) or ovary (T-183.0). The primary site
               of a mesothelioma should normally be coded to one of those sites.
               In the specific case of "Mesothelioma of the lung", the primary
               site should be coded to pleura rather than lung.

3.4.6   Choriocarcinoma of the female genital tract is a malignant
               tumor of trophoblasts which are found either in placental tis-
               sues ("Fetal membranes" T-181.9) or, in rare cases, in the
               ovary (T-183.0). The tumor may also occur in the male testis
               (T-186._). It is recommended that these three sites be used
               to code primary site for such tumors.

3.4.7   Meningiomas are tumors arising in the meninges of the brain or
               the spinal cord. The primary site should be assigned to "Cere-
               bral meninges" T-192.1 or "Spinal meninges" T-192.3 as appro-
               priate.

3.4.8   When no information regarding the origin of the primary is
               available for a patient with "metastatic malignant melanoma",
               the primary site is properly coded to T-173.9, "Skin, NOS".

3.5   Appendix G of this manual lists the edits performed on coded site/
               histology combinations. Cases singled out by these edits are
               referred back to the center for review through the Administrative
               Information Reports.

               Site/histology warnings on these reports indicate that such cases
               have unlikely or highly unusual combinations of these item codes.
               The record in question and the codes should be reviewed to make
               sure the case is entered correctly. If a review changes the coding
               in either item, a correction record should be submitted for the
               case.


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AS LONG AS THERE ARE FINAL EXAMS,
THERE WILL BE PRAYERS IN SCHOOL.
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HISTOLOGY AND BEHAVIOR

ITEM 15

Initial Registration
Character Positions 58-62

Ref.

1.   Code: C.P. 58-61   Histology Code:

                            4-digit histologic type code from the Interna-
                            tional Classification of Diseases for Oncology,
                            (ICD-O), 1976

              C.P. 62   Behavior Code:

                            2 - Carcinoma in-situ
                                Intraepithelial
                                Non-infiltrating
                                Non-invasive

                            3 - Malignant

2.   Description:

2.1   Definition:

         Guidelines for the selection of the proper histology codes are
         found in the Introduction Section of the ICD-O (Pages xi-xii,
         xiv-xv, xviii-xx). In the ICD-O listings the four digits before
         the slash (/) represent the histologic (morphology) code.

2.1.1   For cases of unknown histology, one of the following codes
           should be used:

              8000/3 - Neoplasm, malignant
              9990/3 - No microscopic confirmation

2.1.2   If the positive pathology is based on a cytologic examination,
           the specific histology given by the pathologist should be used.

2.2   Scope:

2.2.1   The histology code should reflect the sign-out of the most
           definitive pathology report. This is usually best determined
           from the specimen obtained at resection of the primary site.
           If this is unavailable, the histology code from a biopsy of
           the primary site, a metastatic site, cytology or a clinical
           determination should be used in descending preference.

                                                              (Cont'd)

HISTOLOGY AND BEHAVIOR (Cont'd)

ITEM 15

Initial Registration
Character Positions 58-62

Ref.

2.2.2   Because radiation therapy can alter some of the histologic
         aspects of a tumor, the biopsy specimen taken before such ther-
         apy may present a more accurate picture of the histology. When
         marked discrepancies occur, the center's pathologist should be
         able to provide guidance in selecting the correct pathologic
         diagnosis.

2.2.3   Qualifying terms which modify the diagnosis, but do not apply
         to the tumor in general, should not be considered in coding.
         (Example: "Epidermoid carcinoma of the cervix with focal kera-
         tinization" is coded to "Epidermoid carcinoma, NOS".)

2.2.4   For those patients who have been treated before admission to the
         center, histologic type is coded according to the best informa-
         tion available in the record.

2.2.5   In general, the center's own pathology diagnosis is the diag-
         nosis which will influence therapy decisions. If there is a
         significant discrepancy between pathology done elsewhere and
         that done at the center, it is suggested that a medical opinion
         be obtained. Generally, when a second opinion or review of
         slides has been requested, the diagnosis from the review should
         be coded.

2.2.6   When no pathology reports are available, but the medical history
         states the patient has a specific type of cancer, the infor-
         mation in the history may be used for coding. Should this be
         changed by further information or a subsequent biopsy, a cor-
         rection record (A2) should be submitted.

3.   Specifics:

3.1   Reference:

         The Introduction to the ICD-O manual contains useful information on
         the development, structure and use of the codes. Some specific
         questions and guidelines are discussed here.

3.2   Compound morphologies:

         When a pathologic diagnosis has more than one histologic compo-
         nent, use the higher code unless there is a special ICD-O code for
         this diagnosis (ICD-O, Page xviii).

                                                              (Cont'd)

HISTOLOGY AND BEHAVIOR (Cont'd)

ITEM 15

Initial Registration
Character Positions 58-62

Ref.

3.3   Reporting skin carcinomas:

             Basal and squamous cell carcinomas of the skin are not reportable
             to CCPDS except for the skin of genital areas, listed under Item
             13, Primary Site. Other skin malignancies whose histology code
             is M-8120/ or above, are reportable to CCPDS. (Page B-1, 1.1.1,
             1.1.2)

3.4   Site/histology relationship:

             Because many histologies are specific to particular types of tis-
             sue or organ sites, the information given under Item 13, Primary
             Site, is also relevant to this item. Item 13 should be reviewed
             for guidelines on site-specific morphologies and the coding of
             malignancies such as lymphomas or leukemias which may present with
             different sites or histologies during the natural history of the
             disease.

3.5   Behavior Code:

3.5.1   Only neoplasms requiring an in-situ or malignant (invasive)
                 behavior code are reportable to CCPDS.

                 In general, CCPDS does not use the behavior codes "6 - Malig-
                 nant, metastatic site" or "9 - Malignant, uncertain whether
                 primary or metastatic site". These behavior codes should be
                 converted to "3 - Malignant" prior to submission to SAQC.

                 It is permissible to use the behavior code "6" provided by ICD-O
                 as part of the histology code only for the following diagnoses:

                     Krukenberg tumor   8490/6
                     Pseudomyxoma peritonei   8480/6

3.5.2   If a pathologist diagnoses a tumor as "in-situ" or "malignant"
                 which is not listed with that particular behavior in the ICD-O,
                 the appropriate behavior code, "2" or "3", should be substituted
                 for that in the ICD-O. The behavior code "2 - In-situ" may be
                 attached to any of the 4-digit morphology codes in the ICD-O
                 if the in-situ form of that neoplasm is diagnosed (ICD-O, Pages
                 xiv-xv).

APPENDIX 5

CCPDS Definitions for Coding Cancer Therapy

From the CCPDS Data Acquisition Manual, Version 2, June 1981. This section last updated July 1982.

OCTOBER 30, 1985

Pages 70 and 72 of this Appendix were noted to be incorrect. The entire Appendix has been reprinted for convenience in updating copies.

APPENDIX F

DEFINITIONS AND GUIDELINES FOR CODING CANCER THERAPY

Ref.

1.   Definition of Cancer-Directed Therapy

1.1   The term "cancer tissue" generally refers to proliferating malig-
             nant cells or to an area of active production of malignant cells.
             The concept of definitive treatment is limited to procedures
             directed toward cancer tissues whether of a primary or metastatic
             site.

1.2   The definition includes only cancer-directed (definitive) therapy
             and excludes therapy which treats the patient but has no effect
             on malignant tissue. Treatment solely for the relief of symptoms
             is thereby excluded. (See also Page F-5, 3.)

1.3   To be coded as treatment, a specific therapy must normally affect,
             control, change, remove, or destroy cancer tissue. It does not
             have to be considered curative for a particular patient in view
             of other factors such as extent of disease, incompleteness of
             treatment, lack of apparent response, size of dose, operative
             mortality, or other criteria. In some instances, malignant cells
             are found in tissues in which they did not originate and in which
             they do not reproduce. A procedure for removing malignant cells
             but not attacking a site of proliferation of such cells is NOT to
             be considered cancer treatment for the purpose of this program.

2.   Guidelines for Coding Cancer-Directed Therapy

2.1   SURGERY (Items 19, 26):

2.1.1   Definition:

                Surgery is the removal of cancer tissues by operative proce-
                dures.

2.1.2   Examples:

                - Hysterectomy for uterine cancer
                - Mastectomy for breast cancer
                - Gastrectomy for stomach cancer
                - TUR (Transurethral Resection) with removal of cancer tissue
                    for bladder and prostate neoplasms
                - Local excision with removal of cancer tissue (including
                    excisional biopsy and excluding incisional biopsy)
                - Subtotal removal of brain tumor to reduce tumor burden
                - Dessication and Curettage for bladder neoplasms
                - Fulguration for skin, rectal and bladder neoplasms

Ref.

- Electrocautery
- Photocoagulation
- Cryosurgery
- Chemosurgery
- Laser Therapy
- Conization for carcinoma in-situ of the cervix uteri (not therapy if invasive carcinoma of cervix)
- Surgery removing metastatic malignant tissue (not therapy if done for diagnostic purposes only)
- Lymph node dissections done whether before or after or as part of the primary cancer removal (the removal can be done either by surgery or radiation therapy.) A lymph node dissection without a surgical or radiation approach to the primary is considered a diagnostic procedure even if nodes containing tumor are removed.

2.1.3   Exceptions:

- Exploratory surgical procedures are excluded.
- Splenectomy in lymphoma or leukemia cases is not coded as therapy unless the spleen is involved with neoplasm.
- Vocal cord stripping is not considered definitive therapy for invasive carcinoma of the vocal cord unless followed by radiation therapy.
- Removal of node(s) in lymphoma cases is not coded unless removal is for more than diagnostic purposes, even if followed by irradiation. Specifically, if the lymphoma is localized to a particular node or chain of nodes and all of these nodes are removed, then it is treatment. If removal of a node is purely for diagnostic purposes and known tumor is left behind, it is not considered treatment.

2.2   RADIATION (Items 20, 27):

2.2.1   Definition:

This includes all beam and other radiation directed to cancer tissues regardless of source of radiation.

2.2.2   Examples:

- X-ray (not including diagnostic X-rays)
- Cobalt bomb
- Linear accelerator
- Neutron beam
- Betatron
- Spray radiation
- Internal use of radioactive isotopes whether given orally, intracavitarily, interstitially, or by intravenous injection
- All implants, molds, seeds, needles, applicators of radioactive material such as radium, radon, radioactive gold, etc.

Ref.

2.2.3   Exception:

             When radiation is given to the nipples before starting hormone
             therapy (e.g., Stilbesterol) for a prostate primary, it is
             not coded as radiation therapy.

2.3   CHEMOTHERAPY (Items 21, 28):

2.3.1   Definition:

             Any chemical which is administered to attack or treat cancer
             tissue and which is not considered to achieve its effect through
             change of the hormone balance is considered chemotherapy.
             The agent to be administered rather than the method of adminis-
             tration (oral, IV, topical, instillation into pleura or abdom-
             inal cavity, etc.) is relevant to coding. (See Subsection 4 for
             CCPDS reporting procedures.)

             Examples:

2.3.2   (See list in Subsection 5. below.)

2.4   ENDOCRINE THERAPY (Items 22, 29):

2.4.1   Definition:

             Endocrine therapy is the primary or secondary use of any type
             of cancer-directed therapy which exercises its effect on can-
             cer tissue via change of the hormone balance of the patient.
             Included are the administration of hormones, anti-hormones,
             steroids, surgery for hormonal effect on cancer tissue, and
             radiation for hormonal effect on cancer tissue. (See Sub-
             section 4 for CCPDS reporting procedures.)

             Specifics:

2.4.2   - Estrogens are considered primary anti-tumor drugs for carci-
               noma of the breast and prostate only.

             - Androgens are coded as therapy for breast cancer only.

             - Thyroid hormones, exogenous or dessicated thyroid should be
               coded as endocrine therapy only if given subsequent to total
               or subtotal thyroidectomy for thyroid cancer.

             - Progesterone and its derivatives are considered treatment for
               carcinoma of the uterus, ovary, kidney and breast.

             - Prednisone and other adrenocorticosteroids are considered
               primary anti-tumor drugs for acute and chronic leukemia,
               Hodgkins and non-Hodgkins lymphoma, multiple myeloma and
               carcinomas of the breast and prostate. (Note: They are
               considered support drugs for primary or metastatic malig-
               nancies of the brain and are not coded as endocrine therapy
               in such cases.)

Ref.

2.4.3   Endocrine ablative procedures, such as oophorectomy, adrenalectomy, hypophysectomy and orchiectomy, are only coded as primary treatment for carcinoma of the breast and prostate.

Endocrine ablative procedures can be done either by surgery or radiation therapy. For paired glands, both, or the remaining gland, must be removed or irradiated for the procedure to be considered therapy.

Example:

An oophorectomy is coded as endocrine surgery for a hormone-dependent tumor such as that occurring in the breast. If the oophorectomy specimen reveals metastatic disease it would be coded both as endocrine therapy (Item 22 or 29) and as definitive surgery (Item 19 or 26).

2.4.4   Endocrine radiation is focused at or directed toward an endocrine organ in order to affect cancer tissue by altering the hormonal balance. Incidental endocrine radiation, such as that which a patient might receive in the course of radiation therapy for a prostate primary, is excluded. Endocrine radiation is coded only when the intent of the radiation is documented. The specific rules for coding endocrine radiation are the same as for endocrine surgery.

2.4.5   All other hormones such as insulin or ACTH are considered support or replacement medications and are not coded as therapy for cancer.

2.5   IMMUNOTHERAPY (Items 23, 30):

2.5.1   Definition:

Immunotherapy includes administration of antigen or antibody or any technique which heightens the patient's immune response. This is almost always used as an adjunct to surgery, radiation, and/or chemotherapy.

Biologic Response Modifier (BRM), considered synonymous with immunotherapy, is the generic term for all substances which change the immune system or the host response (defense mechanism) to the cancer. (See Subsection 4 for CCPDS reporting procedures.)

2.5.2   Examples of immunotherapy and BRM:

- Allogenic Cells
- BCG* (synonyms include MER and TICE)
- Bone marrow transplant
- C-Parvum
- Interferon (different types include leukocyte, fibroblast and lymphoblastoid)

Ref.

- Levamisole
- MVE-2
- Pyran Copolymer
- Thymosin
- Vaccine therapy
- Virus therapy
- Vitamin A
- 13 cis-retinoic acid

* "Challenge doses" of BCG or other immunotherapy agents are
  considered testing, rather than therapy.

2.6   OTHER CANCER THERAPY (Items 24, 31):

2.6.1   Definition:

            This category includes any cancer-directed therapy that is not
            appropriately assigned to the other specific treatment codes.
            It includes any experimental or newly developed method of treat-
            ment differing greatly from accepted types of cancer therapy.

2.6.2   Examples:

            - Hyperbaric Oxygen (as adjunct to definitive treatment)
            - Hyperthermia
            - Renal Artery Blocking

2.6.3   Caution: guidelines for experimental or newly developed methods
            of treatment are the same as those for the traditional types of
            treatment; i.e., these therapies must be used with the intent
            of affecting, destroying, removing, controlling or changing
            malignant tissue.

2.7   NO CANCER THERAPY:

2.7.1   If the patient receives no therapy or gets symptomatic/suppor-
            tive therapy only, this is classifed as "No cancer-directed
            therapy" and Items 19-24, or Items 26-31 should be coded
            "000000".

2.7.2   If a patient receives no cancer-directed therapy within the
            first four months after admission, either in the center or by
            other physicians after discharge from the center, Items 26-31
            should be coded "000000, No cancer-directed therapy". This
            applies also to a patient whose therapy is initiated more than
            four months after admission to the center.

            Note: Whenever Items 26-31 are coded "000000", Item 25, "Date
            of Initial Course of Therapy After Admission to Center", must
            be coded "0000".

Ref.

3.   Palliative Treatment

3.1   Definition:

The term "palliative" is normally used in two senses: a) non-cur-
ative and b) alleviating symptoms. Thus some of the treatments
termed palliative fall within the definition of cancer-directed
treatment and others are excluded because they treat the patient
but not the cancer.

In some cases it cannot be determined from the medical record
whether or not the treatment falls within the definition of
cancer-directed therapy. It is not always clear whether the
treatment was given to attack or to control the cancer or to
provide symptomatic/supportive therapy only. It is important
that a physician interpret the medical record in problem cases.

3.2   Examples of palliative procedures which are not considered defini-
tive therapy and are not reported to CCPDS:

- Bypass surgery: Surgical procedure to divert a passage around
     a tumor or obstruction.

- Cranial decompression: Removal of a piece of cranium to relieve
     intracranial pressure.

- Lobotomy: Division of one or more nerve tracts in a lobe of the
     cerebrum.

- Nerve Block: Blocking of sensory nerves or roots with injection
     of alcohol or other chemical agents.

- Paracentesis: Withdrawal of fluid from the abdominal cavity.

- Rhizotomy: Surgical division of any root, as a nerve.

- Thoracentesis: Withdrawal of fluid from the thoracic cavity.

- Tracheotomy: Surgical incision into the trachea.

- Tractotomy: Surgical resection of a nerve fiber of the central
     nervous system.

4.   CCPDS/SAQC Therapy Tabulations

4.1   In June 1982, the TAC and PAC Executive Committees approved specific
modifications to the CCPDS/SAQC therapy tabulations. Although both
Prior (Items 19-24) and Initial Cancer-Directed Therapy (Items 26-31)
are reported to SAQC as twelve individual data items, for CCPDS
tabulations the database codes for Prior Chemotherapy (Item 21) and
Prior Endocrine Therapy (Item 22), both additive and ablative, are
combined by SAQC into one code, "Prior Chemo/Endocrine Therapy".

Ref.

Also Initial Chemotherapy (Item 28) and Initial Endocrine Therapy (Item 29) are combined into one item, "Initial Chemo/Endocrine Therapy".

Similarily, the coding of Immunotherapy (Items 23, 30) and Other Cancer Therapy (Items 24, 31) are combined at SAQC as "Other Systemic Cancer Therapy" for the relevant therapy items.

4.2   Any required change in data submission practices on the part of the cancer center has been postponed until the next dataset revision. Institutions may choose to continue to separate drugs which have a hormonal effect from those which do not; however, for CCPDS data reporting purposes these categories are collapsed by SAQC into combined codes.

4.3   After July 1, 1982 all CCPDS reports (except for the routine AIR's) will be generated by SAQC in the combined-code format.

4.4   If a center wishes to modify its reporting practices to conform to the new grouping of therapy codes, SAQC will accept data in the revised format prior to the next dataset revision. The SAQC Database Manager should be consulted for advice on the method of submission and for the effective date.

5.   Chemotherapy and Hormone Agent List

Delays in publication of the SEER Program Self Instructional Manual for Tumor Registrars, Book 8 - Antineoplastic Drugs, have prevented incorporation of the Chemotherapy and Hormone Agent List in DAM-2 at this time.

MATZ'S RULE REGARDING MEDICATIONS:

A DRUG IS THAT SUBSTANCE, WHICH,

WHEN INJECTED INTO A RAT, WILL

PRODUCE A SCIENTIFIC REPORT.

APPENDIX 5

CCPDS Definitions for Coding Cancer Therapy

From the CCPDS Data Acquisition Manual, Version 2, June 1981. This section last updated July 1982.

APPENDIX F

DEFINITIONS AND GUIDELINES FOR CODING CANCER THERAPY

Ref.

1.   Definition of Cancer-Directed Therapy

1.1   The term "cancer tissue" generally refers to proliferating malig-
            nant cells or to an area of active production of malignant cells.
            The concept of definitive treatment is limited to procedures
            directed toward cancer tissues whether of a primary or metastatic
            site.

1.2   The definition includes only cancer-directed (definitive) therapy
            and excludes therapy which treats the patient but has no effect
            on malignant tissue. Treatment solely for the relief of symptoms
            is thereby excluded. (See also Page F-5, 3.)

1.3   To be coded as treatment, a specific therapy must normally affect,
            control, change, remove, or destroy cancer tissue. It does not
            have to be considered curative for a particular patient in view
            of other factors such as extent of disease, incompleteness of
            treatment, lack of apparent response, size of dose, operative
            mortality, or other criteria. In some instances, malignant cells
            are found in tissues in which they did not originate and in which
            they do not reproduce. A procedure for removing malignant cells
            but not attacking a site of proliferation of such cells is NOT to
            be considered cancer treatment for the purpose of this program.

2.   Guidelines for Coding Cancer-Directed Therapy

2.1   SURGERY (Items 19, 26):

2.1.1   Definition:

                Surgery is the removal of cancer tissues by operative proce-
                dures.

2.1.2   Examples:

                - Hysterectomy for uterine cancer
                - Mastectomy for breast cancer
                - Gastrectomy for stomach cancer
                - TUR (Transurethral Resection) with removal of cancer tissue
                      for bladder and prostate neoplasms
                - Local excision with removal of cancer tissue (including
                      excisional biopsy and excluding incisional biopsy)
                - Subtotal removal of brain tumor to reduce tumor burden
                - Dessication and Curettage for bladder neoplasms
                - Fulguration for skin, rectal and bladder neoplasms

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Ref.

- Electrocautery
- Photocoagulation
- Cryosurgery
- Chemosurgery
- Laser Therapy
- Conization for carcinoma in-situ of the cervix uteri (not therapy if invasive carcinoma of cervix)
- Surgery removing metastatic malignant tissue (not therapy if done for diagnostic purposes only)

2.1.3   Exceptions:

- Exploratory surgical procedures are excluded.
- Splenectomy in lymphoma or leukemia cases is not coded as therapy unless the spleen is involved with neoplasm.
- Vocal cord stripping is not considered definitive therapy for invasive carcinoma of the vocal cord unless followed by radiation therapy.
- Removal of node(s) in lymphoma cases is not coded unless removal is for more than diagnostic purposes, even if followed by irradiation. Specifically, if the lymphoma is localized to a particular node or chain of nodes and all of these nodes are removed, then it is treatment. If removal of a node is purely for diagnostic purposes and known tumor is left behind, it is not treatment.

2.2   RADIATION (Items 20, 27):

2.2.1   Definition:

This includes all beam and other radiation directed to cancer tissues regardless of source of radiation.

2.2.2   Examples:

- X-ray (not including diagnostic X-rays)
- Cobalt bomb
- Linear accelerator
- Neutron beam
- Betatron
- Spray radiation
- Internal use of radioactive isotopes whether given orally, intracavitarily, interstitially, or by intravenous injection
- All implants, molds, seeds, needles, applicators of radioactive material such as radium, radon, radioactive gold, etc.

2.2.3   Exception: When radiation is given to the nipples before starting hormone therapy (e.g., Stilbesterol) for a prostate primary, it is not coded as radiation therapy.

<u>Ref.</u>

2.2.3   Exception:

               When radiation is given to the nipples before starting hormone
               therapy (e.g., Stilbesterol) for a prostate primary, it is
               not coded as radiation therapy.

2.3   CHEMOTHERAPY (Items 21, 28):

2.3.1   Definition:

               Any chemical which is administered to attack or treat cancer
               tissue and which is not considered to achieve its effect through
               change of the hormone balance is considered chemotherapy.
               The agent to be administered rather than the method of adminis-
               tration (oral, IV, topical, instillation into pleura or abdom-
               inal cavity, etc.) is relevant to coding. (See Subsection 4 for
               CCPDS reporting procedures.)

               Examples:

2.3.2   (See list in Subsection 5. below.)

2.4   ENDOCRINE THERAPY (Items 22, 29):

2.4.1   Definition:

               Endocrine therapy is the primary or secondary use of any type
               of cancer-directed therapy which exercises its effect on can-
               cer tissue via change of the hormone balance of the patient.
               Included are the administration of hormones, anti-hormones,
               steroids, surgery for hormonal effect on cancer tissue, and
               radiation for hormonal effect on cancer tissue. (See Sub-
               section 4 for CCPDS reporting procedures.)

               Specifics:

2.4.2   - Estrogens are considered primary anti-tumor drugs for carci-
                 noma of the breast and prostate only.

               - Androgens are coded as therapy for breast cancer only.

               - Thyroid hormones, exogenous or dessicated thyroid should be
                 coded as endocrine therapy <u>only if given subsequent to total
                 or subtotal thyroidectomy for thyroid cancer.</u>

               - Progesterone and its derivatives are considered treatment for
                 carcinoma of the uterus, ovary, kidney and breast.

               - Prednisone and other adrenocorticosteroids are considered
                 primary anti-tumor drugs for acute and chronic leukemia,
                 Hodgkins and non-Hodgkins lymphoma, multiple myeloma and
                 carcinomas of the breast and prostate. (Note: They are
                 considered support drugs for primary or metastatic malig-
                 nancies of the brain and are not coded as endocrine therapy
                 in such cases.)

- Endocrine radiation is focused at or directed toward an endo-
crine organ in order to affect cancer tissue by altering the
hormonal balance. Incidental endocrine radiation, such as
that a patient might receive in the course of radiation ther-
apy for a prostate primary, is excluded. Endocrine radiation
is coded only when the intent of the radiation is documented.
The specific rules for coding endocrine radiation are the same
as for endocrine surgery.

2.5   IMMUNOTHERAPY (Items 23, 30):

2.5.1   Definition:

Immunotherapy includes administration of antigen or antibody
or any technique which heightens the patient's immune response.
This is almost always used as an adjunct to surgery, radiation,
and/or chemotherapy.

Biologic Response Modifier (BRM), considered synonymous with
immunotherapy, is the generic term for all substances which
change the immune system or the host response (defense mech-
anism) to the cancer.

2.5.2   Examples of immunotherapy and BRM:

- BCG* (synonyms include MER and TICE)
- Bone marrow transplant
- Interferon (different types include leukocyte, fibroblast and
    lymphoblastoid)
- Levamisole
- MVE-2
- Thymosin
- Vaccine therapy
- Virus therapy

*"Challenge doses" of BCG or other immunotherapy agents are
    considered testing, rather than therapy.

2.6   OTHER CANCER THERAPY (Items 24, 31):

2.6.1   Definition:

This category includes any cancer-directed therapy that is not
appropriately assigned to the other specific treatment codes.
It includes any experimental or newly developed method of treat-
ment differing greatly from accepted types of cancer therapy.

2.6.2   Examples:

- Hyperbaric Oxygen (as adjunct to definitive treatment)
- Hyperthermia

Ref.

                    - Levamisole
                    - MVE-2
            | - Pyran Copolymer
                    - Thymosin
                    - Vaccine therapy
                    - Virus therapy
            | - Vitamin A
            | - 13 cis-retinoic acid

                    * "Challenge doses" of BCG or other immunotherapy agents are
                      considered testing, rather than therapy.

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2.6.1   Definition:

                This category includes any cancer-directed therapy that is not
                appropriately assigned to the other specific treatment codes.
                It includes any experimental or newly developed method of treat-
                ment differing greatly from accepted types of cancer therapy.

2.6.2   Examples:

                - Hyperbaric Oxygen (as adjunct to definitive treatment)
                - Hyperthermia
            | - Renal Artery Blocking

2.6.3   Caution: guidelines for experimental or newly developed methods
                of treatment are the same as those for the traditional types of
                treatment; i.e., these therapies must be used with the intent
                of affecting, destroying, removing, controlling or changing
                malignant tissue.

2.7   NO CANCER THERAPY:

2.7.1   If the patient receives no therapy or gets symptomatic/suppor-
                tive therapy only, this is classifed as "No cancer-directed
                therapy" and Items 19-24, or Items 26-31 should be coded
                "000000".

2.7.2   If a patient receives no cancer-directed therapy within the
                first four months after admission, either in the center or by
                other physicians after discharge from the center, Items 26-31
                should be coded "000000, No cancer-directed therapy". This
                applies also to a patient whose therapy is initiated more than
                four months after admission to the center.

                Note: Whenever Items 26-31 are coded "000000", Item 25, "Date
                of Initial Course of Therapy After Admission to Center", must
                be coded "0000".

Ref.

3.   **Palliative Treatment**

3.1   Definition:

The term "palliative" is normally used in two senses: a) non-cur-
ative and b) alleviating symptoms. Thus some of the treatments
termed palliative fall within the definition of cancer-directed
treatment and others are excluded because they treat the patient
but not the cancer.

In some cases it cannot be determined from the medical record
whether or not the treatment falls within the definition of
cancer-directed therapy. It is not always clear whether the
treatment was given to attack or to control the cancer or to
provide symptomatic/supportive therapy only. It is important
that a physician interpret the medical record in problem cases.

3.2   Examples of palliative procedures which are not considered defini-
tive therapy and are not reported to CCPDS:

- Bypass surgery: Surgical procedure to divert a passage around
    a tumor or obstruction.

- Cranial decompression: Removal of a piece of cranium to relieve
    intracranial pressure.

- Lobotomy: Division of one or more nerve tracts in a lobe of the
    cerebrum.

- Nerve Block: Blocking of sensory nerves or roots with injection
    of alcohol or other chemical agents.

- Paracentesis: Withdrawal of fluid from the abdominal cavity.

- Rhizotomy: Surgical division of any root, as a nerve.

- Thoracentesis: Withdrawal of fluid from the thoracic cavity.

- Tracheotomy: Surgical incision into the trachea.

- Tractotomy: Surgical resection of a nerve fiber of the central
    nervous system.

4.   **CCPDS/SAQC Therapy Tabulations**

4.1   In June 1982, the TAC and PAC Executive Committees approved specific
modifications to the CCPDS/SAQC therapy tabulations. Although both
Prior (Items 19-24) and Initial Cancer-Directed Therapy (Items 26-31)
are reported to SAQC as twelve individual data items, for CCPDS
tabulations the database codes for Prior Chemotherapy (Item 21) and
Prior Endocrine Therapy (Item 22), both additive and ablative, are
combined by SAQC into one code, "Prior Chemo/Endocrine Therapy".

Ref.

Also Initial Chemotherapy (Item 28) and Initial Endocrine Therapy (Item 29) are combined into one item, "Initial Chemo/Endocrine Therapy".

Similarily, the coding of Immunotherapy (Items 23, 30) and Other Cancer Therapy (Items 24, 31) are combined at SAQC as "Other Systemic Cancer Therapy" for the relevant therapy items.

4.2   Any required change in data submission practices on the part of the cancer center has been postponed until the next dataset revision. Institutions may choose to continue to separate drugs which have a hormonal effect from those which do not; however, for CCPDS data reporting purposes these categories are collapsed by SAQC into combined codes.

4.3   After July 1, 1982 all CCPDS reports (except for the routine AIR's) will be generated by SAQC in the combined-code format.

4.4   If a center wishes to modify its reporting practices to conform to the new grouping of therapy codes, SAQC will accept data in the revised format prior to the next dataset revision. The SAQC Database Manager should be consulted for advice on the method of submission and for the effective date.

5.   Chemotherapy and Hormone Agent List

Delays in publication of the SEER Program Self Instructional Manual for Tumor Registrars, Book 8 - Antineoplastic Drugs, have prevented incorporation of the Chemotherapy and Hormone Agent List in DAM-2 at this time.

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+------------------------------------------+
|                                          |
|  MATZ'S RULE REGARDING MEDICATIONS:      |
|                                          |
|  A DRUG IS THAT SUBSTANCE, WHICH,        |
|                                          |
|  WHEN INJECTED INTO A RAT, WILL          |
|                                          |
|  PRODUCE A SCIENTIFIC REPORT.            |
|                                          |
+------------------------------------------+
```

APPENDIX 6

Example from the CCPDS Inquiry Reporting System

The Inquiry Reporting System is a formal mechanism for recording questions and answers about coding of difficult or unusual cases. Such a system is used by SEER and CCPDS.

Inquiry No. 139
Date received at SAQC: Revised:
Date of SAQC response: 3/29/82

Item #	Item Name / Comment	Item Code
13	Primary Site	153.9
15	Histology	8220/3

Question:
----

1) When should the histology 8220/3 (adenocarcinoma in adenomatous
   polyposis coli) be used?
2) What sites are appropriate?

Answer:

There are no clear guidelines for use in distinguishing between "multiple
polyps", "intestinal polyposis" or "multiple polyposis". The number of polyps
in these cases can vary from 100 to over 1,000. There is usually a family
history of polyposis of "multiple polyposis". It is best to code according to
the physicians sign-out diagnosis or query the pathologist for the appropriate
designation.

The hereditary colonic polyposes take several forms. Gardner's syndrome is a
familial polyposis of multiple colonic polyps with malignant potential associated
with multiple osteomatosis and multiple tumors of soft somatic tissue. Turcot's
syndrome is also a familial polyposis of the colon, but is associated with
malignant tumors (gliomas) of the CNS The term "familial polyposis" may also
be used without further description. All of these syndromes, when stated to
give rise to carcinomas of the colon/rectum, are coded to 8220/3.

It is the nature of familial polyposis to present with many carcinomas in
polyps as well as insitu and invasive carcinoma. However, it is considered
one disease process starting in the colon. NOTE: (If only the colon is excised,
the disease will recur in the rectum.) To avoid sorting out the various carcinomas
and sites involved and reporting the disease multiple times, CCPDS advises
that site be coded 153.9 (colon, NOS) and histology 8220/3 (adenocarcinoma
in adenomatous polyposis coli). This characterizes these cases most accurately.

Origin of Inquiry:

| -Where- | Who | Date | ---------- Details and Comments -------------- |
| | | 5/15/81 | SEER Inquiry Reporting System |

Schedule for distribution to all centers:

    Inquiry Batch #: 9   Date: 3/29/82

APPENDIX 7

Questionnaire from the Study of CCPDS Case-Definition Practices

The questionnaire contains 40 hypothetical patient situations intended to test a cancer registry's definition of reportable and non-reportable cases.

INCLUSION STUDY FOR DETERMINATION OF CENTER-REPORTED CCPDS CASES

CENTER NAME:_____   CENTER CODE __ __

DATE:_____   COMPLETED BY: _____

Answer each question for the following case presentations.

    A. Would this type of patient come to your center? (If answer is "No", proceed
       to next case.)
    B. Would this patient receive a hospital (cancer center) number?
    C. Would this patient be entered into your registry?
    D. Would you report this patient to CCPDS/SAQC?
    E. Do you think this patient should be reportable to CCPDS?

1. Patient seen in emergency room with difficulty in breathing.
Large tumor mass found in larynx; tracheostomy performed.
Clinical diagnosis of cancer. Biopsy with complete work-up
recommended, but the patient does not return. No previous
diagnosis or treatment of this cancer.

	A	B	C	D	E
NO					
YES					

2. Patient is seen in GYN Screening Clinic for a routine PAP smear;
no previous history of cancer or symptoms. Smear is positive for
invasive cancer; clinical work-up suggested, but patient does not
return.

	A	B	C	D	E
NO					
YES					

3. Patient in for routine physical on an outpatient basis has a
chest x-ray suspicious for carcinoma and a Class V sputum (positive
for malignancy). No previous history of cancer. Bronchoscopy and a
complete work-up recommended. Patient decides to see private phys-
ician and does not return.

	A	B	C	D	E
NO					
YES					

4. Woman with no previous breast cancer history finds a lump on
self-examination and has a biopsy of the lump on an outpatient
basis. Biopsy is positive for cancer and she is referred to her
local medical doctor for a mastectomy.

	A	B	C	D	E
NO					
YES					

5. Patient comes into outpatient clinic with the complaint of
"growth on my tongue". History and physical done, and incisional
biopsy revealed squamous cell carcinoma of the base of the tongue.
Radiation therapy is recommended, but the patient refuses and does
not return.

	A	B	C	D	E
NO					
YES					

Answer each question for the following case presentations.

A. Would this type of patient come to your center? (If answer is "No",
    proceed to next case.)
B. Would this patient receive a hospital (cancer center) number?
C. Would this patient be entered into your registry?
D. Would you report this patient to CCPDS/SAQC?
E. Do you think this patient should be reportable to CCPDS?

---

6. Woman with biopsy proven breast cancer (no prior therapy) is
seen and a physical examination and slide review done. The diagnosis
is confirmed and the patient is referred back to her local physician NO
for treatment; no specific treatment plan recommended.   YES

	A	B	C	D	E
NO					
YES					

7. Patient with clinical diagnosis of brain cancer is sent to center
for a CT scan because no CT facility is available at referring hosp-
ital. No physical examination or other workup is done. The CT   NO
confirms the diagnosis of a brain malignancy. The patient is sent
back to his private physician; no treatment plan or other diagnostic   YES
work-up done.

	A	B	C	D	E
NO					
YES					

8. Patient with a clinical diagnosis of metastatic carcinoma is
seen for confirmation. A history and physical is done. Laboratory
work-up reveals elevated HCG and confirms the diagnosis of chorio-   NO
carcinoma. She is referred back to her private doctor with no
further treatment work-up.   YES

	A	B	C	D	E
NO					
YES					

9. Patient with clinical diagnosis of cancer of the kidney has a
history and physical examination. IVP confirms the diagnosis of
hypernephroma. Patient is sent back to the referring physician   NO
with no treatment plan.   YES

	A	B	C	D	E
NO					
YES					

10. Patient with biopsy proven diagnosis of lung cancer is seen for
confirmation. A bronchoscopy with biopsy confirms the diagnosis;
patient is sent back to the referring physician. No additional   NO
work-up is done here.   YES

	A	B	C	D	E
NO					
YES					

11. Patient with clincial diagnosis of CML, confirmed by a positive
blood smear is seen for confirmation and treatment consult. History
and physical and a bone marrow biopsy confirms the diagnosis. The   NO
recommended treatment is "no treatment". Patient is sent back to
the referring physician.   YES

	A	B	C	D	E
NO					
YES					

12. Patient is referred with a clinical diagnosis of pancreatic
cancer for confirmation and treatment consult. An exploratory lapa-
rotomy, without biopsy, confirms the diagnosis. No recommendations   NO
regarding treatment are made and the patient is sent back to the
referring physician.   YES

	A	B	C	D	E
NO					
YES					

Answer each question for the following case presentations.

    A.   Would this type of patient come to your center? (If answer is "No", proceed to next case.)
    B.   Would this patient receive a hospital (cancer center) number?
    C.   Would this patient be entered into your registry?
    D.   Would you report this patient to CCPDS/SAQC?
    E.   Do you think this patient should be reportable to CCPDS?

---

13. Patient with clinical diagnosis of prostatic cancer has a history and physical, abdominal x-rays and biopsy. Diagnosis is confirmed and a treatment plan is designed. Patient is sent back to referring physicians for implementation of the plan.

	A	B	C	D	E
NO					
YES					

14. Patient with prostatic cancer diagnosed by needle biopsy one week PTA. A history and physical, blood work-up and IVP along with a slide review are completed by the center. The diagnosis is confirmed and a treatment plan is designed for delivery by referring physician.

	A	B	C	D	E
NO					
YES					

15. Patient with pathologically proven colon cancer is seen in the emergency room with abdominal carcinomatosis. Patient dies before any procedures or tests were performed. Patient had never been previously seen.

	A	B	C	D	E
NO					
YES					

16. Patient diagnosed by his local physician with carcinoma of the rectum is seen for confirmation of local physician's treatment plan. A history and physical and outside slide review are done. Diagnosis and treatment plan of radiation therapy and resection are confirmed. Patient is to be treated outside the center.

	A	B	C	D	E
NO					
YES					

17. Patient with pathologic diagnosis of colon cancer is admitted to the Oncology Ward for treatment work-up. History and physical, x-rays and blood work-up are done but patient dies on day of admission.

	A	B	C	D	E
NO					
YES					

18. Patient with a diagnosis of lung cancer by a positive sputum is referred and has a history and physical, x-ray, blood tests, broncho-scopy with positive biopsy and review of outside slides. Diagnosis is confirmed and treatment is recommended for delivery at the Center. Patient refuses the treatment, returns home and dies shortly there-after.

	A	B	C	D	E
NO					
YES					

Answer each question for the following case presentations.

> A. Would this type of patient come to your center? (If answer is "No", proceed to next case.)
> B. Would this patient receive a hospital (cancer center) number?
> C. Would this patient be entered into your registry?
> D. Would you report this patient to CCPDS/SAQC?
> E. Do you think this patient should be reportable to CCPDS?

---

19. A woman is referred with biopsy proven cervical cancer. Diagnosis is confirmed by x-ray, laboratory studies and examination. Inter-cavity radiation is recommended. Patient decides to have radiation elsewhere.

	A	B	C	D	E
NO					
YES					

20. Patient with acute myelogenous leukemia in remission for six months comes to Center for physical examination and laboratory workup. The remission is confirmed and patient is matched with a sibling for future bone marrow transplant. No therapy given at center. Patient returns home.

	A	B	C	D	E
NO					
YES					

21. Patient with previously diagnosed carcinoma of the stomach is referred to Center for admission and possible therapy of liver metastases. After admission, History and Physical, chest x-ray, and slide review, the patient expires secondary to myocardial infarction. No treatment for cancer given at center.

	A	B	C	D	E
NO					
YES					

22. Patient with previously diagnosed and treated carcinoma of sigmoid colon. Referred to Center for outpatient consultation regarding continuation of 5FU for recurrent disease. After history and physical, liver scan, blood work and slide review, Center recommends no further therapy. Patient returns home and follows advice.

	A	B	C	D	E
NO					
YES					

23. Patient with previously diagnosed and treated carcinoma of sigmoid colon. Referred to Center for outpatient consultation regarding continuation of 5FU for recurrent disease. After history and physical, x-ray, blood work, slide review, Center recommends no further therapy. Patient returns home and continues to receive 5FU.

	A	B	C	D	E
NO					
YES					

24. Patient with previously diagnosed osteosarcoma of the femur treated with above knee amputation. Referred to Oncology Clinic at Center for confirmation of adjuvant chemotherapy program. After history and physical, x-rays, blood work, slide review the Center confirms the existing treatment plan. The patient returns home and continues his chemotherapy.

	A	B	C	D	E
NO					
YES					

25. Patient with previously diagnosed carcinoma of the esophagus, currently on radiation therapy, self referred to Center for confirmation of treatment program. Workup includes history and physical, x-rays, blood work, slide and x-ray review. Center recommends change of treatment plan to include chemotherapy. Patient returns to PMD and completes radiation therapy course; no chemotherapy received.

	A	B	C	D	E
NO					
YES					

Answer each question for the following case presentations.

    A. Would this type of patient come to your center? (If answer is "No", proceed to next case.)

    B. Would this patient receive a hospital (cancer center) number?

    C. Would this patient be entered into your registry?

    D. Would you report this patient to CCPDS/SAQC?

    E. Do you think this patient should be reportable to CCPDS?

---

26. Patient with oat cell carcinoma of the lung diagnosed by bronch-oscopy and biopsy. Referred to Center for evaluation of current chemotherapy program. After history and physical x-rays, blood work, and slide review, Center recommended change of chemotherapy program to include Cis Platinum.

	A	B	C	D	E
NO					
YES					

27. Patient diagnosed 1976 in Florida with carcinoma of the colon. Recurrence in 1979 is being managed by weekly treatments of 5FU. While visiting relatives in the mid-west the patient, with a physician referral letter outlining the treatment program, goes to a cancer center for administration of chemotherapy. After review of the letter and discussions with the patient the therapy is admin-istered. The patient returns home at the end of her vacation.

	A	B	C	D	E
NO					
YES					

28. Patient with previously diagnosed and surgically resected embry-onal carcinoma of the testis, presents to outpatient clinic with metastases in the lungs. After history and physical, confirmatory CXR, blood work, and review of slides, because of physical condition no therapy is recommended. The patient returns home and expires.

	A	B	C	D	E
NO					
YES					

29. Patient diagnosed with carcinoma of the tongue with metastases to regional lymph nodes treated with radiation therapy. A biopsy immediately prior to outpatient visit at the Center reveals recur-rence. The patient is referred for pain control. A history and physical is done. No laboratory tests, x-rays or review of slides done. The center recommended glossectomy to be followed by chemo-therapy in an attempt to "cure". The patient refused this therapy and returned home, expiring one month later.

	A	B	C	D	E
NO					
YES					

30. Patient diagnosed with Meibomian gland carcinoma, metastatic to preauricular lymph node, treatment consisted of partial excision of primary and radiation of lymphatic drainage areas. Patient is referred to Center for recommendations regarding additional treatment Physical examination, eye examination was done; no lab work, diag-nostic tests or review of slides done. Several treatment choices were outlined:

	A	B	C	D	E
NO					
YES					

    1. No further treatment.

    2. Additional debulking.

    3. Enucleation of eye and complete resection of tumor and metastatic node areas.

The patient returned home with no indication of his treatment decision.

Answer each question for the following case presentations.

    A. Would this type of patient come to your center? (If answer is "No",
        proceed to next case.)
    B. Would this patient receive a hospital (cancer center) number?
    C. Would this patient be entered into your registry?
    D. Would you report this patient to CCPDS/SAQC?
    E. Do you think this patient should be reportable to CCPDS?

---

31. Patient with diagnosis of endodermal sinus tumor, treated with
unilateral oophorectomy and chemotherapy. Six months after diagnosis
lung metastases are discovered; chemotherapy regimen modified.
Patient referred to Center for second opinion of treatment plan.
Outside slides were reviewed. No diagnostic workup, laboratory
tests, or physical examination done. The treatment recommendations
were to continue the original chemotherapy plan, although other
suggestions were also mentioned. The patient returned home.

	A	B	C	D	E
NO					
YES					

32. Patient diagnosed with carcinoma of the breast with lymph node
metastases; treated with modified radical mastectomy (clinically no
evidence of disease). Referred to Center where slides were reviewed,
physical examination and x-rays done. No further treatment was
recommended by the Center.

	A	B	C	D	E
NO					
YES					

33. Same patient as #32, except the Center recommended adjuvant
chemotherapy which was refused by the patient.

	A	B	C	D	E
NO					
YES					

34. Same patient as #32, except the Center recommended adjuvant
chemotherapy which was begun six weeks after mastectomy in the
Center's outpatient department.

	A	B	C	D	E
NO					
YES					

35. Same patient as #32, except the patient was first seen at the
Center three months after her initial mastectomy and at that time
began adjuvant chemotherapy in the Center's outpatient department.

	A	B	C	D	E
NO					
YES					

36. Patient admitted to Center for acute myocardial infarction.
History reveals that patient was diagnosed five years prior to admis-
sion with chronic myelogenous leukemia. To date no therapy has been
instituted because patient is asymptomatic. Laboratory workup at
the Center confirms diagnosis of CML. No therapy is given or recom-
mended for the disease. Patient is discharged after recovery from
the myocardial infarction.

	A	B	C	D	E
NO					
YES					

Answer each question for the following case presentations.

    A.   Would this type of patient come to your center? (If answer is "No", proceed to next case.)

    B.   Would this patient receive a hospital (cancer center) number?

    C.   Would this patient be entered into your registry?

    D.   Would you report this patient to CCPDS/SAQC?

    E.   Do you think this patient should be reportable to CCPDS?

---

37. Patient with previously excised malignant melanoma enters Center one month after wide excision for evaluation of further therapy (clinically free of disease). Workup included history and physical, laboratory tests and slide review. Regional node dissection recommended but patient refused. Patient returned to his private physician.

	A	B	C	D	E
NO					
YES					

38. Patient with biopsy proven malignant melanoma, enters Center for wide excision. No pathology slides or report are available. At the time of wide excision at the Center no residual tumor is found in the specimen.

	A	B	C	D	E
NO					
YES					

39. Patient with acute myelogenous leukemia in remission for six months, enters Center for bone marrow transplant. The transplant is accomplished and the patient returns home.

	A	B	C	D	E
NO					
YES					

40. Patient with acute myelogenous leukemia enters the Center for bone marrow transplant. Because of physical status and no matched donor, no therapy is delivered. The patient returns home.

	A	B	C	D	E
NO					
YES					

APPENDIX 8

A Novel Method of Assessing Completeness of Tumor Registration

By
Heiberger, R.M., Miller, C.L., Feigl, P., Lane, W., Glaefke, G.
Cancer 51(12):2362-2366, 1983.

A comparison of two methods of assessing the completeness of cancer patient registration is reported and the relative merits of each discussed. Reproduced by permission of the publisher, J.B. Lippincott Co.

A Novel Method of Assessing Completeness
of Tumor Registration

RICHARD M. HEIBERGER, PHD,* CLIFFORD L. MILLER, MS,† POLLY FEIGL, PHD,‡
WARREN W. LANE, PHD,§ AND GWEN GLAEFKE, ART,‡

A random sampling method of measuring the completeness of registration of cancer patients was tested
at a university referral hospital. The target population consisted of all inpatients and nonprivate out-
patients with *in situ* or invasive malignancies. The medical records of a random sample of all hospital
records active in the last five years were reviewed to determine their reportability and inclusion in the
tumor registry (Method A). Traditional casefinding assessment methods were also employed by con-
ducting a complete review of four commonly used hospital sources for a short time period (Method
B). The primary purpose of the study was methodologic; namely, to test the feasibility of Method A
and to characterize it relative to the more traditional Method B. The estimated missed case rates using
Methods A and B (3% and 5%, respectively) are not directly comparable because not all outpatient
information is recorded in the medical record. It is concluded that as a means of completeness as-
sessment, Method A can be feasible, cost effective, and useful in other institutions provided certain
conditions are met: (1) an appropriate random sample of the target population can be obtained; (2) all
relevant information is available in a unit medical record; (3) the reviewer is fully aware of the re-
portability criteria.

Cancer 51:2362–2366, 1983.

THE TUMOR registry is a valuable tool for cancer re-
search at the hospital level as well as in wider ap-
plications. However, usefulness of this tool is vitiated if
a substantial number of eligible cases fail to be registered.
This paper describes recent experience in measuring the
completeness of tumor registration at the Hospital of
the University of Pennsylvania (HUP). The project was
sponsored by the Centralized Cancer Patient Data Sys-
tem (CCPDS), to which the University of Pennsylvania
Cancer Center (UPCC) is a contributor.

The CCPDS is a standard registration system of pa-
tients with reportable malignant neoplasms seen at the
21 Comprehensive Cancer Centers in the United States.
The system has been described elsewhere by Feigl *et al.*[1]
At the inception of CCPDS, it was suspected that a sig-
nificant number of reportable cases would fail to be en-
tered into the system. Studies done by three of the par-
ticipating centers supported this suspicion. Studies at
Duke University (Laszlo[3] and the Mayo Clinic, Golen-
zer,[3]) estimated missed case rates at 50–60% and 12–
25% respectively. Site-specific studies at Mayo and the
Johns Hopkins Oncology Center (Lenhard[4] identified
significant numbers of cases missed by their tumor regis-
tries.

The New Approach

New case identification by a tumor registry is a com-
plex function, since all cancer patients cannot be found
through a single information source. Institutions at-
tempting to identify their cancer patient population gen-
erally devise a system in which several independent
sources are reviewed, either by registry personnel, or by
source personnel who send selected cases to the registry.
A survey of 18 centers, conducted by the Statistical Anal-
ysis and Quality Control (SAQC) office of CCPDS in
1978, revealed that the most common sources utilized
were medical record and pathology departments, on-

cology and radiation therapy clinics, and diagnostic indices.

Because of the wide variation in patient characteristics, institutional structure, and experience of registry staff, it is difficult to assure that any system will capture close to 100% of all cancer patients seen at an institution. The CCPDS Quality Control and Training Subcommittee found that the most commonly utilized method for assessing casefinding completeness was a re-review of a sample of several casefinding sources. This method provides an estimate of cases lost because of carelessness or lack of expertise, but not how many reportable cases never appear on the sources. It is precisely those cases which determine whether the current sources are adequate to cover the patient population. Consequently, for the assessment of the missed-case rate for CCPDS participating centers, it is important to use some method which samples the *entire* group of patients seen by the associated hospital or hospitals, and estimate a missed-case rate based on that sample.

This "saturation" approach to assessing casefinding completeness has seldom been undertaken. The feasibility of obtaining a random sample of all patients, and the resources necessary to conduct such a study, were unknown. CCPDS therefore elected to sponsor a pilot project at a single center to compare the costs, efforts, and outcomes in terms of missed cases found using the "source-review" with those using the saturation method. The UPCC volunteered to perform the pilot study, and a detailed protocol for the study was prepared by the Subcommittee, SAQC, and the UPCC Biostatistics Program. Specific objectives of the study were as follows: (1) Estimate from a sample of all patients assigned medical record numbers at HUP, the proportion of CCPDS-reportable cases actually reported for a specified time period; (2) Compare the rate of missed cases determined from this method with that discovered by re-examining the current HUP casefinding sources; and (3) Evaluate the feasibility and costs of assessment methods used in the study as a means of developing methods applicable to other comprehensive cancer centers.

Casefinding at the University of Pennsylvania Cancer Center

The UPCC is a multidisciplinary program in cancer research, education, and clinical care and (jointly with the Fox Chase Cancer Center) is a National Cancer Institute (NCI) designated comprehensive cancer center. New CCPDS reportable cancer patients account for approximately 4% of all HUP admissions.

HUP tumor registry personnel use several methods for identifying reportable cases. Principally, the Medical Record Department routes records of cancer patients to the registry. In addition, the registry receives: (1) pa-

thology, cytology, bone marrow, and autopsy reports; (2) notes from several clinical units; and (3) diagnostic index listings of all inpatients discharged with a primary or secondary diagnosis of cancer.

Methods

Method A

A random sample of all records in the HUP medical record room was drawn and the records reviewed to ascertain diagnosis of cancer and inclusion in the hospital tumor registry.

The patient population of UPCC includes hospital inpatients, hospital outpatients, and private group practice outpatients. The patient population for Method A was originally intended to include all inpatients and outpatients receiving hospital numbers. However, during the course of the study it was determined that the hospital records sampled in Method A routinely excluded most outpatient material because outpatient clinics maintain separate filing systems and do not forward copies to the main Medical Record Department. Therefore, in retrospect, it was determined that Method A did not sample the total hospital population.

HUP admits approximately 25,000 inpatients annually. Patient records are stored in the Medical Record Department using terminal digit filing. In this system, records with the same last three digits are filed next to each other. For example, records numbered 000,014, 001,014, 002,014 through (as of December 1979) 565,014 are next to each other. Records are kept on the active shelves for a minimum of five years after last contact or death.

The sampling plan used for this study is based on the filing arrangement. A sampling unit is a set of 566 record numbers with the same last three digits. Ten adjacent sampling units (all with the same last 2 digits) form a cluster. It is safe to assume that both the assignment of numbers and the physical location of the records are independent of diagnosis. Records were reviewed until the end of the cluster in which the 60th CCPDS reportable tumor was identified (if the null hypothesis is a true missed case rate of $P = 0.02$, a one sample one-sided test with significance level of .05 would require a sample size of n = 59 tumors for 90% power against an alternative of $P = 1.10$).

All medical records with patient contact at HUP between July 1, 1977 (the initial reporting date for CCPDS) and December 31, 1979 were in the target population. UPCC personnel examined the records to determine whether they represented reportable cancer cases and, if so, whether they were entered into the HUP tumor registry and subsequently reported to SAQC. Initially, 172 (4.4%) records were "not present" (Table 1); all were

TABLE 1.   Classification of Medical Records Reviewed
by UPCC: Method A

Sampling Cluster	NA	PE	TE	NR	RT	MC*	%	Total
×14	10	3695	1034	889	32	(1)	3	5660
×26	10	3728	933	954	35	(1)	3	5660
Total	20	7423	1967	1843	67	(2)	3	11320

The total missed case rate for Method A is 3%.

* Missed cases are not added in the totals but are included in Reportable Tumors.

NA: Not assigned; numbers initially assigned to patients with previously assigned numbers; and not subsequently reassigned; PE: Presumed early; not on shelves, no sign-out slip, and number prior to 500,000 (assigned 12/76); TE: Too early; no contact during study time frame; NR: Not reportable; Contact within study time frame other than for a CCPDS reportable tumor; RT: Reportable tumor; first HUP contract for a CCPDS-reportable tumor within the sample time frame (7/77 to 12/79); MC: Missed case; reportable tumor not in tumor registry; %: Percentage of MC:RT.

eventually located. Three sampling units were randomly selected for re-review by SAQC personnel duplicating HUP procedures but without pursuit of "not present" records.

Method B

Method B (Table 2) utilized samples of hospital patients with contact in March, 1979 from the following sources: (1) surgical pathology, cytology, and bone marrow reports; (2) inpatient disease index; (3) lists of all inpatients and outpatients seen by Medical Group physicians including hematology–oncology; (4) all initial

TABLE 2.   Cancer Contacts by Clinical Units: Method B

Source	NP	OC	NR	RT	MC*	%	Total
Pathology	0	20	2	128	(1)	1	150
Disease index	0	0	78	182	(7)	4	260
Medical group	1	38	99	199	(5)	3	337
Radiation therapy	0	0	19	61	(6)	10	80
Other	45	20	1091	189	(5)	3	1345
Total contacts	46	78	1289	759	(24)	3	2172
Unique tumors				501	(24)	5	

The total missed case rate for Method B is 5%.

* Missed cases are not added in the totals but are included in Reportable Tumors.

NA: Not assigned; numbers initially assigned to patients with previously assigned numbers and not subsequently reassigned; PE: Presumed early; not on shelves, no sign-out slip, and number prior to 500,000 (assigned 12/76); TE: Too early; no contact during study time frame; NR: Not reportable; contact within study time frame other than for a CCPDS reportable tumor; RT: Reportable tumor; first HUP contact for a CCPDS-reportable tumor within the same time frame (7/77 to 12/79); MC: ·Missed case; reportable tumor not in tumor registry; %: Percentage of MC:RT; NP: Not present; signed out for clinical or research use, or missing (not on shelves, not signed out, and record number greater than 500,000); OC: Outside case; no medical record number (consultation, private outpatient, or Veteran's Administration Hospital patient).

contacts from radiation therapy; and (5) several other clinical units. Reportable cases were determined for each source and compared with the tumor registry file. Fifty percent of the Radiation Therapy patients were re-reviewed by SAQC personnel as an audit.

Results

Method A

Table 1 presents the final outcome of Method A as determined by UPCC personnel. This sample represents the entire inpatient population at the UPCC and some of the hospital outpatients.

Of the 11,320 records in the sample, 7423 were presumed early, and 3897 records were actually examined. Of these, 1967 cases had their last contact prior to July 1977, 1843 cases had no contact for cancer from July 1977 through December 1979, and 20 cases had improperly assigned hospital numbers. Sixty-five of 67 reportable tumors identified were in the tumor registry, representing a missed case rate of 3%. A chi-square analysis showed no significant difference in the proportion of cases assigned to each code by sampling unit. There was no difference in the rate of reportable tumors between those cases initially present in the record room and those located subsequently. Examination of primary site distribution for the 67 reportable cases showed the sample to be representative of the usual pattern seen at UPCC.

The results of a re-review of three sampling units by SAQC personnel essentially concurred with the results of UPCC. Two records were coded as reportable tumors by SAQC and not by UPCC. One case, based on clinical impression, was eventually resolved in favor of SAQC coding. The other record was "too early" (UPCC coding) because an earlier admission was not available to SAQC.

Method B

Method B results are found in Table 2. If possible, the clinical units prepared a listing or log of cancer contacts for March of 1979. Otherwise, all clinic records for March 1979 were reviewed, accounting for wide variation in numbers of not reportable cases. Of the 2172 contacts reviewed, 46 were not located, and 78 were "outside contacts" (Tables 1 and 2). First cancer contact for this tumor was prior to July 1977 in 322 cases. Because of considerable overlap among clinical units, the 759 cancer contacts represent only 501 unique reportable tumors. On the average, each tumor was identified in 1.5 clinical units.

Of the 501 reportable tumors, 24 were not in the tumor registry (5%). No systematic characteristics were found among missed cases. Thirteen of the 67 cases found in Method A were again identified through

Method B. It is interesting to note that 19% of the hospital cancer cases from the sample seen in a 2½-year period had contact in one month. This reflects the long-term care necessary for chronic diseases such as the various forms of cancer.

Costs

The principal costs in this study were for personnel, supplies and computer time. A subcontract ($15,000 direct costs) between UPCC and SAQC provided the bulk of planning and analysis costs. In addition, SAQC and the CCPDS Quality Control and Training Working Group incurred planning costs. The clinical units absorbed some implementation costs, primarily in procedural design. Additional costs were covered by various other grants (see Acknowledgments). The total direct cost of the study is estimated to be approximately $25,000.

About ten days were required to determine a feasible manner of sampling the population for Method A. The actual record review required a total of approximately 33 days full-time equivalent (FTE). The first review required 20 days and accounted for 96% of those records not presumed early. An additional ten days FTE over a six-month period were required to locate remaining cases. It should be emphasized that had the medical record been a complete unit record, including all outpatient contacts, it might have taken twice as long to accomplish the actual review. The re-review of three sampling units required an additional three FTE days.

Determination of an appropriate sampling procedure for each clinical unit in Method B required ten days. A total of 42 days FTE were necessary to complete the source review. FTE expenditures for individual components of Method B were as follows: pathology review, two days; radiation therapy, five days; disease index, 10 days; medical group listings, 10 days; remaining units, 15 days.

Discussion

The Method A population is not identical to the Method B population (since the hospital medical record does not include most outpatient contact), hence the missed case rates determined from Methods A and B are not immediately comparable. Instead, this article reports the populations considered by each method and the missed case rate determined by each.

The design of a feasible, systematic sampling plan for Method A required several iterations. Initially, a direct sample was considered for the time period of interest using billing information. At HUP, diagnosis billing information was available only for inpatient admissions and did not cover the sample time period uniformly. Review of all medical records with numbers assigned

during a specified time period was considered. However, this was not appropriate, since many patients with contact during the sample period would have had a previous hospital contact for some other diagnosis, hence, an earlier number, and would be excluded from the sample.

The final procedure, selection of sampling units based on the filing arrangement in the record room, has as advantages: ease of access to the relevant records; complete coverage of all years of assignment of numbers to patients; use of the medical record itself (not a secondary source) as the determining factor for eligibility; complete coverage of the entire period of CCPDS existence. Elimination of cases with no contact during the specified time period was accomplished quickly by reviewing the list of admissions in the record. Each day of the initial review about 200 records were actually examined and 360 records presumed early.

The most difficult task was the determination of the population for whom records appear in the record room. The procedures for assigning numbers to some outpatients, but not others, and criteria for including outpatient contacts in the central medical record were not fully understood until some time after the review was completed.

Each clinical unit studied in Method B required its own sampling procedure. Procedures included review: (1) log books or file copies of reports; (2) listings from computerized billing systems; and (3) appointment books. As a result of the study, some changes in standard operating procedure have been implemented.

Conclusions

In a hospital unit record system with terminal digit filing, the filing arrangement can be exploited to yield a random sample of all hospital records on file (Method A). The success of the method depends on the shelves actually containing a *complete* record (or pointer to a complete record) for every hospital patient in the target population. Attention to the implications of removing records from the shelf for inactive or deceased cases is essential.

More generally, a sampling approach to measurement of registry completeness is useful provided certain conditions are met: (1) A sampling frame (list) is available for the target population, such that a random sample can be conveniently drawn. In addition to the record room filing system, possibilities include billing records and admissions lists for specified time periods. Definitions of patients included in the sampling frame must be evaluated critically to assure that they encompass the entire target population; (2) All relevant information is in the medical record that is reviewed. A common pitfall is that some outpatient documents may not be included

in the unit record; and (3) The reviewer of the records is fully versed in the subtleties of registry reportability criteria.

Method A can be modified to work in other institutions. The cost would be less than development costs at the UPCC because many of the problems have been delineated, as reported by Heiberger and Miller.[5]

Consistency across sampling units suggests the 2% sample done at HUP was more extensive than necessary for a low precision estimate of the missed case percentage, *i.e.*, for distinguishing between a 5% and 15% missed case rate.

Scientific sampling of hospital records is potentially useful as a means of measuring completeness of registration (assessment) but it would not be useful as a casefinding technique in most institutions. Except in cancer speciality centers, inordinate energy would be expended reviewing noncancer cases. In a cancer speciality center,

the sampling method might serve as a casefinding technique if done on a recurrent basis for admissions in successive time periods.

Method B can be used to determine an estimate of the number of cancer contacts not currently included in the tumor registry patient definition. An approximation of the costs involved for extension to include these contacts can then be determined.

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APPENDIX 9

A Survey of American College of Surgeons Hospital Based Tumor Registries

By
Bender, A.P., Olsen, G.W.
Journal of AMRA, 55:20-23, 1984.

This paper presents the results of a survey of approved hospital tumor registries undertaken to determine the best predictors of cost of operation. Reprinted from the January 1984 *Journal of the American Medical Record Association* with permission of the publisher. ©1984 American Medical Record Association. All rights reserved.

A Survey of the American College of Surgeons Hospital Based Tumor Registries

BY ALAN P. BENDER, DVM, PhD
GEARY W. OLSEN, DVM, MPH

Recently, several states including Minnesota have investigated the feasibility of statewide cancer surveillance systems. A major limiting factor in the feasibility of cancer registries (statewide or hospital) is the cost of operation. As part of its investigation, the Minnesota Department of Health conducted a stratified random sample survey of American College of Surgeons (ACOS) approved hospital tumor registries. The best predictor for cost of operation was found to be the number of cancer cases diagnosed annually in the hospital. Bed size of the hospital was a poor predictor of annual cancer case load. Large variability in cost per case suggested a lack of standardization in operational methods of ACOS registries.

The Minnesota Department of Health (MDH) recently investigated the feasibility of a statewide (population-based) cancer surveillance system.[1] During the course of this investigation more than one hundred articles published between 1969 through 1981 about cancer registration were reviewed and annotated.[2] The literature search yielded little substantive information on the actual performance and resultant costs of registry operation. This lack of detailed information, which has been commented on by others,[3] makes it very difficult to estimate the impact of operational components on quality and cost of registry data.

The World Health Organization[4] recommends that one of the aims of hospital-based registries should be to facilitate information exchange with population-based cancer registries. In view of the limited available data and the possibility that hospital-based registries could be coordinated with a statewide population-based system in Minnesota, MDH conducted several surveys of cancer registries in the United States. The purpose of the surveys was to develop background information for designing a feasibility study of a statewide cancer surveillance system. This article summarizes results from a survey of the American College of Surgeons (ACOS) hospital tumor registries.

The ACOS hospital tumor registries comprise the largest hospital-based tumor registry system in the United States. These registries are an integral part of the ACOS Cancer Program which promotes improvements in cancer prevention, early diagnosis, pretreatment evaluation, staging, optimal treatment, rehabilitation, surveillance for recurrent and multiple primary cancers, and care of dying patients.[5] In order to pursue these goals and obtain approval from the American College of Surgeons, a hospital must comply with four basic requirements. The hospital must: 1) establish a cancer committee; 2) have a clinical cancer program; 3) research patient care evaluation; and 4) provide cancer patient follow-up and end-results reporting. To support these activities, ACOS requires the development of a hospital-based tumor registry. As of June 1983, the American College of Surgeons had accredited 1,013 hospital tumor registries.[6] These 1,013 hospitals represent approximately 15 percent of all hospitals and together they contain 33 percent of all hospital beds in the United States.[7]

The American College of Surgeons requires that a standardized data set of 28 data elements be maintained for each patient

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by an approved hospital tumor registry.[8] Data on patient identification, cancer identification, extent of disease at diagnosis, first course of treatment, follow-up and quality of life (survival) are required. However, ACOS affords some latitude to hospital cancer committees in determining the methods by which case information is obtained. Therefore, in spite of the standardized product of the registry, there may be considerable variability in the costs of collecting and maintaining data required for approval of the Cancer Program.

Methods

The MDH's Chronic Disease Epidemiology Section surveyed 15 percent of all ACOS approved hospital tumor registries listed in the directory of the American Hospital Association.[9] At the time of the survey in May 1982 there were 975 approved hospitals listed, but only 953 of the listings included bed size. The hospitals were stratified by region of the country (North, South, East, West) and by bed size as listed in the directory (less than 400 or greater than or equal to 400 beds). The states included in each regional category are listed below:

- North Region—Illinois, Indiana, Iowa, Kansas, Michigan, Minnesota, Missouri, Nebraska, North Dakota, Ohio, South Dakota, and Wisconsin
- South Region—Alabama, Arkansas, Florida, Georgia, Kentucky, Louisiana, Mississippi, North Carolina, Tennessee, Texas and Virginia
- East Region—Connecticut, Delaware, District of Columbia, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, Vermont, and West Virginia
- West Region—Alaska, Arizona, California, Colorado, Hawaii, Idaho, Montana, New Mexico, Nevada, Oregon, Utah, Washington and Wyoming.

Table 1
Numbers of Randomly Selected Hospitals and Distribution of Responses by Strata

| Stratum | Responses | | | Total Surveyed | Number of Hospitals |
	Complete	Partial	None		
North, < 400 Beds	9	2	4	15	111
North, ≥ 400 Beds	14	3	1	18	109
South, < 400 Beds	10	1	4	15	113
South, > 400 Beds	12	0	2	14	99
West, < 400 Beds	23	1	5	29	196
West, ≥ 400 Beds	6	1	1	8	57
East, < 400 Beds	12	5	5	22	161
East, ≥ 400 Beds	11	4	1	16	107
TOTAL	97	17	23	137	953

Approximately 15 percent of the hospitals in the eight strata were randomly selected and a questionnaire was mailed to the directors of the 137 selected registries. In order to maximize response, the questionnaire inquired only about the number of cancer cases diagnosed in 1980, and the 1980 budget for their registry, or an approximation if the registry budget was not separate from the medical record department budget. If no response was received within one month a follow-up request was sent.

Total cost per year, cost per case, cost per bed, cases per bed, number of beds and region were the data obtained from each hospital in this survey. The data were analyzed using standard multiple regression and analysis of variance techniques.[10] Residual analyses and possible statistical interactions were evaluated to determine the appropriateness of the statistical models. Parameter averages for a region or stratum were constructed as simple averages of the individual hospital values. Point estimates and confidence intervals for the stratified random sample were constructed as described in Scheaffer et. al.[11]

Ninety-seven of the 137 hospitals responded (70.8 percent). Seventeen registries gave partial responses; they provided the number of cancer cases accessed but did not provide budget data. Twenty-three registries did not respond. Complete and partial responses amounted to a response rate of 83.2 percent.

The number of hospitals in the eight strata and the distribution of responses are given in Table 1. Overall, there were no statistically significant differences in response rates by stratum (p greater than 0.5). The smaller hospitals (less than 400 beds) represented a larger proportion of non-respondents than the larger hospitals (18 out of 81 versus 5 out of 56).

The average annual cost of an ACOS hospital tumor registry was $29,000 (1980 dollars) with a 95 percent confidence interval of $25,000-$33,000 (Table 2). The total cost of registry operations for the 953 ACOS hospital tumor registries was estimated at $27,500,000 with a 95 percent confidence interval of $23,500,000-$31,500,000. The average number of cancer case accessed in 1980 was 579. The average hospital bed size for the respondents was 387. There were

Table 2
Average Cost Per Year, Number of Cancers, Bed Size, Cost Per Case, Cost Per Bed and Cases Per Bed
for Hospitals with ACOS Cancer Registries, 1980

| Stratum | Total Cost ($) | Average | | | | |
		Number of Cancers	Bed Size	Cost Per Case ($)	Cost Per Bed ($)	Cases Per Bed
North, < 400 Beds	13,087	219	205	105	64	1.0
North, > 400 Beds	45,344	754	652	62	68	1.1
South, < 400 Beds	17,035	283	211	89	92	1.5
South, > 400 Beds	33,352	884	695	44	47	1.3
West, < 400 Beds	19,534	405	196	71	98	2.2
West, > 400 Beds	67,253	927	496	67	135	1.9
East, < 400 Beds	21,892	429	255	55	89	2.3
East, ≥ 400 Beds	45,572	1,188	704	44	68	1.8
All Strata	28,981	579	387	67	82	1.7
	(24,771-33,131)*	(492-666)*	(349-425)*	(54-80)*	(71-93)*	(1.3-2. 1)*

*95% Confidence Interval

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Table 3
Pearson Correlation Coefficients for Total Cost Per Year, Number of Cancer Cases, Number of Beds, Cost Per Case, Cost Per Bed, and Cases Per Bed in ACOS Hospital Sample

	Total Cost	Number of Cancer Cases	Number of Beds	Cost Per Case	Cost Per Bed
Number of Cancer Cases	.83**				
Number of Beds	.73**	.72**			
Cost Per Case	-.01	-.24**	-.15		
Cost Per Bed	.45**	.21*	-.12	.23**	
Cases Per Bed	.16	.35**	-.09	-.27**	.57**

* $p < 0.05$
** $p < 0.01$

approximately 1.7 cancer cases accessed per hospital bed. However, Table 2 illustrates the great variability in this estimate, ranging from 1.0 case per bed to 2.3 cases per bed. Additionally, regression analysis indicated that only 10 percent of the variability in the number of cases could be attributed to hospital bed size. Ninety percent of the variability was due to other factors. The number of 1980 cancer cases was also independent of the geographic region of the registry (p greater than 0.3).

Table 3 contains the Pearson correlation coefficients for the continuous variables studied. As expected, total cost was highly correlated with the number of cancer cases. The strong correlation between total cost and number of beds was probably an expression of the correlation between the number of beds and the number of cancer cases. The cost per case was negatively correlated with the number of cases. Multiple regression analyses were conducted to further explore these relationships.

Because of the strong correlation (multicollinearity) between the number of beds and the number of cases, they could not be used jointly to estimate the total cost per year or the cost per case of ACOS registries. Individually, both the number of cases and bed size were significant predictors of total cost, with 69 percent and 52 percent of the variability in total cost explained by these variables respectively (Table 4).

The average cost per case was $67 and ranged (depending on region and bed size) from $44 to $105 (Table 2). The number of cases was a statistically significant predictor of the cost per case (Table 5). The negative regression coefficient (equivalently, the negative correlation coefficient described above) implies that as the number of cases increased, the cost per case decreased. This trend can also be seen in Table 2 where the

The lack of statistical significance was attributable to the extreme variability in cost per case estimates. None of the variables studied or their linear combinations were satisfactory predictors of the cost per case.

average cost per case for the larger hospitals was less than the average cost per case for smaller hospitals in each region. However, only six percent of the variability in average cost per case was explained by the number of cases. The ratio of the largest variance to the smallest variance of the cost per case estimates for the eight strata was 72.9. Statistically (p less than 0.001) the variances were not homogeneous, indicating that there were great differences in the variability of cost per case estimates despite controlling for bed size and region.

Discussion
It is clear from the results presented that there was large variability in the costs,

Table 4
Results from Regression of Total Cost of Operation of ACOS Registries on Number of Cases and Number of Beds

Independent Variable	Constant	Co-efficient	Significance	R²
Number of Cases	10,733.5	32.0	.0005	69%
Bed Size	3,388.1	67.1	.0005	52%

Table 5
Results from Regression of Cost Per Case of ACOS Registries on Number of Cases and Number of Beds

Variable	Constant	efficient	Significance	R²
Number of Cases	-62.9	-.17	.022	6%
Bed Size	62.8	-.29	.338	2%

number of cases and costs per case in ACOS registries in 1980. This variability calls into question the validity of "rules of thumb," such as estimating the number of newly diagnosed cancer cases per year as approximately equal to the number of beds in the hospital. The point estimate derived was 1.7 cases per bed. However, this estimate was imprecise since bed size was generally a poor predictor of case load.

The average cost per case decreased with higher case loads, indicating that larger registries may be more efficient in their operations. The average cost per case was higher in the North than the East (Table 2), although this difference was not statistically significant. The lack of statistical significance was attributable to the extreme variability in cost per case estimates. None of the variables studied or their linear combinations were satisfactory predictors of the cost per case.

The inherent variability of the cost per case was probably indicative of a lack of standardization in registry operation. Methods of accession, quality control programs, sophistication of data base management and amount of data collected can substantially modify a registry's cost per case. Unfortunately, questions about operational components were beyond the scope of the survey. Resolution of the reasons for the variability in cost per case despite controlling for hospital size and regional (economic) differences requires further study.

Public and private health institutions recognize the need for the general public to be informed about cancer. Such information includes the probability of acquiring as well as surviving cancer. Population-based and hospital tumor registries must collect and disseminate this information. This has resulted in cooperation between professionals in public health departments, hospital tumor registries and medical record departments. The results of this survey should assist in determining the cost of tumor registry data for hospitals as well as centralized cancer registries which utilize ACOS and hospital registry data. Cooperation between centralized and hospital-based registries should be encouraged in order to eliminate costly duplication in cancer case accession. ■

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APPENDIX 10

Examples of CCPDS Edit Checks

Complete listings of the CCPDS edit checks are available from SAQC, Fred Hutchinson Cancer Research Center, 1124 Columbia St., Seattle, Washington, 98104.

Index to CCPDS Edit Checks by Item Number

```
Item #        Item Name          Edit # - Description
------        ---------          -------------------
```

```
   0       Operation
                             102  Invalid transaction code for record type
                             109  Only blanks allowed in positions 26 - 100 of deletion record


   0       Record Type
                             101  Invalid record type
                             102  Invalid transaction code for record type
                             109  Only blanks allowed in positions 26 - 100 of deletion record
                             110  Record type "A" is not blank in character positions 40-43, 90-100
                             111  Record type "F" is not blank in character positions 26-81, 90-100


   0       Version
                             100  Invalid version code


   1       Institution
                             103  A dataset matching this ID already exists
                             104  No dataset exists matching this patient ID
                             200  Invalid institution code


   2       Patient ID
                             103  A dataset matching this ID already exists
                             104  No dataset exists matching this patient ID
                             201  Invalid patient ID


   3       File Number
                             103  A dataset matching this ID already exists
                             104  No dataset exists matching this patient ID
                             202  Invalid file number
                             626  Sequence code conflicts with file number
                             800  Cannot add this file number, since preceding file does not exist
                             802  Birthplace differs from that in patient's other dataset(s)
                             803  Race/ethnicity differs from that in patient's other dataset(s)
                             804  Sex differs from that in patients other dataset(s)
                             805  Date last contact/death conflicts with file number
                             806  Autopsy code conflicts with autopsy in file number
                             807  Date of initial diagnosis conflicts with that of previous tumor
                             808  Birthdate differs from birthdate in other datasets
                             809  Sequence for this tumor conflicts with sequence for other file
                             810  Vital status code conflicts with vital status code in file no.
                             904  **Note only** Sequence changed to 1 on lowest file to reflect multiple primary


   4       Birthdate
                             113  Patient's birthdate does not match the one from initial registration
                             203  Invalid birthdate
                             600  Birthdate cannot follow date of first admission
                             601  Birthdate cannot follow date of initial diagnosis
                             602  Birthdate cannot follow date of initial therapy
                             603  Birthdate cannot follow date of last contact/death
                             808  Birthdate differs from birthdate in other datasets


   5       Birthplace
                             204  Invalid birthplace geocode
                             802  Birthplace differs from that in patient's other dataset(s)


   6       Race/Ethnicity
                             205  Invalid race/ethnicity code
                             803  Race/ethnicity differs from that in patient's other dataset(s)


   7       Sex
                             206  Invalid sex code
                             606  Sex code conflicts with primary site code
                             804  Sex differs from that in patients other dataset(s)


   8       Geocode, Residence at Admission
                             207  Invalid residence (geocode)
                             245  Geocode and zip code conflict for residence-at-admission


   9       US Zip Code, Residence at Admission
                             208  Invalid residence (zip code)
                             245  Geocode and zip code conflict for residence-at-admission
```

```
Item #        Item Name          Edit # - Description
- - - - - -   - - - - - - - - -   - - - - - - - - - - - - - - - - - -

    10        Date of First Admission
                                 209   Invalid date of first admission
                                 210   Date of first admission is before CCPDS start-up date
                                 600   Birthdate cannot follow date of first admission
                                 607   Date of first admission cannot follow date of initial therapy
                                 608   Date of first admission cannot follow date of last contact/death
                                 906   **Warning only** Admission precedes diagnosis by more than 1 month

    11        Sequence
                                 211   Invalid sequence code
                                 626   Sequence code conflicts with file number
                                 807   Date of initial diagnosis conflicts with that of previous tumor
                                 809   Sequence for this tumor conflicts with sequence for other file
                                 904   **Note only"" Sequence changed on file 1 to reflect multiple tumor status

    12        Date of Initial Diagnosis
                                 212   Invalid date of diagnosis
                                 601   Birthdate cannot follow date of initial diagnosis
                                 612   Date of initial diagnosis cannot follow date of initial therapy
                                 613   Date of initial diagnosis cannot follow date of last contact/death
                                 807   Date of initial diagnosis conflicts with that of previous tumor
                                 906   **Warning only** Admission precedes diagnosis by more than 1 month

    13        Primary Site
                                 213   Invalid primary site code
                                 606   Sex code conflicts with primary site code
                                 621   Stage of disease conflicts with histology and site
                                 640   Primary site conflicts with laterality code
                                 642   Primary site (skin) with this histology is not a CCPDS reportable tumor
                                 644   Primary site conflicts with stage of disease
                                 645   Primary site conflicts with stage of disease
                                 651   Diagnostic confirmation code conflicts with histology and/or primary site
                                 902   **Warning only** Primary site has unusual histology
                                 907   **Warning only** Unusual primary site for histology

    14        Laterality
                                 214   Invalid laterality code
                                 640   Primary site conflicts with laterality code

    15        Histology and Behavior
                                 215   Histology of lymphoma must have behavior of 3
                                 216   Invalid histology code
                                 217   Invalid histologic behavior (5th digit) of histology
                                 219   Histology of leukemia must have behavior (5th digit) of 3
                                 616   Diagnostic confirmation code conflicts with histology code
                                 621   Stage of disease conflicts with histology and site
                                 622   Stage of disease conflicts with histology (leukemia)
                                 623   Stage of disease conflicts with behavior of histology
                                 642   Primary site (skin) with this histology is not a CCPDS reportable tumor
                                 651   Diagnostic confirmation code conflicts with histology and/or primary site
                                 902   **Warning only** Primary site has unusual histology
                                 907   **Warning only** Unusual primary site for histology

    16        Histologic Grade
                                 218   Invalid histologic grade code

    17        Diagnostic Confirmation
                                 220   Invalid diagnostic confirmation code
                                 616   Diagnostic confirmation code conflicts with histology code
                                 617   Diagnostic confirmation code conflicts with initial surgery code
                                 618   Diagnostic confirmation code conflicts with prior surgery code
                                 651   Diagnostic confirmation code conflicts with histology and/or primary site

    18        Stage of Disease at Admission
                                 222   Invalid stage of disease code
                                 621   Stage of disease conflicts with histology and site
                                 622   Stage of disease conflicts with histology (leukemia)
                                 623   Stage of disease conflicts with behavior of histology
                                 644   Primary site conflicts with stage of disease
                                 645   Primary site conflicts with stage of disease

    19        Prior Surgery
                                 223   Invalid prior surgery code
                                 618   Diagnostic confirmation code conflicts with prior surgery code
```

```
Item #        Item Name           Edit # - Description
------        -------------       --------------------

   20       Prior Radiation Therapy
                          224   Invalid prior radiation therapy code

   21       Prior Chemotherapy
                          225   Invalid prior chemotherapy code

   22       Prior Endocrine Therapy
                          226   Invalid prior endocrine therapy code

   23       Prior Immunotherapy
                          227   Invalid prior immunotherapy code

   24       Prior Other Cancer Therapy
                          228   Invalid prior other cancer therapy code

   25       Date of Initial Therapy
                          229   Invalid date of initial therapy
                          602   Birthdate cannot follow date of initial therapy
                          607   Date of first admission cannot follow date of initial therapy
                          612   Date of initial diagnosis cannot follow date of initial therapy
                          633   Initial surgery code conflicts with date of initial therapy
                          634   Initial radiation therapy conflicts with date of initial therapy
                          635   Initial chemotherapy conflicts with date of initial therapy
                          636   Initial endocrine therapy conflicts with date of initial therapy
                          637   Initial immunotherapy conflicts with date of initial therapy
                          638   Initial other therapy conflicts with date of initial therapy
                          641   Date of init. therapy is present, but all therapy items coded "0" or "9"
                          646   Date of initial therapy cannot follow date of last contact/death

   26       Initial Surgery
                          230   Invalid initial surgery code
                          617   Diagnostic confirmation code conflicts with initial surgery code
                          633   Initial surgery code conflicts with date of initial therapy
                          641   Date of init. therapy is present, but all therapy items coded "0" or "9"

   27       Initial Radiation Therapy
                          231   Invalid initial radiation therapy code
                          634   Initial radiation therapy conflicts with date of initial therapy
                          641   Date of init. therapy is present, but all therapy items coded "0" or "9"

   28       Initial Chemotherapy
                          232   Invalid initial chemotherapy code
                          635   Initial chemotherapy conflicts with date of initial therapy
                          641   Date of init. therapy is present, but all therapy items coded "0" or "9"

   29       Initial Endocrine Therapy
                          233   Invalid initial endocrine therapy code
                          636   Initial endocrine therapy conflicts with date of initial therapy
                          641   Date of init. therapy is present, but all therapy items coded "0" or "9"

   30       Initial Immunotherapy
                          234   Invalid initial immunotherapy code
                          637   Initial immunotherapy conflicts with date of initial therapy
                          641   Date of init. therapy is present, but all therapy items coded "0" or "9"

   31       Initial Other Cancer Therapy
                          235   Invalid initial other cancer therapy code
                          638   Initial other therapy conflicts with date of initial therapy
                          641   Date of init. therapy is present, but all therapy items coded "0" or "9"

   32       Date of Last Contact or Death
                          237   Invalid date of last contact
                          402   Date of last contact prior to previous value
                          603   Birthdate cannot follow date of last contact/death
                          608   Date of first admission cannot follow date of last contact/death
                          613   Date of initial diagnosis cannot follow date of last contact/death
                          646   Date of initial therapy cannot follow date of last contact/death
                          805   Date last contact/death conflicts with file number
```

Item #   Item Name   Edit # - Description
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33   Vital Status at Last Contact
                        248   Invalid vital status code
                        408   Vital status code is inconsistent with previous value
                        648   Vital status code conflicts with tumor status at death
                        649   Vital status code conflicts with cause of death
                        650   Autopsy code conflicts with vital status code
                        810   Vital status code conflicts with vital status code in file no.

34   Tumor Status at Death
                        247   Invalid tumor status at death
                        407   Tumor status at death is inconsistent with previous value
                        648   Vital status code conflicts with tumor status at death

35   Tumor-Specific Cause of Death
                        246   Invalid cause of death code
                        410   Cause of death is inconsistent with previous value
                        649   Vital status code conflicts with cause of death

36   Autopsy
                        238   Invalid autopsy code
                        409   Autopsy code is inconsistent with previous value
                        650   Autopsy code conflicts with vital status code
                        806   Autopsy code conflicts with autopsy in file number

APPENDIX 11

Accuracy of Basic Cancer Patient Data:
Results from an Extensive Recoding Study

By
Polissar, L., Feigl, P., Lane, W., Glaefke, G., Dahlberg, S.
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Report of a study in which coding differences were classified according to frequency and severity. Reproduced by permission of the publisher, The National Cancer Institute.

Accuracy of Basic Cancer Patient Data: Results From an Extensive Recoding Survey[1,2]

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Gwen Glaefke, A.R.T.,[3] and Steven Dahlberg, M.S.[3,7]

ABSTRACT—The accuracy of data coded from the medical records of 985 patients from 22 major U.S. cancer centers was checked by recoding during 1978-81. The 29 items covered demographics, diagnosis, and therapy. Original codes were compared to recodes, and disagreements were classified as major or minor. The highest rate of major disagreements, 23%, was for stage of disease, followed by 10% for histology and 7% for site. Major disagreement rates for most other items were under 7%. Only 3% of a large sample of major disagreements involved justifiable differences in interpretation; the others were due to errors in the use of records. Major disagreement rates varied by a factor of 10 across sites, 4 across centers, and 2 across stage of disease. For several items the code "unknown" was overused and led to disagreements. A new procedure is presented for analysis of disagreement rates. The results from this procedure can guide training effort to improve coding accuracy.—JNCI 1984; 72: 1007-1014.

Many medical research studies depend on data abstracted from patient medical records. Although the usefulness of these studies is dependent on the accuracy of these data, the issue of accuracy is treated only sparsely in the literature. Accuracy is crucial for comparative studies when data are collected from a number of different centers. Such programs include clinical trials, such as the Southwestern Oncology Group; centralized tumor registries, such as the Surveillance, Epidemiology, and End Results Program; and multi-institution screening programs, such as the Breast Cancer Detection and Demonstration Project. Good data collection in these programs is essential for drawing correct conclusions about incidence, survival, treatment efficacy, and patterns of care.

In this paper we report on accuracy of data collected in a large, multicenter cancer registry based on patient medical records. We compare codes originally submitted to the coordinating center with codes determined by expert reabstracting and recoding of the same patient records.

The literature includes a limited number of studies of data quality. The results specifically related to cancer concern the accuracy of site coding. We found one study of cancer codes and recodes. This was the 1978 study by Demlo et al. (1) comparing coding by private coding services, such as the Professional Activity Study, with recoding of the same records by specially trained technicians. For breast and lung cancer cases (the only cancer sites reported), codes and recodes disagreed on a three-digit site code for about 20% of the cases, corresponding to a 20% "major disagreement rate" in our study. Three articles compared hospital

diagnosis with cause of death on the death certificates. A 1958 study by Dorn and Cutler (2) found that 18% of a population-based sample of cancers had a different major site group or a noncancer cause on the death certificate. A 1981 study by Percy et al. (3) found a 15% disagreement rate in cancer site between hospital abstracts and death certificates. In a 1982 study by Gittlesohn and Senning (4), a sample of death certificates listing a neoplastic disease as the cause of death was compared with hospital discharge diagnoses. Seventeen percent of the records showed a different organ or a nonneoplastic disease.

In a study related to our findings, Feigl et al. (5) sent the same set of 25 typed and standardized cancer patient charts to 18 of the cancer centers that are included in the present study. The charts were coded at the centers and returned. Compared to the standard code, which was the one most frequently used by the 18 centers, the rate of major disagreements was 1% for anatomic site, 14% for stage of disease, and 5% for histology. Rates for most other key items were under 5%. These disagreement rates are low, relative to what would be expected in routine field experience, due to the standardized format of the test charts and their easy recognition by coders as test charts.

Other studies report on the reliability of coding for conditions other than cancer: Herrmann et al. (6), Hendrickson and Myers (7), Monson and Bond (8), and Clum and Bowen (9). Corn (10) reports on quality-control programs used in several large abstracting-coding operations.

To improve the understanding of cancer coding, we

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present results of nearly 1,000 independent recodes of basic patient data routinely submitted to a statistical coordinating center from 22 cancer centers. We also present new methods for analyzing this type of data.

MATERIALS AND METHODS

The study was performed during 1977-81 by the CCPDS as part of its data quality-control program. The CCPDS was established in 1977 to collect selected patient information according to uniform definitions at all 22 U.S. Comprehensive Cancer Centers (*see* "Appendix" for list of centers). Admissions from July 1, 1977, are included. Data were coded at each center and forwarded to the coordinating center at the Fred Hutchinson Cancer Research Center in Seattle. The data for each patient consist of 29 simplified items, including demographic characteristics, tumor description, therapy, and survival. The coding procedures followed one of three forms at the institutions: 1) coding directly from the medical record; 2) coding from abstracts of medical records; 3) using direct coding for some items such as sex, race, and therapy, and abstracting followed by coding for more difficult items such as site, stage, and histology. In the present study of coding quality, we did not attempt to duplicate the coding practice of each center; the intent was simply to arrive at accurate recodes that could be compared to original codes.

From 1978 to 1981, we attempted to develop expert codes to compare with a sample of original codes from each center. We abstracted cases and coded from the abstracts, whether or not an institution used abstracting as a step in coding. Representatives from the coordinating center visited each cancer center and abstracted information from the original inpatient and outpatient records. The sample of cases had been randomly selected before the visit. Cases were restricted to those that had passed computer edit checks and had been newly diagnosed at each center. Both the original codes and the reabstracts used only material that was dated before the date of last contract with the patient, as indicated by the original coder.

Most of the centers contributed approximately 50 cases each, though centers that entered later contributed fewer than 50. Approximately 55,000 cases were eligible, of which 1.8% were sampled. The sample size per center was not proportional to the number of eligible cases, since the major purpose of the study was to evaluate each institution with a minimal number of cases. The sampling fraction at centers varied from 0.6 to 8%, except for two centers with only a small number of patients on file, where the sampling fraction was 20 and 80%, respectively. These two centers register protocol patients only.

Recoding of cases was done by the coordinating center staff, who had written the coding guidelines in use at all centers. Two of these expert coders prepared independent sets of recodes on each case without reference to the original center codes. Subsequently, the expert coders and supervisory staff consulted about differences between the two sets of recodes. The expert coders prepared a final set of recodes, which were then compared to the original center codes. Differences between the codes were classified as major or minor. A report of disagreements between expert and original codes was sent to each center with opportunity for rebuttal. Following rebuttal the expert codes were changed to agree with the center codes if the center documented the fact that a difference came about either through an abstracting or coding error by the expert coder or because some relevant item of information had not been available to the reabstractor. For example, the original coder may have had access to a physician's follow-up letter regarding therapy for a particular case, but the letter was not included in the hospital records used by the reabstractor. In a few cases both the coordinating center codes and the original center codes were considered to be acceptable alternatives. These cases were kept as justifiable disagreements. One of us (G. G.) determined the frequency of justifiable disagreements by reviewing cases from the 1st year of reabstracting.

We left some cases out of our analysis, because certain cancer centers did not follow the coding guidelines for some items. These deviations were typically due to unavailability of the information required for coding; e.g., a patient's birthplace was not recorded in the medical record of some institutions. In our analysis of each item, only the cases where the standard guidelines were being followed are included. This number of cases varies by item.

Among the 29 items coded we singled out eight as "key items" being of special interest and importance in cancer research: site, stage, histology, initial therapy (surgery, radiation, and chemotherapy), admission date, and diagnosis date. The codes for these key items are noted in table 1, along with definitions and examples of major and minor disagreements. Definitions for the other 21 items, listed in table 2, reflect a similar level of detail.

We used two different methods to examine disagreement rates for an item (e.g., center) while controlling for the effects of a second item (e.g., site). We first used the method of direct standardization as described in many sources, including Fleiss (*11*). These rates were standardized to the entire group of study cases. We also used a stratified logistic regression model (*12, 13*) to find statistically significant differences in disagreement rates between categories (e.g., specific sites) of one item while controlling for other related items (e.g., center and stage).

RESULTS

A total of 985 cases were sampled and included in the study. The site distribution of the sample was very similar to that of all CCPDS newly diagnosed cases. The sample thus can be considered reflective of all newly diagnosed cases submitted to the coordinating center.

TABLE 1.—*Codes and major and minor disagreements for eight key items*

Data item	Code categories[a]	Minor disagreement[b]	Major disagreement[b]
Primary site	4-digit ICD-O	Difference in 4th digit only	Difference in first 3 digits
Example		Fundus vs. body of stomach	Stomach vs. colon
Stage[c]	In situ, local Regional (4 categories) Nonlocalized—NOS Distant, unknown	Difference within regional	Any difference except within regional
Example		Regional, direct extension vs. regional nodes	Regional vs. distant
Histology	4-digit ICD-O	Difference in 4th digit only	Difference in first 3 digits
Example		Adenocarcinoma vs. superficial spreading adenocarcinoma	Squamous cell carcinoma vs. adenocarcinoma
Initial therapy Surgery Radiation Chemotherapy	Therapy given Therapy not given Unknown if given	Any difference involving unknown	Therapy mode given vs. not given
Example		Surgical resection vs. unknown surgical status	Surgical resection vs. no surgical resection
Dates Admission Diagnosis	Month and year	Difference of 1 mo	Difference of >1 month
Example		7/80 vs. 8/80	10/80 vs. 8/80

[a] ICD-O=International Classification of Diseases for Oncology; NOS=not otherwise specified.
[b] Special rules define minor–major disagreements for a few sites.
[c] Ann Arbor staging is used for lymphomas. Any disagreement is considered major.

Agreement Rates by Item

Among 29 items, 23 had major disagreement rates of 5% or less, and all but three items had minor disagreement rates of 10% or less (table 2). In the following we shall mainly discuss major disagreements.

Stage of disease had the highest major disagreement rate among all items (23%), followed by histology (10%). Primary site had a major disagreement rate of 7%. The high disagreement rate of stage probably reflects the larger number of reports that have to be reviewed to determine stage.

In site, stage, and histology coding, use of "unknown" codes and nonspecific codes versus more specific codes caused a large fraction of the disagreements. About half of the 215 stage major disagreements, more than one-third of the 101 histology major disagreements, and about one-fifth of the 70 site major disagreements were of this type. For other key items, use of the unknown code caused few or no major disagreements. The coding of unknown stage was particularly troublesome. In the 67 cases analyzed in which the centers used this code, fully 81% had a major disagreement. Among the remaining stage major disagreements, there was also a tendency for the original center to code a lower stage, indicating less severe disease, than the coordinating center code. In site coding, about one-fifth of the major disagreements involved use of adjacent sites (e.g., stomach vs. distal esophagus).

Among disagreements involving the eight key items noted in table 1, 41% of the major disagreements occurred in stage alone and 71% occurred in one of the "big three" items—site, stage, and histology. We found that the disagreement rates over a 2-year time-trend

period were remarkably constant for the pooled eight key items.

Disagreements tended to cluster on certain cases leaving more cases free of major disagreements than might have been expected by chance alone. Fifty-eight percent of the cases were free of major disagreements in any of the eight key items, whereas 48% would have been expected by chance alone, a highly significant difference ($P<.0001$).

The last column of table 2 shows the number of cases for each item. Any departure from the maximum of 985 cases occurs where centers followed local coding practices rather than the standard guidelines. Among key items, only stage and date of diagnosis involved local coding variations, but less than 10% of the cases are affected for each item.

Disagreements Versus Errors

Each disagreement in the earliest half of the 985 cases was reviewed by one of us (G. G.), who was also coauthor of the coding guidelines, to determine how frequently both codes of a disagreement were acceptable. If both codes were acceptable, then the disagreement reflects justified differences in interpretation. If both codes are not acceptable, then the disagreement represents a coding error. Codes, recodes, reabstracts, and rebuttal statements from centers were reviewed for this purpose. We found that only 10 of 315 major disagreements in key items represented justified differences in interpretation between coders, and only 6 of 259 minor disagreements were justified. Thus almost all disagreements represented errors in coding. Site had

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TABLE 2.—*Agreement rates for 29 items*

Item	Percent of cases			No. of cases
	In exact agreement	In minor disagreement	In major disagreement	
Key items				
Primary site	73	20	7	985
Stage of disease at time of admission	73	4	23	939
Histologic type	84	6	10	985
Initial surgery	93	1	6	985
Initial radiation therapy	94	3	3	985
Initial chemotherapy	94	3	3	985
Date of first admission to center for this tumor	94	5	1	985
Date of initial diagnosis	85	11	4	910
Other items				
Birth date	96	0	4	985
Birthplace	93	0	7	921
Race–ethnicity	93	4	4	751[a]
Sex	99	0	1	985
State of residence	99	0	1	943
Zip code of residence	95	0	5	914
Sequence of this tumor with other tumors	96	0	4	985
Laterality	95	5	0	969
Histologic behavior	99	0	1	985
Histologic grade	88	12	0	985
Method of diagnostic confirmation	99	0	1	985
Prior surgery	95	0	5	963
Prior radiation therapy	99	0	0	963
Prior chemotherapy	99	0	1	963
Prior endocrine therapy	99	0	1	886
Prior immunotherapy	100	0	0	963
Other prior cancer therapy	100	0	0	938
Initial endocrine therapy	93	0	7	906
Initial immunotherapy	99	0	1	985
Other initial cancer therapy	98	0	2	935
Date of initial course of therapy	89	3	7	936

[a] 234 cases did not follow coding guidelines on the distinction between Spanish and non-Spanish surnames, a distinction since dropped.

4 of 32 disagreements considered justified, the largest proportion (13%) of any item. We found that the unjustified disagreements or errors were usually due to information being missed by the original coder. Our rate of justified disagreements is consistent with our earlier, related study, where only 15 of 96 disagreements (16%) in stage codes were justified (5).

Groups of Items

Items are usually used in groups for tumor description or other purposes. Table 3 indicates several such common groups. In describing a tumor by site, stage, and histology, only about two-thirds of the cases can be expected to be free of major disagreements on the three items. This low rate is mainly due to the large disagreement rate for stage. The other groups of items show moderately high to high percentages of completely "clean" cases.

Multiple Sources of Disagreements

We found that disagreement rates varied widely by center, site, and stage. It was desirable to analyze disagreement rates for each of these factors while controlling for the others, since, for example, each center might have a different mix of sites to code, implying a different average level of difficulty. We did a logistic regression analysis which controlled for this confounding effect.

For this analysis we calculated a new combined disagreement rate. This rate was the proportion of cases with a disagreement in at least one of the three tumor description items—site, stage, and histology. These three items are most commonly used in cancer research and are often used together. We studied the effect of site, stage, and center on the combined disagreement rate. We did not, however, study the effect of histology because of the large number of distinct histologies that would have to be considered. Of 985 cases, 46 that involved use of a nonstandard stage code were excluded. Sixty-seven other cases with unknown stage were also removed from that analysis, since, as noted earlier, the coding of unknown stage was a unique and clearly identifiable problem.

We found that site, center, and stage all significantly affected disagreement rates. We rejected the hypothesis of no site effect on the combined disagreement rate at $P=.00004$ in a logistic regression analysis stratified by center and stage. We also rejected the hypothesis of no

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TABLE 3.—*Percent of cases without a major disagreement in a group of items[a]*

Group	No. of cases	Percent with no major disagreements in group
Tumor description	939	66
Site		
Stage		
Histology		
Initial treatment	985	89
Surgery		
Radiation		
Chemotherapy		
Demographic description	694	83
Birth date		
Birthplace		
Race		
Sex		
Zip code		
State–country of residence		
Patient contact dates	910	96
Admission		
Diagnosis		

[a] Excluding cases from a group where center was not following coding guidelines for all items in the group.

center effect on the combined disagreement rate at $P=.015$ in an analysis stratified by site and stage. Finally, we rejected the hypothesis of no stage effect at $P=.004$, in an analysis stratified by site. The analysis of stage, which included 837 cases, controlled only for site, since controlling for center and site simultaneously led to a severe loss of power because of small numbers of cases in various strata. From the stage analysis we also excluded lymphoma cases staged using the Ann Arbor classification system; its categories do not correspond to solid tumor staging.

The combined disagreement rates by site are presented in table 4. The directly standardized rates adjust for the effect of centers. We used the number of cases by center for all sites combined as the standard. Sites with particularly high disagreement rates are esophagus, small intestine combined with the residual group "other digestive organs," and unknown and ill-defined sites. Low rates occurred for urinary system, rectum, leukemia, and the residual group "other specified sites." For some sites, the difference between standardized and crude rates in table 4 is large. The rates for buccal cavity and pharynx, soft tissue, and other female genital organs all differ by at least 10 percentage points between standardized and crude versions. The rank order of rates also changes by at least eight for these sites.

The combined disagreement rates by center are shown in table 5. The directly standardized rates adjust for the effect of site. We used the number of cases by site for all centers combined as the standard. Center R has been dropped because of its small number of cases available for this analysis. The variation in standardized rates across centers in table 5 (range 13.5–50.8 and SD 12.2) is not as large as the variation in standardized rates across

TABLE 4.—*Standardized and crude combined disagreement rates for 28 sites[a]*

Site	Standardized rate, %[b]	Crude rate, %	No. of cases
Buccal cavity and pharynx	29.3	40.0	45
Esophagus	75.0	75.0	12
Stomach	34.4	33.3	21
Colon	29.7	34.1	44
Rectum	6.3	9.5	21
Pancreas	29.5	33.3	18
Small intestine and other digestive organs	62.1	54.6	11
Lung	29.8	27.6	105
Other respiratory system	38.3	47.4	19
Bones and joints	36.4	38.5	13
Soft tissue (and heart)	43.4	33.3	6
Melanomas, skin	21.2	18.0	39
Breast, female	30.4	27.9	122
Cervix	26.9	32.8	58
Corpus	31.9	28.1	32
Ovary	25.8	29.4	17
Other female genital	20.0	31.6	19
Prostate gland	40.0	43.2	37
Other male genital	18.4	15.4	13
Urinary bladder	9.1	11.1	18
Kidney, renal pelvis, and other urinary organs	45.1	40.0	20
Brain and nervous system	35.5	30.0	20
Thyroid and endocrine system	29.2	31.2	16
Non-hodgkin's lymphoma	32.8	39.5	38
Hodgkin's lymphoma	26.5	18.2	11
Leukemia	10.8	9.4	64
Other specific sites	14.8	12.5	8
Unknown and ill-defined sites	62.9	56.0	25
All sites	30.3	30.3	872

[a] Percentage of cases with at least one major disagreement in tumor description—site, stage, and histology.
[b] Directly standardized by center.

TABLE 5.—*Standardized and crude combined disagreement rates by center[a]*

Center	Standardized rate, %[b]	Crude rate, %	No. of cases
A	32.2	36.7	49
B	32.9	36.0	50
C	18.7	30.2	43
D	28.0	29.6	44
E	22.3	24.0	50
F	47.2	46.8	47
G	39.6	44.4	18
H	14.3	20.8	48
I	49.6	46.0	50
J	19.8	21.2	33
K	44.1	23.9	46
L	40.0	46.0	37
M	16.5	18.2	22
N	32.7	30.6	49
O	25.1	27.1	48
P	34.9	37.5	40
Q	13.5	16.7	48
S	16.1	19.2	47
T	50.8	52.8	36
U	15.2	14.3	21
V	24.7	16.3	43
All centers	30.3	30.3	872

[a] Percentages of cases with at least one major disagreement in tumor description—site, stage, and histology.
[b] Directly standardized by site.

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TABLE 6.—*Disagreement rates[a] by stage of disease for selected sites and for all sites*

	Rates, %, by stage of disease[b]					
	In situ	Localized	Regional	Distant	Unstaged–unknown	All stages
All sites[c]	25 (36)	35 (295)	37 (245)	22 (261)	80 (64)	34 (901)
Selected sites						
Buccal cavity and pharnyx	0 (1)	43 (14)	38 (24)	50 (6)	100 (3)	44 (48)
Colon		54 (13)	33 (18)	15 (13)	100 (6)	42 (50)
Lung		41 (27)	33 (24)	19 (54)	46 (13)	30 (118)
Melanoma		10 (29)	29 (7)	66 (3)	100 (1)	20 (40)
Breast	36 (11)	36 (39)	25 (57)	13 (15)		28 (123)
Cervix	18 (17)	43 (21)	36 (14)	33 (6)	75 (4)	35 (62)
Corpus uteri	0 (1)	17 (18)	60 (10)	0 (3)		28 (32)
Prostate gland		41 (22)	43 (7)	50 (8)	100 (4)	49 (41)
Leukemia				9 (64)		9 (64)
Unknown and ill-defined sites			100 (3)	50 (22)	85 (13)	66 (38)

[a] Percentage of cases with at least one major disagreement in tumor description—site, stage, and histology.
[b] *Numbers in parentheses* are numbers of cases.
[c] Includes all eligible cases except those using Ann Arbor staging system.

sites in table 4 (range 6.3–75.0 and SD 15.7). This, along with the finding that site has a more statistically significant effect on disagreement rates than center, suggests that site is a more important factor than center in affecting disagreement rates. As noted earlier, the difference betwen the standardized and crude rates can be large. The rates for centers C and K change by over 10 percentage points and six to ten ranks when comparing the two types of rates.

Combined disagreement rates by stage for several of the more frequent sites and for all sites combined are shown in table 6. These rates have not been standardized. There is no one pattern that summarizes the stage coding across the individual sites. For example, for lung, distant stage has the highest rate, while for colon, local stage has the highest rate. For cervix, in situ stage has the lowest rate, while for female breast, in situ has a rate as high as or higher than the rates for other stages.

For all sites combined, the coding of local and regional stages is less accurate than the coding of in situ and distant stage. However, as is evident from the table, this ordering of rates may vary significantly by site. As pointed out earlier, the disagreement rate for coding unknown stage is extremely high.

DISCUSSION

This study has shown that in a large multicenter data collection program, basic cancer information can be coded and abstracted with moderate to excellent accuracy with the exception of stage. From a detailed review of cases, we also found that disagreements in coding overwhelmingly involved errors rather than justifiable differences in opinion. [This finding is consistent with our earlier study (5).] Such discrepancies are usually due to coders' missing information.

Disagreements in the use of unknown codes were common and may also be due to coders' missing

information. Certain primary sites also had high disagreement rates.

The only item for which accuracy in CCPDS and in another data system can be compared is site. An error rate of 20% on a three-digit site code was quoted in 1978 by Demlo et al. (1). This is considerably higher than the 7% major disagreement rate for a comparable three-digit code in the present study. CCPDS is a training-intensive organization, and its greater accuracy is probably a result of that. The CCPDS training program includes both centralized and on-site workshops. In addition, all centers receive answers to any coding questions of general interest.

We suggest the following standard procedure for identifying sources of disagreements. The standard procedure is more time-consuming than methods used in past evaluation studies; however, the procedure will serve as a clear guide for training effort.

1) Calculate crude disagreement rates by item (e.g., table 2) and by categories of an item (e.g., each stage of disease and each site). The rates by category of an item are important; some infrequently used categories of an item (e.g., rare sites) may have high disagreement rates that will be "washed out" when averaged with low rates for the common categories, yielding a low overall error rate for the item.

2) Items that are commonly used together (e.g., site, stage, and histology) can be grouped to calculate a group disagreement rate, as in table 3.

3) If there are a sufficient number of cases, disagreement rates also should be calculated by institution, coding unit, or coder.

Steps 1–3 will initially identify some problem items or centers. (For example, in our study, coding problems were identified for unknown stage and at particular centers.) Usually, there will be a few key items that should be emphasized in the next steps.

4) Calculate standardized disagreement rates for categories of an item (e.g., each center or each site), as in

tables 4 and 5, to adjust for confounding. We found that some sites had high crude disagreement rates simply because those sites were seen more frequently at centers that did less accurate coding. The standardized rate for site, controlling for center, removed this effect. A comparison of the standardized and crude rates in tables 4 and 5 shows that the crude rate can be misleading in a few cases. Fleiss (*11*) and others describe the method of standardization in clear terms.

5) A mathematical model for the effect of each of several items (e.g., site, stage, and center) on disagreement rates can be fit to the data. The logistic regression model is a good choice in this situation (*13*). Standard statistical tests can be performed for differences in disagreement rates between categories of an item while adjusting for one or more confounding factors. Stratification by one item when testing for differences in disagreement rates between categories of another item also can be incorporated into the logistic regression model (*12*). We did this type of analysis for the joint effect of center, site, and stage on disagreement rates. We found that all three factors significantly affected disagreement rates and that the effect of each factor was not spuriously due to confounding by the other factors.

The role of training with the use of procedures such as that just defined is critical, and the present study shows that good coding can be achieved. For example, some centers did have low disagreement rates, and the fact that variation in agreement rates by center was both large and statistically significant suggests that the low rates were not due to chance. We found that even for the most intractable item—stage—5 out of 22 centers had a major disagreement rate of 12% or less as compared to a rate of 23% for all centers combined.

A comment on methods of measuring quality of coding is possible by comparison of the results presented here, based on recoding of actual medical records, with the results of the related study by Feigl et al. (*5*) which involved most of the centers studied here. In the earlier study, standardized typed medical charts were presented to coders. For the eight key items, the present study has disagreement rates averaging 4 percentage points higher than the earlier study. Thus standardized charts cannot replace real charts when one estimates disagreement rates. However, standardized charts can be a good tool for spotting coding problems.

In comparing studies or in designing a study of accuracy, it is important to clearly note the definition of accuracy used. In our study accuracy was measured by comparison of original codes from medical records to expert recodes. Another definition of accuracy is the correspondence of the information in the medical records to the actual state of the patient, as determined, for example, by autopsy. This type of accuracy has been studied less frequently, although the studies of Rosenblatt et al. (*14*) and Ehrlich et al. (*15*) are examples of autopsy studies where such accuracy was measured. Finally, accuracy is sometimes defined as reproducibility, i.e., the rate with which multiple

coders agree on a code, which may or may not be the correct code. Our earlier study (*5*) was, in part, a study of reproducibility.

We have found that the glib and often-heard notion that the complexity of medical records leads to a morass of contradictory interpretation is not true. In our experience well-defined items, even complex ones, can be accurately coded, provided sufficient resources are directed to that goal.

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APPENDIX: COMPREHENSIVE CANCER CENTERS

In the following listing, the first person named is the Data Coordinator for the Center; the second is the primary CCPDS registry contact.

Comprehensive Cancer Center
University of Alabama in Birmingham, Birmingham, Ala.
Herman F. Lehman, *D.D.S., M.P.H.*
Carl Ames

Kenneth Norris, Jr. Cancer Research Institute-University of Southern California Comprehensive Cancer Center, Los Angeles, Calif.
John T. Casagrande, Dr.P.H.
Bridget Cook

UCLA-Jonsson Comprehensive Cancer Center, Los Angeles, Calif.
Mildred Weiss
Nancee Relles

Colorado Regional Cancer Center, Inc., Denver, Colo.
Jeffrey V. Sutherland, Ph.D.
Kathy Hass, A.R.T.

Yale University Comprehensive Cancer Center, New Haven, Conn.
Diana B. Fischer, Ph.D.
Marilyn Hurst, M.S.

Georgetown University Comprehensive Cancer Center, Washington, D.C.
Leonard Chiazze, Jr., Ph.D.
Mary Ann Bush

Howard University Comprehensive Cancer Center, Washington, D.C.
Zahur Alam, Sc.D.
Rosemary Williams

Comprehensive Cancer Center for the State of Florida, University of Miami School of Medicine, Miami, Fla.
Robert Duncan, Ph.D.
Susan Hilsenbeck, M.S.

Illinois Cancer Council, Chicago, Ill.
Craig B. Dickson, M.P.H., M.B.A.
Diane Tuteur, R.R.A.

Johns Hopkins Oncology Center, Baltimore, Md.
Anne L. Kammer, A.R.T.
Joyce Kane, A.R.T.

Mayo Comprehensive Cancer Center, Rochester, Minn.
Helen Golenzer
Gail Caron

Memorial Sloan-Kettering Cancer Center, New York, N.Y.
Sara Bretsky, Ph.D.
Bernard Hillian

Roswell Park Memorial Institute, Buffalo, N.Y.
Warren W. Lane, Ph.D.
Lydia Betz, R.R.A.

Comprehensive Cancer Center Duke University Medical Center, Durham, N.C.
Edwin B. Cox, M.D.
Wanda Hinshaw, M.S.

Ohio State University Comprehensive Cancer Center, Columbus, Ohio
Nancy A. Reiches, Ph.D.
Nina Upperman

Fox Chase-University of Pennsylvania Comprehensive Cancer Center, Philadelphia, Pa.
Hari H. Hayal, Ph.D.——Fox Chase
Greg Ross, M.S.
Clifford Miller, M.S.——University of Pennsylvania
Carolyn Costa

Fred Hutchinson Cancer Research Center, Seattle, Wash.
Steven Dahlberg, M.S.
Camille Bohling, R.R.A.

The University of Wisconsin Clinical Cancer Center, Madison, Wis.
Steven Entine, M.S.
Kathleen R. Rieck

The University of Texas System Cancer Center, M.D. Anderson Hospital and Tumor Institute, Houston, Tex.
Luceli Cuasay, M.P.H.

Columbia University Cancer Research Center, New York, N.Y.
Jeanne Stellman, Ph.D.
Dennis Timony

Comprehensive Cancer Center of Metropolitan Detroit, Detroit, Mich.
Donald P. Ragan, Ph.D.
Cindy Delos Santos

Dana Farber Cancer Institute, Boston, Mass.
Joanne Keesey

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APPENDIX 12

Protocol for an Intra-Institutional Reabstracting Study

Explicit procedures are given for estimating agreement rates between a registry's database and the medical records of registered patients.

PROTOCOL FOR AN INTRA-INSTITUTIONAL QUALITY CONTROL STUDY

1. INTRODUCTION

    The basic feature of the quality of tumor registry data is the agreement between the data entered into the data base and the actual information contained in the patient's medical history. This protocol was designed to monitor this important relationship. The study was developed by the Centralized Cancer Patient Data System's (CCPDS) Quality Control and Training Subcommittee in consultation with the Statistical Analysis and Quality Control Center (SAQC) staff.

2. PURPOSE

    This reabstracting study is designed to accomplish the following goals:

    a. Assess the agreement between data routinely entered into the data base and information found in the medical record during an independent evaluation.

    b. Provide a training forum for discussion of coding guidelines and definitions.

    c. Provide on a sample basis a measure of the reliability of the data in the tumor registry's data system.

3. DESCRIPTION OF THE STUDY

    3.1 Sample Size
    In several hospitals all or a majority of the cases are routinely reabstracted by the lead registrar or supervisor. However, there are many other institutions where this is impractical, but the need for quality control still exists. In these registries the number of cases reabstracted should represent about 10 percent of the yearly accrual. Since even this is not always possible, 3-4 cases per registrar per month seems a practical and still valid alternative.

    The following table is a guide to the selection of sample size.

Number of Registrars	1	2	3-6	7 or more
Cases per Registrar	10	5	4/mo.	3/mo.

    3.2 Study Population
    The study population consists of cases previously abstracted and entered into the tumor registry data file. Cases diagnosed at least one year prior to the year of the study are eligible. For practical purposes, especially in a large registry, one or two diagnoses could be designated as the Study Population each calendar year.

3.3 Sample Selection

It is important that a representative sample be selected from the eligible cases. Since many registries have more than one registrar, care must be taken that each registrar's work is represented equally in the sample. A list of all Eligible Cases is compiled in accordance with 3.2. From this the cases for reabstracting are selected by starting at the top of the list and taking in consecutive order every n's cases. "n" is chosen so that the resulting "Sample Pool" contains about 10% of the Eligible cases.

Starting with the first identifier in the Sample Pool, records in consecutive order are examined until the required number of cases per abstractor is reached. The cases selected are the "Study Cases" and the list of their identifiers make up the Master List for this study.

4. CONDUCT OF THE STUDY

4.1 Time Frame

Time frame for the completion of the study is one year. However, the reabstracting is done in monthly increments (see 3.1) and the cases are discussed in monthly mini-workshops thus distributing the benefits of continuing education across the entire year.

4.2 Reabstracting

Reabstracting starts only after the selection of the Study Cases has been completed and the Master List is compiled. Each case is independently reabstracted and coded by all the abstractors in the registry. Should a case fail to meet eligibility requirements, the reasons are documented. A substitute case is then selected from the Sample Pool following guidelines described in 3.3 and the patient identifier for the substitute case is entered on the Master List.

4.3 Intracenter Workshop

In a workshop attended by the entire abstracting staff, the reabstracted cases are discussed, codes are compared between registrars and with the codes on file in the data base. Consensus codes for each case are developed at this workshop, if necessary in consultation with other sources (pathologist, medical director of registry, etc.). The center's lead abstractor is responsible for approving the final codes, and organizing the workshop. All differences found and background for development of consensus codes are documented. Any necessary corrections to files in the data base are made.

5. EVALUATION

At the conclusion of the study decisions made during the workshop(s) should be summarized and evaluated in terms of their effect on the registry's guidelines as documented in the manual. In the case of computerized registries, these changes have to be evaluated as to their effect on computer programs, edit checks, etc., which might have to be revised. However, modifications to the guidelines should be made only after consultation with the registry's medical director.

The Quality Control Subcommittee of CCPDS established the following standards as minimal requirements for accuracy. These are shown below for three important groups of data elements.

Patient Contact Dates:	84% correct*
Admission, diagnosis	
Tumor Descriptors:	76% correct*
Primary site, histology, stage	
Initial Therapy:	98% correct*
Treatment modalities only	

*These figures are based on results of reabstracting studies done by SAQC.

APPENDIX 13

CCPDS Definitions of Major and Minor Disagreements
and Standards for Reabstracting

For each data item in the CCPDS dataset, all coding disagreements are classifiable as either major or minor. System wide quality goals (standards) are then specified in terms of the percent of cases found to be free of major disagreements under conditions of independent reabstracting/recoding.

CCPDS DEFINITIONS OF CODING DISAGREEMENTS AND ADOPTED STANDARDS

ITEM NO. DESCRIPTION	DISAGREEMENTS		ADOPTED STANDARD*
	MINOR	MAJOR	
Basic Identification			
1 Institution Code	---	Any difference	100%
2 Patient Identification Number	---	Any difference	100
3 File Number	---	Any difference	100
4 Birthdate	---	Any difference	96
Demographic Information			
5 Birthplace	---	Any difference	96
6 Race/Ethnicity**	Difference between 10 or 11 or 12	Any other difference	96
7 Sex	---	Any difference	100
Residence at Time of Admission			
8 Geocode	---	Any difference	96
9 Zip Code	---	Any difference	96
Diagnosis			
10 Date of First Admission	Difference +/- one month	Any other difference	96
11 Sequence	--- EXCEPTION: Tumors diagnosed simultaneously	Any difference	96
12 Date of Initial Diagnosis	Difference +/- one month	Any other difference	92

* Standard is % of cases free of major disagreements

** Item 6 - Race/Ethnicity: SAQC field representatives will code according to the center's chosen method for coding Race/Ethnicity, i.e., 10, 20, or 30 vs. 11, 12, 20 or 30.

	MINOR	MAJOR	ADOPTED STANDARD
13 Primary Site	Same first 3 digits with difference in 4th (see Exceptions, page 4)	Difference in first 3 digits	96%
14 Laterality*	Any difference	---	None
15 Histology	Same first 3 digits with difference in last digit (see Exceptions, Page 4)	Difference in fourth digit	96
Behavior	---	Any difference	100
16 Histologic Grade	Any difference	---	None
17 Diagnostic Confirmation	---	Any difference	100
18 Stage of Disease at Time of Admission to Center			
Solid Tumors	Any difference within regional (2 vs. 3 vs. 4 vs. 5)	Any other difference	88
Lymphomas	---	Any difference	88
Therapy			
Cancer Therapy Prior to Admission to Center			
19 Surgery	Difference not given, given (0,1) vs. unknown (9)	Any difference not given vs. given (0 vs. 1)	96
20 Radiation Therapy	Difference not given, given (0,1) vs. unknown (9)	Any difference not given vs. given (0 vs. 1)	96
21 Chemotherapy	Difference not given, given (0,1) vs. unknown (9)	Any difference not given vs. given (0 vs. 1)	96
22 Endocrine Therapy	Difference not given, given (0,1) vs. unknown (9)	Any difference not given vs. given (0 vs. 1)	Not at this time

*Item 14 - Laterality: SAQC field representatives will code according to each center's own list of sites for which laterality is coded.

	MINOR	MAJOR	STANDARD
23 Immunotherapy	Difference not given, given (0,1) vs. unknown (9)	Any difference not given vs. given (0 vs. 1)	96%
24 Other Cancer Therapy	Difference not given, given (0,1) vs. unknown (9)	Any difference not given vs. given (0 vs. 1)	96
25 Date Initial Therapy	Difference +/- one month	Any other difference	96

Initial Course of Cancer Therapy at Center   OVERALL STANDARD   98

	MINOR	MAJOR	STANDARD
26 Surgery	Difference not given, given (0,1) vs. unknown (9)	Any difference not given vs. given (0 vs. 1)	96
27 Radiation Therapy	Difference not given, given (0,1) vs. unknown (9)	Any difference not given vs. given (0 vs. 1)	96
28 Chemotherapy	Difference not given, given (0,1) vs. unknown (9)	Any difference not given vs. given (0 vs. 1)	96
29 Endocrine Therapy	Difference not given, given (0,1) vs. unknown (9)	Any difference not given vs. given (0 vs. 1)	Not at this time
30 Immunotherapy	Difference not given, given (0,1) vs. unknown (9)	Any difference not given vs. given (0 vs. 1)	96
31 Other Cancer Therapy	Difference not given, given (0,1) vs. unknown (9)	Any difference not given vs. given (0 vs. 1)	96

Patient Status

	MINOR	MAJOR	STANDARD
32 Date of Last Contact/ Death	Difference not calculated at this time		None
33 Vital Status of Patient at Last Contact	---	Any difference	None
34 Tumor Status at Death	Any difference within "Dead" (1 vs. 2 vs. 3 vs. 4 vs. 9)	Any difference "Alive" (0) vs. "Dead" (1, 2, 3, 4, or 9)	None
35 Tumor Specific Cause of Death	Any difference within "Dead" (1 vs. 2 vs. 9)	Any difference of "Alive" (0) vs. "Dead" (1, 2, or 9)	None
36 Autopsy	---	Any difference	None

EXCEPTIONS TO DEFINITIONS OF CODING DISAGREEMENTS

1. **PRIMARY SITE**

1.1 <u>These would be Minor Disagreements</u>

    1.1.1   143.8-9 (Gum) vs. 144.8-9 (Floor of Mouth)

    1.1.2   143.8-9 (Gum)   vs. 149.0, 149.8, 149.9
             144.8-9 (Floor of Mouth) (Pharynx and Ill-defined
             145.8-9 (Oral Cavity)   Sites in Lip, Oral Cavity
             146.8-9 (Oropharynx)   and Pharynx)
             147.8-9 (Nasopharynx)
             148.8-9 (Hypopharynx)

    1.1.3   153.3 (Sigmoid) vs. 154.0 and 154.1 (Rectosigmoid and Rectum)

    1.1.4   156.9 (Biliary Tract NOS) vs. 155.1 (Intrahepatic Bile Duct)

1.2 <u>These would be Major Disagreements</u>

    1.2.1   141.0-1 (Base of Tongue) vs. 141.2-5 (Oral Tongue)

    1.2.2   153.0-9 (Colon) any difference (except 153.8 vs. 153.9 is "minor")

    1.2.3   164.0 or 164.1 (Heart, Thymus) vs. 164.2, 164.8-9 (Mediastinum)

    1.2.4   170.0-9 (Bone, Joints and Cartilage) any difference

    1.2.5   171.0-9 (Connective, Subcutaneous Tissues and Other Soft Tissues) any difference (except 171.8 vs. 171.9 is "minor")

    1.2.6   173.0-9 (Skin) any difference (except 173.8 vs. 173.9 is "minor")

    1.2.7   196.0, 196.1, 196.3 (Lymph nodes above diaphragm) vs. 196.2, 196.5, 196.6 (Lymph nodes below diaphragm)

    1.2.8   195.0, 195.8 (Ill-defined Sites) any difference

2. **HISTOLOGY**

2.1 <u>These would be Minor Disagreements</u>

    2.1.1   814 (Adenocarcinoma, NOS) vs. any 814-838, 848 (Adenomas and Adenocarcinomas)

    2.1.2   Any difference within 959-964, 969 (Non-Hodgkins Lymphoma)

    2.1.3   Any difference within 965-966 (Hodgkins Lymphoma)

2.2 <u>This would be a Major Disagreement</u>

    2.2.1   959-964, 969 (Non-Hodgkins Lymphoma) vs. 965-966 (Hodgkins Lymphoma)

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CCPDS REABSTRACTING STANDARDS

Background

During 1982 an Ad Hoc Committee of the Quality Control and Training Subcommit-
tee, chaired by Carl Ames, developed a set of standards to be applied to for-
mal CCPDS Reabstracting Studies. As approved by that committee in 1982, these
standards are being monitored by SAQC in accordance with the philosophic ap-
proach outlined below.

Philosophy for Defining CCPDS Coding Standards

The standards proposed are viewed as a mechanism to identify problems, not as
a policing action. It is SAQC's contractual responsibility to conduct quality
control reabstracting studies, discuss the disagreements with the center rep-
resentatives, and assist the center in identifying problems and potential
solutions. It is a center's individual responsibility to meet or exceed these
standards, to conduct in-house training of abstractors and to attempt to solve
any problems discovered by the CCPDS reabstracting studies. It is assumed
that when temporary difficulties at a center contribute to that center's fail-
ing to meet the standards, information regarding those difficulties and the
center's proposals for addressing them will be sent to the NCI along with the
Final Quality Control Report. All parties involved, the center, SAQC and NCI
are working toward an accurate, complete database; cooperation is expected in
striving for this common goal.

Adopted Standards

These standards refer to the percentage of major disagreements (see Attachment
1). Since each reabstracting study consists of 25 cases, the standards were
proposed in multiples of 4%. Thus, the 96% standard allows one major dis-
agreement for that data item while maintaining compliance with the standard.
The individual data item standards were developed using two criteria; first,
the degree of interpretation required, and second, the agreement level
achieved in previous reabstracting studies. Items which require no inter-
pretation by the abstractor/coder have a standard of 100%.

No Adopted Standard

Prior and initial endocrine therapy have no individual standard because of an
item definition change recommended by the Clinical Coding Committee. In addi-
tion, no standards were adopted for Laterality, Histologic Grade, Date of Last
Contact, Vital Status, Tumor Status, Tumor Specific Cause of Death or Autopsy.
Laterality and Histologic Grade by definition cannot have a major disagree-
ment; the other items depend on an agreed upon Date of Last Contact between
the center and SAQC. The adopted individual standards are shown in Attachment
1.

Overall Standards for Therapy

Two "Overall Standards" were adopted. An overall standard allows for a maxi-
mum of three major disagreements within each treatment group, rather than the
five possible if individual therapy item standards alone were applied.

Centralized Cancer Patient Data System
SAQC Center
May 17-18,1983

Prior Therapy (Items 19, 20, 21, 23, 24) [excludes prior endocrine therapy].
Adopted standard: 98% agreement

Initial Therapy (Items 26, 27, 28, 30, 31) [excludes initial endocrine therapy].
Adopted standard: 98% agreement

Cluster Standards

Two "Cluster Standards" were adopted. A cluster standard requires a certain number of cases to be free of any major disagreements for the items involved.

Tumor Descriptors (Primary Site, Histology, Stage)
Adopted standard: 76% agreement
No major disagreements in these items for 19/25 study cases.

Patient Contact Dates (Date of Admission, Date of Diagnosis)
Adopted standard: 84%
No major disagreements in these items for 21/25 study cases.

APPENDIX 14

CCPDS Protocol for a Reliability Study

Detailed procedures are given for a study of center-to-center coding agreement conducted by the CCPDS. Results appear in Appendix 16.

CENTRALIZED CANCER PATIENT DATA SYSTEM

Statistical Analysis and Quality Control
1124 Columbia Street, Seattle, Washington 98104 (206) 292-2985

May 30, 1978

PROTOCOL FOR CCPDS DATA CODING RELIABILITY STUDY

PURPOSE

The Centralized Cancer Patient Data System (CCPDS) is a registration system
for patients of Comprehensive Cancer Centers in the United States. The pur-
pose of this reliability study is to measure intercenter reproducibility of
CCPDS coding by having each contributing center code the same standardized
set of test charts under routine abstracting and coding conditions. Although
the primary emphasis is on reproducibility, measurements of validity will
also result from this work. This reliability study is one component of the
program to assess the quality of CCPDS data.

METHODS

Simulating routine abstracting and coding procedures, each center will code
a common set of 25 standardized charts provided by SAQC. The 34 initial
registration items as defined in the CCPDS Data Acquisition Manual consti-
tute the information to be coded. Charts have been selected for specific
sites based on frequency of occurence and degree of difficulty. The site
mix includes several cases each of lung, breast, and colo-rectal cancer
with the remaining cases distributed among less common sites. Only analytic
cases are included in the study. The test charts were prepared by SAQC
staff from actual charts provided by a few CCPDS centers and the SEER Pro-
gram. The reliability study is not blind, that is, the test charts are
distinguishable from regular centers' charts.

In a standard format, the test charts consist of a face sheet, discharge
summary, operative notes, pathology reports, etc., but not nurses' notes
or doctors' orders. All patient and institutional identifiers such as
name, number, and residence have been removed. CCPDS reporting forms will
be provided for submission of codes to SAQC. However, it is recognized
that some centers routinely extract CCPDS data from a larger computerized
database, and that this process often involves some code conversions. Such
centers are asked to handle the test charts in a manner that simulates the
usual preparation of their own CCPDS data--namely to code using local pro-
cedures, and then apply computer conversions. Finally, the data should be
copied onto the CCPDS forms provided, which should be a more economical
means of sending such a small number of records than by tape. Differences
among centers' staffs and job assignments are also recognized: some ab-

stractors specialize in certain sites and where this is the practice, test
charts should be assigned accordingly. If the usual practice is to have
charts assigned randomly within the registry, then the entire test set
should not be processed by just one person. Each center should apply its
internal quality control measures (reabstracting, verifying key entry) in
a routine fashion. Some centers may choose to evaluate intra-center reli-
ability by having the test charts coded by more than one person. However,
this is not a requirement of the Reliability Study.

At each step in the preparation of the test cases the centers are asked
to approximate routine handling of CCPDS data as closely as practical.

TIMETABLE

One set of test charts and report forms will be sent by SAQC to each par-
ticipating center in early June, 1978. Code sheets should be returned to
SAQC four to six weeks later. The data coordinator will be asked to coor-
dinate this simulation exercise.

REPORTS

SAQC will provide the tabulations of agreement rates for the various data
items and with advice from the Study Committee will prepare a report on
the results of the Reliability Study for the Technical Advisory Committee.
Subject to the guidelines of the Policy Advisory Committee, an effort will
be made to publish the findings, provided they seem to be of general interest.

Study Committee

Polly Feigl, Ph.D., SAQC
Alvin Freiman, M.D., Memorial Sloan-Kettering Institute
Vincent Guinee, M.D., M. D. Anderson Hospital and Tumor Institute
Warren Lane, Ph.D., Roswell Park Memorial Institute

PF:cj

APPENDIX 15

Example of a CCPDS Test Case

Copies of other test cases are available upon request from SAQC, Fred Hutchinson Cancer Research Center, 1124 Columbia St., Seattle, Washington, 98104.

Site	Number of Cases
Head and Neck	12
Esophagus	3
Stomach	2
Small Bowel	1
Colon/Rectum	19
Lung	25 (9 Oat Cell)
Breast	13
Endometrium	3
Prostate	3
Bladder	1
Sarcoma	1
Leukemia	1
Lymphoma	1
	85 cases

These data are taken from actual medical records; however, identification of patients and physicians has been changed to preserve confidentiality.

==

CCCE RELIABILITY STUDY

NAME: JONES, Mary   PATIENT NUMBER: 4

ADDRESS: 1113 Spring Street
          Boise, Idaho 83703

BIRTHDATE: 12-31-33   BIRTHPLACE: Oregon

AGE: 50   SEX: Female   RACE: White

INSURANCE: Blue Cross

DATE ADMITTED: 1-12-84   DATE DISCHARGED: 1-20-84

ADMITTING DIAGNOSIS: Breast Mass

==

FINAL DIAGNOSIS: Infiltrating Lobular Carcinoma of the Right Breast

OPERATIVE PROCEDURES: Segmental mastectomy; total mastectomy with axillary
        node dissection.

DISCHARGE SUMMARY

PATIENT'S NAME: Mary Jones

ADMISSION DATE: 1/12/84
DISCHARGE DATE: 1/20/84

ADMISSION DIAGNOSIS: Right breast mass, etiology unclear.

DISCHARGE DIAGNOSIS: Infiltrating Lobular carcinoma of the right
                                  breast.

HISTORY OF PRESENT ILLNESS: This is a 50-year-old white female who discovered
                             a lump in her right breast three weeks prior to
admission. The patient denied any pain, skin or nipple changes.

Past medical history was significant for three cesarean sections, a right ret-
inal detachment and a D&C. Menses began at age 11. Her last menstrual period
was the 18th of December. The patient denied the use of any oral hormones.

Family history was positive for her mother with breast cancer.

PHYSICAL EXAM: Pertinent physical findings revealed the chest
                                  was clear to auscultation. There was a 2 cm.
mass in the right upper outer quadrant which was freely movable. There were
no skin or nipple changes. Cardiovascular revealed normal sinus rate without
murmur. Abdomen was soft, nontender and nondistended with physiologic bowel
sounds. The rest of the physical examination was within normal limits.

HOSPITAL COURSE: On 1/13/84 the patient was taken to the Operating
                                  Room where a segmental resection was done. The
pathologists were unable to make a definitive diagnosis from frozen section,
so the patient was sent home on pass, and the specimen was put through stat.
The specimen came back as infiltrating lobular carcinoma. The patient was
taken back to the Operating Room on 1/16/84 where a right modified radical
mastectomy was performed. The patient did well in the postoperative period
and was discharged on the fourth postoperative day.

LABORATORY: Admitting laboratory data included an SMA-6, a
                                  CBC, urinalysis, LDH and a SGOT which were
                                  within normal limits.

FINAL DIAGNOSIS: Infiltrating lobular carcioma of the right
                                  breast.

                                  Dr. Roston

HISTORY AND PHYSICAL EXAMINATION

PATIENT'S NAME: Mary Jones

ADMISSION DATE: 1/12/84

REASON FOR ADMISSION: Lump in right breast.

HISTORY OF PRESENT ILLNESS: Pleasant 50-year-old white female referred after discovering a lump in her right breast on a routine self breast exam. She denies any skin changes, nipple bleeding or discharge, or pain in breast. Has not noted any changes in left breast. Bilateral mammograms of 1/11/84 showed an abnormal density posterior toward the chest wall in the upper outer quadrant of the right breast.

PAST MEDICAL HISTORY: C-section x 3, D & C x 1, LMP 12/18/83.

CURRENT MEDICATIONS: Tylenol for migraines.

FAMILY HISTORY: Significant in that two aunts and her mother had breast cancer.

PHYSICAL EXAMINATION:

General: Well developed female in NAD.
HEENT: Negative.
Neck: Supple with no adenopathy or thyroid nodularity.
Chest: Clear to A&P.
Back: No CVA tenderness, no edema.
Abdomen: Soft without organomegaly or mass.
Extremities: Negative.
Genital/Rectal: Rectal negative, no masses. Bimanual: retro-verted uterus, no masses, adnexae not appreciated.
Breast: Left breast within normal limits. Right breast with a 2-3 cm. mass in UOQ, no skin or nipple changes.

LAB: Chest x-ray normal. Mammograms as above. LDH 170. SGOT 451 (0-110 - nl.).

IMPRESSION: Right breast mass, etiology unclear. Mammogram shows a density which is nondiagnostic. Status post several GYN procedures.

PLAN: 1) Segmental resection down to chest wall on UOQ, right breast.

                    2) Possible modified radical mastectomy with axillary node dissection.

                                        Dr. Roston

PROGRESS NOTES

PATIENT'S NAME: Mary Jones

Admission Note: 50 year old white female referred for a suspicious mass in
right breast noted by patient on routine self examination. Admit for segmen-
tal resection and possible mastectomy and axillary dissection.

1-12-84
Preop Note: Dignosis right breast mass, rule out carcinoma. Orders written
and permit signed.

1-13-84
BRIEF OPERATIVE NOTE: General Surgery with Dr. Roston

Preop/Postop Note: Right breast mass - rule out carcinoma
Procedure: Excisional wedge biopsy Right breast
Findings: Frozen section inconclusive as to carcinoma - await permanent
                    section for definite diagnosis. Will discuss with patient
                    when fully awake.
Specimen: Wedge resection right breast. Patient tolerated procedure
                    well and was taken to Recovery Room in satisfactory
                    condition.

1-14-84
Afebrile, vital signs stable.
Pathology: Infiltrating lobular carcinoma vs carcinoid.
Plan: modified radical mastectomy on Monday.

1-15-84
On pass.

1-16-84
BRIEF OPERATIVE NOTE:
Right modified radical mastectomy for infiltrating lobular carcinoma versus
carcinoid.
Postop check: Awake and alert, feels nauseated.

1-17-84 Nurse Oncologist
Reviewed chart. Path report pending. Will follow, order bone scan and ar-
range an appointment with one of our oncologists.

1-18-84
Vital signs stable, C/O of some stiffness.

1-19-84
Vital signs stable, drainage decreasing, will pull drains if present rate con-
tinues. Bone scan today.

1-20-84
Discharge home today.

OPERATION RECORD

PATIENT'S NAME: Mary Jones

DATE: 1-13-84

PRE-OP. DIAGNOSIS: Right breast mass.

POST-OP. DIAGNOSIS: Fibrocystic disease, unable to tell from frozen
                                   section if there is an infiltrating ductal
                                   carcinoma.

OPERATION: Right segmental mastectomy.

OPERATIVE FINDINGS: The patient was taken to the operating room and
                                   placed in the supine position. After an adequate
level of general anesthesia was obtained, the patient was prepped and draped
in the usual sterile manner. A right areolar elliptical incision was made on
the lateral aspect of the breast slightly inferior to the mass. This was
taken down to the subcutaneous tissues. Then very small skin flaps were made
around the wound edge. Starting at the lateral edge, the breast was dissected
down to the pectoral fascia. The breast was then lifted off the chest wall
underneath the mass. Using fingers as a guide, the breast was then resected
down in a paw-shaped fashion with the apex being at the areolar edge. The
specimen was then cut. Looking at the suspicious area, it was then sent to
Pathology for frozen section, along with the instruments used in cutting.
Hemostasis was obtained of the wound using hemostats and free ties of 2-0
chromic. The breast tissue was then reapproximated using interrupted 2-0
chromics with a cutting needle first closing the posterior portion and then
the anterior portion. The dead space was then closed using 9-0 chromic on a
round needle. The wound's edges were then reapproximated using a 3-0 plain
subcuticular running suture.

OPERATIVE FINDINGS: It was unclear from the frozen section whether
                                   this was an infiltrating ductal carcinoma. The
pathology specimen will be run through rush and interpreted tomorrow. The
patient will have a modified radical mastectomy as soon as possible if the
tissue diagnosis comes back carcinoma.

                                            Dr. Roston

PATHOLOGY REPORT

PATIENT'S NAME: Mary Jones   DATE: 1-13-84

SPECIMEN: F.S. right breast; wedge resection of the right breast

===

DIAGNOSIS: Infiltrating lobular carcinoma, breast, right.

===

GROSS: Specimen is labeled F.S. right breast mass.
                               Specimen consists of a 7 x 5 x 3 cm. mass of
fibroadipose tissue partly covered by an ellipse of skin 3.5 x 1.3 cm. in
dimension. Within this mass of fibroadipose tissue there is a firm hemor-
rhagic tumor mass that measures 1.5 x 1.5 x 1 cm. FROZEN SECTION DIAGNOSIS is
suspicious for carcinoma. Representative portions are submitted.

MICROSCOPIC: Sections are of portions of breast tissue. In
                               many areas, the lobules are increased in number
and size and are filled with a relatively uniform population of atypical cells
that have enlarged, hyperchromatic, pleomorphic nuclei. In some areas, simi-
lar cells can be seen in the surrounding stroma arranged in a single file pat-
tern. The cells are surrounded by a stroma that is desmoplastic with reactive
fibrous tissue in varying stages of maturity. A moderate to large number of
chronic inflammatory cells consisting primarily of lymphocytes and histiocytes
are present. In some areas, the malignant cells are present in fat. Special
stains reveal that a few of the malignant cells have argyrophilic granules
within them. This is not an uncommon finding in many types of breast carcino-
mas. Therefore, the pathologic and diagnostic significance of this finding is
uncertain.

OPERATION RECORD

PATIENT'S NAME: Mary Jones

DATE: 1-16-84

OPERATION: Total mastectomy with axillary node dissection.

OPERATIVE FINDINGS: Under general endotracheal anesthesia the patient
                                    was prepped and draped in the usual manner and
through an elliptical incision around the previously-made segmental resection
incision on the lateral portion of the breast, skin and subcutaneous tissues
were dissected down to the pectoralis major muscle. The breast tissue was
removed over to the lateral border of the pectoralis major. At this point the
major was elevated and the minor was removed from the coracoid process and the
contents of the axilla stripped from the apex at the sternoclavicular joint to
the base at the latissimus dorsi muscle removing the vessels from the vein and
artery as we moved laterally. The lateral thoracic vessels were identified
and double clamped and ligated and the thoracodorsal nerve was taken proximal-
ly and distally along with the lateral thoracic vessels. The long nerve of
Bell was identified and spared with the rest of the axillary material removed
downward to the Level 1 area at the latissimus dorsi. The specimen removed
and sent to pathology. Bleeders were tied with 000 cotton. The skin was su-
tured with black interrupted silk. A large lumen hemovac was placed in the
axillary area and subcutaneously over the pectoralis major muscle. A dry,
light dressing was applied. The patient seemed to tolerate the procedure well
and returned to her room in good condition.

                                    Dr. Roston

PATHOLOGY REPORT

PATIENT'S NAME: Mary Jones   DATE: 1-16-84

SPECIMEN: Right breast

===

DIAGNOSIS: Right breast removed for infiltrating lobular carcinoma, no
                 residual tumor present.

===

GROSS: Specimen is labeled right breast. Specimen con-
                              sists of a right breast with attached axillary
tail. The ellipse of skin covering the specimen measures 18.5 x 8.0 cm. The
underlying pink-yellow adipose tissue measures 20 cm. x 14.0 cm. x 4.0 cm.
The attached axillary tail measures 12.0 cm. x 8.0 cm. x 3.0 cm. There is a
nipple which is 1.2 cm. in diameter. The surrounding areola is 2.5 cm. in
greatest dimension. Over the lateral quadrant of the breast there is a su-
tured surgical incision which is 6.5 cm. in length. The area beneath the in-
cision is serially sectioned. There is a cavity where there is hemorrhage and
some sutures. The defect measures approximately 7.5 cm. x 2.0 cm. x 2.0 cm.
No grossly visible tumor is seen in this area. The specimen will be fixed and
representative sections will be submitted following adequate fixation. The
axillary tail will be removed and fixed separately in Bouin's solution for
examination for lymph nodes.

MICROSCOPIC: Multiple sections taken from the region where a
                              previous specimen was removed (S84-472) are
examined. In that specimen, an infiltrating, lobular carcinoma was noted.
The present slides taken from that area are labeled TC. In them, there is
interstitial hemorrhage and reactive fibrosis in some areas. In the ducts of
the breast, there are focal areas of papillomatosis. However, no tumor is
seen. Sections of the skin overlying the biopsy site are labeled S. They
also show no tumor. Random sections of the breast are unremarkable. Sections
of the deep fascia beneath the tumor show no involvement with tumor. The nip-
ple is examined and is free of Paget's disease or other abnormalities. Random
sections of the breast also are unremarkable. A total of 11 axillary lymph
nodes are examined and all are free of tumor.

RADIOLOGY REPORTS

PATIENT'S NAME: Mary Jones

Mammogram   1-11-84

Left breast: Three views show a moderately increased amount of fibrous tissue deep to the areola. No localized significant lesions are visible.

Right breast: The multiple views show a poorly defined area of increased density (about 1.8 cm. in greatest dimension) at 11 o'clock slightly closer to the chest wall than at the site of the palpable mass. This same area could not be demonstrated on the craniocaudad view and its nature is not known.

Impression: Indeterminate area of increased density at 11 o'clock in the right breast.

PA and Lateral Chest   1-11-84

Impression: Normal PA and lateral chest radiograph.

Bone Scan   1-19-84

The study shows no scintigraphic abnormalities.

Impression: Negative bone scan.

LABORATORY REPORT

PATIENT'S NAME: Mary Jones

Test	Normal Range	Date	Date	Date
		1-11	1-18	
CBC				
WBC	4.5 - 11.0	8.2	6.4	
RBC	4.2 - 5.4	4.97	3.77	
HGB	12.0 - 16.0	14.8	10.8	
HCT	37.0 - 47.0	42.5	32.4	
MCV	81 - 99	85	86	
MCH	25.5 - 35.5	29.9	28.8	
MCHC	28.8 - 38.0	34.9	33.8	

NURSES NOTES

PATIENT'S NAME: Mary Jones

DATE/ HOUR	REMARKS
1-12-84	
1500	Admitted to room and oriented.
2400	Made NPO after 2400 for R mastectomy in AM. Verbalizes understanding of NPO.
1-13-84	
0530	Awoken for self AM care in BR. Voided. No C/O. Made ready for OR.
0935	Rec'd in Rec. Room.
1050	Returned to room. Drowsy but arouses easily. Nauseated at present time.
1800	Refused clear liquid dinner.
2100	R breast dressing sealed and dry. Resting comfortably.
1-14-84	
0830	Ate well for breakfast. Self AM care. OOB.
1000	Off floor with family on pass.
1-15-84	
0830	Self AM care. OOB ad lib. Patient out on pass.
2000	Rt breast incision dry and intact. Area ecchymotic - dressing dry. Preop teaching reinforced.
1-16-84	
0600	Slept well, offers no C/O.
1145	OR checklist complete. Voided in BR.
1215	Rec'd in holding area. Procedures explained.
1545	Rec'd in RR.
2030	Pt sleeping room, side gates up.
1-17-84	
0100	VSS. Sealed breast dressing dry and intact.
1415	OOB ambulates well.
1-18-84	
1500	Pt instructed on mastectomy care, exercises and breast self examination. Voiced good understanding of instructions. Shown samples of breast prostheses and given list of dealers where these can be purchased.
1-19-84	
0600	Slept well. Hemovac emptied.
0745	To bone scan via litter.
1200	Good appetite for lunch. Dressings dry and intact.
2030	HS care given. Side gates up. OOB ad lib earlier.

1-20-84
    0600   Slept well. No C/O pain.
    0800   Alert and oriented x3. Self AM care. Hemovac D/C by physician.
    1130   Hemovac was D/C with no signs of drainage. In good spirits. No
                   pain. Dsch home.

Outpatient/Clinic Records

CLINIC NOTES

PATIENT'S NAME: Mary Jones

1-4-84
Complains of lump in right breast x 3 weeks; noticed on routine self exam.
Patient denies pain, skin or nipple changes. Family history positive for
breast carcinoma.
    Impression: Right Breast Mass
    Plan: Bilateral mammograms. Patient will probably need a biopsy.

1-11-84
Mammogram - mass not cystic. Will plan a wedge resection.

3-6-84 MEDICAL ONCOLOGIST CONSULT-Dr. Aldrich
The patient is a 50-year-old, married, white housewife referred for consider-
ation of adjuvant therapy of Stage I breast carcinoma.

The patient noticed a right breast lump on breast self examination at the end
of December. She reported here on January 4 and was found to have a right
upper outer quadrant 2 x 3 cm. breast mass. A mammogram was suspicious and
the patient underwent breast biopsy on 1-13-84. This proved to be an in-
filtrating lobular carcinoma of the breast. On 1-16-84, the patient underwent
right total mastectomy with axillary dissection, with the finding of no
residual tumor in the surgical specimen and 0 of 11 positive axillary nodes.
We called to check with Pathology and there is no indication that estrogen
receptor assay was ordered for either the biopsy specimen or the surgical
specimen. It is not mentioned that it was sent in the pathology reports
either.

The patient had a negative bone scan, negative chest x-ray, and normal SMA-12
as part of her staging evaluation. Her preoperative CBC was normal as well.

Since the time of the surgery, she has healed very nicely with no complica-
tion, has regained full range of motion of her shoulder, and has suffered no
edema of her arm. She is essentially asymptomatic at present, is on no spe-
cial diet, and is taking no medicines whatsoever.

A REVIEW OF SYSTEMS is totally normal.

FAMILY HISTORY is most interesting in that the patient relates that her mother
and two of her mother's sisters all have breast carcinoma. Her mother was
about 75 at the time of diagnosis but the patient's aunts were in their 50s.
The patient has a sister and a brother both of whom are healthy. The patient
does not know if the sister is getting regular mammograms. The patient has
two sons and two daughters, all children between ages 22 and 28.

PHYSICAL EXAMINATION: The patient presents as a pleasant, white woman in no
distress with blood pressure 150/90, left arm sitting, pulse 70 and regular,
respirations 13.

Lymph nodes - no palpably enlarged nodes are present in the cervical, sub-
clavicular, supraclavicular, axillary areas. Lungs are clear to percussion
and auscultation. There is no percussion tenderness over the spine or cos-
tovertebral angle areas. The right chest wall shows a recent and very well-
healed mastectomy scar with no evidence of nodularity or recurrence. The left
breast is normal to palpation. On heart examination, the PMI is within the
midclavicular line in the fifth intercostal space. There are no murmurs or
gallops heard and she is in normal sinus rhythm. Abdominal examination is
normal with no palpable liver or spleen or any mass present. There is no ex-
tremity edema.

ASSESSMENT: Infiltrating lobular carcinoma of the breast, status post
                 right mastectomy and axillary dissection.

                 Axillary nodes negative (Stage I).

The patient is in a premenopausal age range. Estrogen receptors on the tumor
are unknown.

Both the lack of receptor data and the long time interval since her surgery
preclude her participation in the NSABP Stage I breast carcinoma trial. Since
there is no data on the efficacy of chemotherapy in her setting, I would not
recommend this treatment for her. The more interesting question is whether
she should have a mirror-image biopsy on the opposite. This is a very con-
troversial area in surgical oncology at present with no clear answer avail-
able. I suspect that a course of close follow-up with frequent mammogram will
be satisfactory for her since her left breast is quite small and easy to
examine.

PLAN: I discussed these things with the patient. I also stressed having her
speak with her sister about getting yearly mammograms because of her increased
risk of breast cancer. In addition, I recommend that the patient's daughters
be examined regularly and that they learn breast self-examination since their
risk of breast carcinoma is also quite high.

The patient will be returned to Dr. Roston for his continued close follow-up
care.

APPENDIX 16

Reliability of Basic Cancer Patient Data

By
Feigl, P., Polissar, L., Lane, W., Guinee, V.
Statistics in Medicine 1:191-204,1982.

RELIABILITY OF BASIC CANCER PATIENT DATA*

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SUMMARY

Pooling patient data from multi-institutional medical chart review occurs commonly in the study of cancer and other diseases. To determine the consistency of reporting among institutions, we presented a test set of 25 standardized medical charts to coders at 18 Comprehensive Cancer Centers and compared their resulting codes. This study measures the reproducibility of coding by different persons, but does not assess the accuracy of the underlying medical record. Among 34 data items, we found high disagreement rates in coding stage of disease (14 per cent) and date of diagnosis (8 per cent). Primary site, histologic type and other key items had good reproducibility (disagreement rates ≤ 5 per cent). A number of minor disagreements indicated that detailed distinctions could not be reliably coded from medical charts.

KEY WORDS   Patient data quality   Cancer

INTRODUCTION

Medical chart review constitutes the major source of descriptive data on cancer patients in the United States. Two national examples are the Centralized Cancer Patient Data System (CCPDS), which collects information on approximately 50,000 cases annually from the 21 officially designated U.S. Comprehensive Cancer Centers, and the SEER Program (Surveillance, Epidemiology and End Results), which collects incidence and survival data on about 80,000 patients annually from 10 population-based cancer registries. Pooled cancer data from hospitals also form the basis for central tumour registries in 30 states.[1] Pooling data occurs commonly in cooperative clinical trials and in registries of diseases other than cancer. Cancer patient data systems have the common characteristic of routine coding of information from hospital charts according to a standard set of instructions. Given the extensive use of such data, it is important to know the reliability of coding on basic items, including primary site, histologic type, and stage of disease, in

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order to interpret properly the descriptive reports and analytic studies of cancer which use this information.

To date, few studies have dealt with the reliability of coding from medical records, and only some have touched on cancer issues. Gittlesohn and Senning[2] compared an abstracting service's code for hospital discharge diagnosis to the code for cause of death on the death certificate for 9724 cases in Vermont. They found that for 17 per cent of the death certificates with neoplastic disease as the cause of death, the coding of the discharge diagnosis indicated a different organ or a non-neoplastic disease. A comparable study by Percy *et al.*[3] reported a 15 per cent disagreement rate between hospital abstracts and death certificates for 30 cancer sites. In the largest study to date, Demlo *et al.*[4] compared coding by private coding services such as The Professional Activity Study (PAS) and re-coding of the same data by a specially trained group of technicians. They found accurate coding for demographic information and admission date. The International Classification of Diseases Code[5,6] was used to classify anatomic site for breast and lung cancer cases (the only cancer sites reported). The 3-digit site code differed for about 20 per cent of the cases between code and re-code (e.g. pleura vs. lung). The authors also found a 24 per cent disagreement rate on what clinical procedures were performed for all diseases combined, including cancer.

Herrmann *et al.*[7] studied accuracy in coding emergency medical services data from hospital records and found that the degree of complexity of medical records affected the quality of the coding, and that misreading of handwriting was a primary cause of error for some items. Hendrickson and Myers[8] found extremely high error rates in information coded for PAS from one large hospital, and concluded that errors resulted from a lack of coder training, lack of review of codes before submission, and lack of computer edit checks. Other coding studies in the literature report on reliability of coding outpatient drug therapy[9] and chronicity of mental illness[10] and on quality control programmes used by several large abstracting-coding operations.[11]

Most of these studies have focused neither on variables of interest nor on the type of data collection used in cancer research. We designed this study to determine the reliability of basic cancer patient data items as coded at 18 Comprehensive Cancer Centers and a central statistical co-ordinating centre. Abstractors at all the centres read the same set of 25 test charts and used a common coding protocol. The resulting rates of coding agreement have particular relevance for cancer studies but apply to other co-operative data collection systems as well.

MATERIALS AND METHODS

Staff of the Centralized Cancer Patient Data System (CCPDS) carried out the study as part of a data quality control programme. CCPDS collects selected patient information according to uniform definitions at all 21 U.S. Comprehensive Cancer Centers. It is a standard registration system of persons with malignant neoplasms admitted to the contributing centres on 1 July 1977 and later. Each Comprehensive Cancer Center forwards its data on computer tape quarterly to the Statistical Analysis and Quality Control (SAQC) Center, located at the Fred Hutchinson Cancer Research Center in Seattle, Washington. Eighteen Comprehensive Cancer Centers participated in the current study (see Appendix). The registration data collected for each patient in CCPDS consist of 34 items concerning demographic characteristics, tumour description, therapy, and survival (Table I).

From actual medical charts contributed by several centres 25 test charts were prepared. The charts referred to patients admitted to a centre within four months after diagnosis and were selected from the most prevalent primary sites in rough proportion to their frequency of occurrence in the U.S. We selected five charts each from colon–rectum, breast, and lung sites, three each from prostate and uterus sites, and one each from bladder and stomach sites, lymphoma and

Table I. List of data items in the CCPDS minimal patient data set

Item number	Description
	Identification
1	Institution code
2	Patient identification number
3	File number
4	Birthdate
	Demographic information
5	Birthplace
6	Race/ethnicity
7	Sex
8	Residence at time of admission to centre
	Diagnosis
9	*Date of first admission to centre for this tumour
10	Sequence
11	*Date of initial diagnosis
12	*Primary site
13	Laterality†
14	*Morphology
15	Diagnostic confirmation
16	Date of best diagnostic confirmation
17	*Stage of disease at time of first admission to centre
	Cancer therapy prior to admission to centre
18	Surgery
19	Radiation therapy
20	Chemotherapy
21	Endocrine therapy
22	Immunotherapy
23	Other cancer therapy
	Initial therapy after admission to centre
24	Date of initial therapy at centre
25	*Surgery
26	*Radiation therapy
27	*Chemotherapy
28	Endocrine therapy
29	Immunotherapy
30	Other cancer therapy
	Patient status
31	*Status at last contact†
32	*Date of last contact/death†
33	Autopsy performed†
34	Cancer/treatment related to death

* Key items
† Data item updated at annual follow-up

leukemia. We chose cases that in our judgement were typical of those admitted to Comprehensive Cancer Centers.

For each of the 25 patients, SAQC prepared a set of standardized medical charts. In a standard format, the 25 test charts consisted of a face sheet, discharge summary, operative notes, and pathology reports. These pages were typed verbatim from the original text. The charts excluded

Table II. Codes for 10 key items

Data item	Code
Primary site	Four digit ICD-0 topography code (Reference 3)
Morphology	Six digit ICD-0 morphology code (Reference 3). The first 4 digits indicate the histological type of tumour, the fifth digit indicates *in situ* vs. invasive behaviour, and the sixth digit is used for coding grade (differentiation).

Stage

Solid tumours
  0 *In situ*
  1 Localized
  2 Regional, direct extension
  3 Regional, nodes only
  4 Regional, direct extension and nodes
  5 Regional, not otherwise specified
  6 Non-localized, not otherwise specified
  7 Distant
  9 Unstaged or no data available

Lymphomas (Ann Arbor classification)
  1 Stage I
  5 Stage II
  7 Stage III
  9 Unstaged or no data available

Initial therapy*

0 None (This therapy not given)
1 This therapy given at centre
2 This therapy given outside centre
3 This therapy given both at the centre and outside of the centre
8 This therapy given inside or outside centre, not specified where
9 Unknown if this therapy given

Status at last contact

1 Alive, no evidence of cancer
2 Alive, with any cancer
3 Alive, cancer status unknown
4 Dead, no evidence of cancer at death
5 Dead, this cancer present at death
  (even if another cancer is also present)
6 Dead, no evidence of this cancer, but another cancer present at death
7 Dead, cancer present at death but it cannot be established whether it was this or another cancer
8 Dead, indeterminate whether cancer was present at death

Dates†

Month	Day	Year
01 January	01	Use last 2 digits
02 February	.	
.	.	99 Year is unknown
.	.	
.	.	
12 December	31	
88 Year is estimate	88 Month is estimate	
99 Month unknown	99 Day unknown	

* One item each for surgery, radiation and chemotherapy. The radiation code further distinguishes between beam radiation and radioisotope therapy.
† One item each for dates of admission, diagnosis, last contact.

nurses' notes and doctors' orders. We distributed copies of the charts to each of the participating 18 Comprehensive Cancer Centers with instructions for staff coders to assign codes in a manner simulating routine methods. Thus, the study was not blind—staff coders at each centre could clearly distinguish the test charts from their regular charts.

Among the 34 items in the minimal patient data set we singled out ten key items, noted in Table I, which are used more frequently than other items in cancer studies. The detailed codes for these items appear in Table II. Codes for other items are not shown but reflect a similar level of detail.

For each pair of centres, we classified the coding responses to a particular item (such as 'site') on the same chart as having exact agreement, or minor or major disagreement. (Definitions of 'exact', 'major' and 'minor' for the ten key items appear in Table III.) The 'major–minor' designation for disagreements reflects what might be of major or minor importance in typical use of the data. For example, in the coding of stage, a 'local' vs. 'regional' designation is a major disagreement, whereas 'regional stage with nodal involvement' vs. 'regional stage without nodal involvement' is a minor disagreement. A pair of site codes, one with 'colon' and the other with 'rectum', constitutes major disagreement whereas 'central portion of breast' vs. 'lower-outer quadrant of breast' is a minor disagreement.

In addition to comparing each centre's codes with those at each of the other centers, we established a standard set consisting of the codes most frequently used by the centres for each item. These modal codes were highly consistent with the coding by the personnel at SAQC who have responsibility for training in CCPDS on the use of codes, and for quality control of submitted data. The SAQC codes and the centres' modal codes had only four major disagreements among the ten key items on all test charts. (These four major disagreements included one each for histology and stage and two for diagnosis date, both coded as adjacent months, day unknown.) Thus, the modal codes overwhelmingly agreed with expert coding. We compared each centre's codes with the modal codes.

Table III. Definitions—degree of coding agreement for 10 key items

Data item	Exact agreement	Minor disagreement	Major disagreement
Primary site*	4 digit agreement	Difference in 4th digit only	Difference in first 3 digits
Morphology Histology (4 digits) Behaviour (1 digit) Grade (1 digit)	6 digit agreement	Difference in last 3 digits only	Difference in first 3 digits
Stage†	1 digit agreement	Agree except within regional	Any other difference
Initial therapy Surgery Radiation Chemotherapy	1 digit agreement	Agree except as to place of therapy	Difference in therapy given vs. not given
Status	1 digit agreement	Agree except on presence of cancer	Difference in alive vs. dead
Dates Admission Diagnosis Last contact	6 digit agreement	Agree within one month	Any other difference

* Special rules define minor/major disagreements for a few sites.
† Any disagreement in Ann Arbor staging for lymphomas is major.

RESULTS

Table IV shows the agreement rates for all items. The rates for major disagreements are eight per cent or less for all items except stage. Among the ten key items, the highest rates of major disagreement occur for stage (14 per cent), date of diagnosis (8 per cent) and histologic type (5 per cent), whereas the remaining items all have major disagreement rates of 2 per cent or less. In particular, site coding had a very low major disagreement rate (1 per cent). Major disagreement rates for the other items were low except for zip code (8 per cent) and date of best diagnostic confirmation (6 per cent). Over half of the major disagreements on zip code arose from one centre, and most of the remainder from a single chart. The majority of the major disagreements in date of best diagnostic confirmation were two months or less, usually consisting of agreement on year, a difference of one in month, and unspecified day of month in one or both codes. The definitions for coding this item were cumbersome and have since been simplified.

Table IV. Percentage agreement between centre codes and modal codes
(18 centres coding 25 charts, N = 450 cases)

Items	Percentage of 450 cases in		
	Exact agreement	Minor disagreement	Major disagreement
Key items			
Site	86	13	1
Morphology	83	12	5
Stage	82	4	14
Vital status	78	22	1
Initial therapy:			
Surgery	90	9	2
Radiation	95	4	1
Chemotherapy	98	1	1
Date of admission	86	12	2
Date of diagnosis	59	32	8
Date of last contact*	77	21	2
Other items			
Birthdate	98	0	2
Birthplace*	98	0	2
Race	58	42†	0
Sex	99	0	1
Country/state of residence	98	0	2
Zip code*	92	0	8
Sequence of tumour with other tumours	98	0	2
Laterality of tumour	100	0	0
Method of diagnostic confirmation	99	0	1
Date of best diagnostic confirmation*	77	17	6
Initial therapy:			
Endocrine	96	0	3
Immunotherapy	97	0	2
Other	100	0	0
Date of initial therapy*	88	9	4
Autopsy performed	99	0	1

* One centre does not code these items for all cases. Percentages based on N = 425 codes from 17 other centres.
† 189 out of 190 minor disagreements were due to 'Caucasian, non-Spanish surname' being coded to 'Caucasian, NOS'. This distinction has since been dropped as a requirement by CCPDS.

The minor disagreement rates for most items represent coding differences of detail. In race coding, for example, 189 out of the 190 minor disagreements consist of 'Caucasian, non-Spanish surname' vs. 'Caucasian, not otherwise specified (NOS)'. We subsequently dropped the non-Spanish surname category as a coding requirement. As a second example, the minor date disagreements are by definition less than one month, and are rarely of medical significance. The average minor disagreement rate for the ten key items was 13 per cent. Subsequent sections focus on major disagreements for the key items.

Agreement by item

Site

There were six major disagreements in the colon and stomach sites. In half of the six, centre codes used the less specific NOS category rather than the more specific modal code. In the remaining three major disagreements, the centre coded an adjacent site within the gastro-intestinal tract as compared to the modal code.

Morphology

Among the 22 major disagreements, 16 (73 per cent) fell into one of four patterns. Two involved transcription errors; three occurred when centres used codes which were consistent with, but less specific than modal codes; four involved the unimportant difference between adenocarcinoma, NOS, and adenocarcinoma arising in an adenomatous polyp; and seven disagreements occurred when centre coders erroneously used a newly introduced 'infiltrating *ductular* carcinoma' code in place of the modal 'infiltrating *duct* carcinoma' code. This latter error is regarded as a one time phenomenon associated with a new ICD-O[3] code category.

Among 15 minor histology disagreements, three would usually be considered medically significant. For example, one centre coded 'myeloid leukemia, NOS' in place of the modal code 'acute myeloid leukemia'. An additional 41 cases agreed exactly on the 4-digit histology code, but disagreed with respect to behaviour (*in situ* vs. malignant), or grade (cell differentiation), the 5th and 6th digits of the morphology code.

In some instances, coders chose an NOS classification when a more specific description was clearly stated. It should be stressed to coders that they use an NOS diagnosis only after exclusion of all other diagnoses. Over-use of NOS suggests the 'top-of-the-page syndrome' that occurs when a coder chooses the first term that will fit rather than searches for the best fit.

One would expect that the application of a set of coding rules to reports produced by numerous pathologists would uncover some differences in the style of report composition. Coders have a standing rule to use the diagnosis section of the pathology report and not rely on the commentary. However, unless the pathologist is aware of this rule, opinions expressed in the comment section may unintentionally influence the abstractor. Then, too, the qualifying terms which may appear in the diagnosis also have rules for coding. In several instances the coder was misled by the word 'suggestive'. A 'probable' diagnosis is acceptable, a 'suggestive' diagnosis is not. But with clear specification of histologic diagnosis, the abstractors almost always coded properly. Most errors occurred when pathologists used unfamiliar terms or qualifying notations.

Stage (extent of disease at admission to centre)

Of the 63 major disagreements on stage, 27 (43 per cent) involved the presence of direct extension (whether the tumour had spread by direct extension beyond the organ of origin into surrounding organs or tissues). Nineteen of the 20 minor disagreements also involved direct extension. In 11 of the major disagreements (17 per cent), the centre code was less specific (unknown or NOS) than the

modal code. In another 11 disagreements, the centre code indicated distant spread of disease while the modal code showed less extensive disease. Five codes were invalid, and nine disagreements were of miscellaneous kinds.

As a means of comparing consistency with accuracy in the coding of stage, one of us (W.W.L.) conducted a careful study of cases to assess a 'correct' stage code for each case. In comparing the actual codes with this standard, 354 (79 per cent) of the 450 codes agreed, and another 15 (3 per cent) were acceptable, being based upon equivocal readings of radiographic findings. This left 81 (18 per cent) of the codings in clear error.

Of the 81 errors, 44 (54 per cent) involved the precise definition of direct extension. (Excluding these errors in accuracy, major disagreements drop from 63 to 35, resulting in a rate of 8 per cent instead of 14 per cent.) In one case, 12 of the 18 centres failed to regard positive peritoneal washings as evidence of distant metastasis, accounting for an additional 12 (15 per cent) of the errors. (In this particular case the modal code was incorrect.) The remaining 25 errors were diverse, with five caused by the use of invalid codes.

Initial therapy

In 13 of the 14 major disagreements approximately equal thirds of the centre codes added a therapy modality, dropped a therapy modality, or used 'unknown' when the modal code was specific ($N = 4$, 4 and 5, respectively).

Vital status at last contact

There were only three disagreements (on the same lung cancer chart) as to whether the patient was alive at last contact. The 97 minor disagreements reflected differences in describing the status of the tumour at last contact.

Dates of admission, diagnosis and last contact

The major disagreements in dates included a number of instances of adjacent calendar months and with 'unknown' for one or both codes for calendar day. Hence, there was a potential disagreement of up to two months, which technically counted as a major disagreement. Elimination of these slight differences from the major disagreement category, along with other differences of two months or less, results in major disagreement rates of (corresponding to those in Table IV): admission date, 0·7 per cent instead of 1·4 per cent; diagnosis date, 2·2 per cent instead of 8·2 per cent (a substantial reduction); date of last contact, 1·1 per cent instead of 2·1 per cent.

Agreement for clusters of items and sites

Since data items are not usually used singly, but in combination, Table V presents results for several such combinations. For example, in calculating survival time (cluster No. 3), one needs to know the time interval between dates of admission and last contact and whether the patient was last known to be alive or dead (vital status). Table V shows the frequency of encountering a case with at least one major disagreement among the items in a cluster. The most basic cluster, the description of the tumour, has the highest percentage of cases with major disagreements, mainly due to the high disagreement rate for stage. The therapy and survival clusters have the lowest percentages. The major portion of the disagreements in the demographic and date clusters arise from disagreements in zip code and diagnosis date, respectively.

By site, disagreements did not occur with equal frequency, as shown in Table VI. The highest rates of disagreement on stage occurred with the less common cancers. There was a low disagreement rate for stage of breast cancer cases, probably because breast cancer is relatively easy to stage. There were only five stage disagreements of any kind (major or minor) for this site. The

Table V. Occurrence of major coding disagreements in clusters of items
(18 centres coding 25 charts, $N = 450$ cases)

Cluster	Percentage of cases with any major disagreement in cluster
1. Tumour description site, stage, histology	19
2. Initial therapy Surgery, radiation, chemotherapy	4
3. Survival time* Vital status, date of admission, date of last contact	4
4. Demographic description* Birthdate, birthplace, race, sex, state of residence, zip code	14
5. Patient contact dates* Date of admission, date of diagnosis, date of last contact	10

* One centre does not code at least one item in this cluster for all cases, $N = 425$.

Table VI. Percentage major disagreement in stage and histology coding by site

Site	Number of charts	Number of codes	Percentage of codes with major disagreement	
			Stage	Histology
Colon	5	90	14	6
Breast	5	90	3	10
Lung	5	90	8	7
Prostate	3	54	17	1
Uterus	3	54	22	2
Others (bladder, stomach lymphoma, leukemia)	4	72	26	1
All study sites	25	450	14	5

lung cancer cases had a moderately low major disagreement rate for stage, but also had the highest total disagreement rate (major plus minor) of any site. Most of the minor stage disagreements were due to differences in coding direct extension in cases with regional node metastasis.

The low rate of histology disagreements for prostate cases stems from the lack of variation in histologies for this site. Virtually all prostate cases are adenocarcinoma. Breast cancer, which has the highest major disagreement rate, includes numerous histologies.

Agreement from centre to centre

The preceding sections compared the individual centre's code with a modal code. Table VII shows the disagreement rate in coding for all pairs of centres. These rates are higher than those for comparison of individual centre's codes with the modal code, because, by definition, a substantial number of centre codes agree with the modal code. The first column of Table VII summarizes major disagreements between pairs of centres for each key item. For example, among all possible pairs of centres, an average of 3 per cent of the pairs had major disagreements on site codes. The second, third and fourth columns of Table VII give some idea of the *variation* in agreement found between pairs of centres. For example, 93 per cent of the pairs of centres disagreed on only one site code or none, and there were no pairs of centres that disagreed on five or more site codes for the 25 test charts.

Table VII. Major disagreements for all centre-to-centre pairwise comparisons of codes

Key items	Average major disagree-ment, percentage*	Percentage of 153 centre pairs that disagreed on		
		0 or 1 codes on 25 charts	2–4 codes on 25 charts	5 or more codes on 25 charts
Site	3	93	7	0
Histology	9	33	60	7
Stage	23	0	67	33
Initial therapy:				
Surgery	3	78	21	1
Radiation	1	100	0	0
Chemotherapy	1	89	11	0
Status at last contact	1	100	0	0
Date of admission	3	82	17	1
Date of diagnosis	12	20	63	17
Date of last contact†	10	74	25	1

* Average major disagreement percentage for any pair of centres (based on 18 × 17/2 = 153 pairs).
† Based on 17 centres, 136 pairs.

The centres had fairly uniform agreement on all key items except histology, stage and date of diagnosis (see Table VII, last column). In histology coding, only 7 per cent of the pairs of centres disagreed on five or more charts out of the 25. But the level of disagreement was substantial for stage coding and for date of diagnosis with, respectively, 33 per cent and 17 per cent of the centre pairs disagreeing on five or more out of the 25 charts. As noted earlier, many of the 'major' disagreements in diagnosis date are medically inconsequential.

In summary, the results show that disagreement rates vary by item and by site. Major disagreements tended to be confined to certain centres and to certain of the test charts. One centre was at an extreme with 23 major disagreements in the ten key items—nearly one per chart. The next centre had about one-half major disagreement per chart for the ten key items.

DISCUSSION

Overall, the codes were quite reproducible from centre to centre, with stage being the most difficult to capture consistently. When combining items into clusters, as in Table V, the number of cases

without major disagreements declines rapidly as items are added into a cluster. The relatively large number of minor disagreements suggests that an effort to define a finely detailed coding scheme for medical records cannot prevent inconsistencies, as coders must increasingly rely on judgment in interpreting sketchy or confused information. In short, there is a limit to what can be gleaned from medical records. (For an amusing discussion of problems in using medical charts, see Reference 12.)

A limitation of the present study is the standardized, typed format for presenting data to coders. Herrmann, et al.[7] found that misreading of handwriting seemed to be primarily responsible for errors in abstracting vital signs. The elimination of the ambiguities of handwritten material may have inflated the apparent reliability in the current study. Also, the clear identification of the test charts as such probably led to unusual care and attention in their coding, with a consequent increase in reliability compared with data routinely collected. On the other hand, the coders' accuracy at the time of this study was probably less than it is today because the study was undertaken early in the development of CCPDS, before correction and adjustment of the misinterpretations of coding guidelines.

The reproducibility levels obtained in this reliability study serve as target levels for routine CCPDS data. For comparison, agreement rates for routine CCPDS submissions are available from the system's formal data quality monitoring programme. The data monitoring programme requires SAQC field representatives to visit each contributing centre annually for the purpose of reabstracting and recoding a random sample of cases previously submitted under routine conditions. The major disagreement rates based on comparison of centre and SAQC codes for over 1000 routine cases are 1–10 percentage points higher than those shown here, with the 10 per cent increment applying to the stage item. Thus, under routine conditions about a quarter of stage codes are in dispute, a sizeable fraction of which involves use of an 'unknown' code by one or the other coder.

As a result of this study we concluded that the disagreement rate for stage was unacceptably high. We are attacking this problem by intensive training activities, including annual national workshops, as well as formal review and simplification of guidelines. Moreover, we reaffirmed the decision not to expand the stage code to include more detail; e.g. vessel invasion. This coding experiment also resulted in a revision of the definitions of major and minor disagreements; e.g. by introducing a series of site-specific exceptions to the definition of histology disagreements. We modified the codes for race, as well as those for method and date of best diagnostic confirmation.

Studies such as this confront a methodological problem. Ideally, one might wish to validate the correspondence of the code with the patient's actual disease state as garnered, for instance, by pathological review of slides or clinical re-examination of patients. The current study was limited only to reproducibility of codes based on a chart; if the chart is incomplete or erroneous, the resulting codes are inaccurate even if reproducible. Moreover, in some instances the coding is genuinely a matter of choice between acceptable alternatives. One commonly uses consensus decisions as a standard for comparison, as we did in using the modal code. We find it reassuring that our modal codes were also strongly supported by independent expert coding. It is important, however, to remember that, owing to the inherent uncertainty in medical records, disagreements are not in every instance errors.

Generalization of the results presented here to other data systems depends upon several factors: the complexity of the items coded; the numbers of centres and coders involved; the qualifications, supervision and continuity of the coders; and finally the time, money and quality control resources dedicated to the project. CCPDS is a well-funded, multi-centre co-operative system of registries with a formal data monitoring system supported by a high-level policy group of cancer centre representatives, and a full-time experienced staff. Moreover, its patient dataset is deliberately designed for simplicity. One would expect that data systems without active quality control would

fall short of the reproducibility figures given here. More complex multi-institutional systems probably require special efforts to improve substantially on the results shown.

The extent of variation demonstrated here under experimental conditions indicates that any multi-institutional abstracting and coding effort should have a quality control programme with feedback to the coders involved. The implied cautions for users of routinely collected patient data are evident. The user of data abstracted from medical charts can rely on the bold features of the coding to portray a realistic picture, but would be wise not to over-interpret detailed features.

APPENDIX: LIST OF INVESTIGATORS*

I. Comprehensive cancer centres

Comprehensive Cancer Center
University of Alabama in Birmingham, Birmingham
    Herman F. Lehman, D.D.S., M.P.H.

Kenneth Norris, Jr. Cancer Research Institute
University of Southern California Comprehensive Cancer Center, Los Angeles
    John T. Casagrande, Dr. P. H., Brian E. Henderson, M.D.

UCLA Jonsson Comprehensive Cancer Center, Los Angeles
    Mildred Weiss, Richard J. Steckel, M.D.

Colorado Regional Cancer Center, Inc., Denver
    Jeffrey V. Sutherland, Ph.D.

Yale University Comprehensive Cancer Center, New Haven, Connecticut
    Diana B. Fischer, Ph.D., Colin White, M.D.

Georgetown University Comprehensive Cancer Center, Washington, D.C.
    Sidney J. Cutler, Sc.D.

Howard University Comprehensive Cancer Center, Washington, D.C.
    Zahur Alam, Sc.D., Jack E. White, M.D.

Comprehensive Cancer Center for the State of Florida,
University of Miami School of Medicine, Miami
    Guy Burton Seibert, Ph.D.

Illinois Cancer Council, Chicago
    Craig B. Dickson, M.P.H., Richard Warnecke, Ph.D.

Johns Hopkins Oncology Center, Baltimore
    Anne L. Kammer, Raymond E. Lenhard, Jr., M.D.

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* The first person named is the Data Co-ordinator for the Center; the second is the Policy Committee member. If only one name is listed, the same person serves in both capacities.

Mayo Comprehensive Cancer Center, Rochester, MN
 Helen Golenzer, William F. Taylor, Ph.D.

Memorial Sloan-Kettering Cancer Center, New York
 Sara Bretsky, Ph.D., Roger M. Yurko, M. A., M.P.A.

Roswell Park Memorial Institute
 Warren W. Lane, Ph.D., Roger L. Priore, Sc.D.

Comprehensive Cancer Center
Duke University Medical Center, Durham
 Edwin B. Cox, M.D., John Laszlo, M.D.

Ohio State University Comprehensive Cancer Center, Columbus
 Nancy A. Reiches, Ph.D., Martin Keller, M.D., Ph.D.

Fox Chase/University of Pennsylvania Comprehensive Cancer Center, Philadelphia
 Fox Chase: Hari H. Dayal, Ph.D., Paul F. Engstrom, M.D.
 University of Pennsylvania: Clifford Miller, M.S., John S. J. Brooks, M.D.

Fred Hutchinson Cancer Research Center, Seattle
 Steven Dahlberg, M.S., Donovan Thompson, Ph.D.

The University of Wisconsin Clinical Cancer Center, Madison
 Steven Entine, M.S.

II. Program offices

Statistical Analysis and Quality Control Center (SAQC)
Fred Hutchinson Cancer Research Center, Seattle

Project Head:	Polly Feigl, Ph.D.
Unit Heads:	Kathie Roth, Administration
	Mark Schmidt, Data Processing
	Gwen Glaefke, Field Operations
	John Crowley, Ph.D., Statistics

Centers Program
National Cancer Institute, Bethesda

Project Officer:	Thomas C. Dundon, M.A.

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APPENDIX 17

CCPDS Protocol for a Therapy Reporting Study

Plans are given for a study to estimate the quality and completeness of a registry's therapy data. This study was never undertaken by the CCPDS despite considerable agreement about the need.

CENTRALIZED CANCER PATIENT DATA SYSTEM
QUALITY CONTROL AND TRAINING SUBCOMMITTEE

THERAPY REPORTING STUDY

PROTOCOL

1. INTRODUCTION

1.1 There is evidence, based upon preliminary studies of therapy data in the CCPDS database, that therapies given outside the centers are, in many cases, not being recorded in the patient medical record or reported to CCPDS. Since any substantial under-reporting of data for therapies actually given would make the therapy data information in the CCPDS dataset virtually useless, the Quality Control and Training Subcommittee (QCTS) has determined that it is imperative to measure the extent to which such under-reporting occurs.

1.2 This study is an exploratory one, designed by the Working Group of the QCTS in consultation with the SAQC staff. It will be conducted jointly by the Comprehensive Cancer Centers and SAQC under the direction of the QCTS.

2. PURPOSE

The purpose of this study is to assess the accuracy of therapy data in the CCPDS database by canvassing primary physicians.

3. PLAN OF STUDY

The study will be primarily conducted by center personnel. A sample of 50 cases from each center, representing five primary site groups, will be selected from among cases submitted to CCPDS. The center staff will apply to the primary physician for each case, asking that a questionnaire be completed. Follow-up will be performed as necessary, including requests to other sources of information, in order to ensure that all therapies given to the patient are determined. The questionnaires will be collected and coded at the center, then returned to SAQC for analysis.

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* Centers for which this study is not feasible may request modification from SAQC. Such modification will be subject to approval by the Chairman of the Quality Control and Training Subcommittee.

3.1 Selection of Sample

3.1.1 Criteria for sampling frame.

The sampling frame will consist of all cases which,

a. are 'analytic', i.e., whose "Date of Initial Diagnosis" is either after the "Date of First Admission to the Center for This Tumor" or within four months before "Date of Admission";
b. were first diagnosed in 1979 or 1980;
c. fall into one of the five diagnostic categories of the study (see below);
d. did not expire before the second month following "Date of Admission".

3.1.2 Stratification of sample.

a. By center. Fifty cases will be selected from each of the Comprehensive Cancer Centers.
b. By diagnosis. Ten cases will be selected at each center from each of the following:

 - Female breast cancer, CCPDS stages 3 and 4 (positive regional nodes).
 - Colon cancer, all stages beyond localized.
 - Lung cancer, all stages beyond localized.
 - Ovarian cancer, all stages.
 - Non-Hodgkin's lymphoma, all stages.

Site groups for inclusion will be those used by CCPDS (Attachment 1). In the event that sufficient cases are not available for any group, substitute cases will be drawn from other years, or if necessary, fewer cases will be used.

3.2 Study Operation

3.2.1 SAQC will furnish to the data coordinator of each center by July 1, 1982,

a. a list of patient identification numbers for the 50 selected cases;
b. a sample letter to physicians (Attachment 2);
c. a sufficient supply of physician questionnaires (Attachment 3);
d. a pre-printed treatment summary form for each case (Attachment 4).

The data coordinator will make arrangements for the study and supervise its execution within the center. Should any cases be discovered by the center to fail to meet the sampling criteria, the center will notify SAQC, which will supply a substitute case number.

3.2.2 Physician contact.

a. Each center will obtain necessary clearances to contact the patients' physicians.

b. A letter and treatment form will be sent to the physician deemed by the center to be the best source of information for each case. If deemed more efficient by the center, contact may be made by telephone, with responses entered on the physician form by the center.

c. Responses not received within a reasonable time (four weeks) will be followed up. If the physician is unable to give a complete response, the center will make every reasonable effort to secure adequate treatment information from other physicians or from other sources as appropriate.

d. The center will also check its own medical records to make sure that all treatment information recorded therein is captured.

e. The center will fill out the summary form from the question-naire for each case. Coding will follow CCPDS guidelines for reporting "Initial Course of Therapy After Admission to Center". The center will return the summary forms to SAQC, together with a copy of all completed questionnaires and other supporting material as appropriate, on a quarterly basis (October 1, 1982, January 1 and April 1, 1983).

3.3 Analysis by SAQC

3.3.1 Upon receipt of the above material, SAQC will verify the center's coding, resolving differences with the center personnel. Within three months of receipt of all cases from a center, SAQC will prepare a list comparing the treatment codes from the study with those on the CCPDS database and send a copy of this list to the center's data coordinator.

3.3.2 Standard statistical analysis will be performed on the results. Center-specific results will be reported to each center's data coordinator, and will be available to the Chairperson of the CCPDS Policy Advisory Committee and to NCI.

3.3.3 Aggregate and/or center-coded results will be reported to all data coordinators, the CCPDS Technical Advisory Committee, the QCTS, the Policy Advisory Committee, and the NCI.

3.4 Each data coordinator will distribute results to the cooperating physicians as requested.

4. CONFIDENTIALITY

The usual procedures will be followed to maintain patient confidentiality. Patient-identifying matter, other than the CCPDS identification number and birthdate, will be removed from the material submitted to SAQC.

5. TIMEFRAME

Case numbers to be sent to centers: July   1, 1982.
All cases to be received by SAQC: April 1, 1983.
Preliminary report from SAQC: July   1, 1983.

CENTRALIZED CANCER PATIENT DATA SYSTEM
Statistical Analysis and Quality Control
1124 Columbia Street, Seattle, Washington 98104 (206) 292-2965

CCPDS GROUPINGS FOR ICD-O PRIMARY SITES

#	Site	Codes
01	Buccal Cavity and Pharynx	140.0 to 149.9
02	Esophagus	150.0 to 150.9
03	Stomach	151.0 to 151.9
04	Small Intestine	152.0 to 152.9
05	Colon	153.0 to 153.9
06	Rectum	154.0 to 154.1
07	Pancreas	157.0 to 157.9
08	Other Digestive Organs	154.2 to 156.9, 158.0 to 159.9
09	Lung	162.2 to 162.9
10	Other Respiratory System	160.0 to 161.9, 162.0, 163.0 to 163.9, 164.2 to 165.9
11	Bones and Joints	170.0 to 170.9
12	Soft Tissue (Including Heart)	164.1, 171.0 to 171.9
13	Melanomas, Skin	173.0 to 173.9 Histology 8720 to 8780
14	Other Skin	173.0 to 173.9
15	Breast, Female	174.0 to 174.9
16	Breast, Male	175.9
17	Cervix	180.0 to 180.9
18	Corpus	182.0 to 182.8
19	Ovary	183.0
20	Other Female Genital Organs	179.9, 181.9, 183.2 to 183.9, 184.0 to 184.9
21	Prostate	185.9
22	Other Male Genital Organs	186.0 to 187.9
23	Urinary Bladder	188.0 to 188.6, 188.8 to 188.9
24	Kidney and Renal Pelvis	189.0, 189.1
25	Other Urinary Organs	188.7, 189.2 to 189.9
26	Eye and Orbit	190.0 to 190.9
27	Brain and Other Nervous System	191.0 to 192.9
28	Thyroid	193.9
29	Endocrine System (Including Thymus)	164.0, 194.0 to 194.9
30	Non-Hodgkin's Lymphoma (Including Nodal and Extranodal)	Histology 9590 to 9642, 9690 to 9701, 9740 to 9750 Primary Site: Nodal - 141.6. 146.0, 147.1, 149.1, 164.0. 169.0 to 169.9, 196.0 to 196.9 Extranodal - All Other Sites
31	Hodgkin's Lymphoma (Including Nodal and Extranodal)	Histology 9650 to 9662 Primary Site: Nodal - 141.6. 146.0, 147.1, 149.1, 164.0, 169.0 to 169.9, 196.0 to 196.9 Extranodal - All Other Sites
32	Multiple Myeloma	9730 to 9731
33	Leukemia, NOS	9800, 9802, 9804, 9810, 9820, 9822, 9824, 9825, 9830, 9840, 9850, 9860, 9862, 9864, 9865, 9866, 9870, 9880, 9890, 9892, 9894, 9900, 9910, 9920, 9930, 9940
34	Leukemia, Acute	9821, 9861, 9891, 9801, 9841
35	Leukemia, Chronic	9823, 9863, 9893, 9803, 9842
36	Other Hematopoeitic System	169.0 to 169.9 Histology Other Than Above
37	Unknown Primary	195.0 to 195.8, 196.0 to 196.9, 199.9

179

SAMPLE LETTER TO PHYSICIANS

(CANCER CENTER XYZ letterhead)
XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
YYYYYYYYYYYYYYYYYYYYYYYYYYYYYYYYY
ZZZZZZZZZZZZZZZZZZZZZZZZZZZZZZZZ

July 15, 1982

Homer A. Hippocrates, M.D., F.G.C.S.
1253 Acropolis Road
Athens, Georgia 05263

RE: Alice B. Patient
1200 Malaise Lane
Tulsa, Oklahoma 55555

TYPE OF CANCER: Breast

Dear Dr. Hippocrates:

Our Center is conducting a study to determine the accuracy with which we record cancer treatment actually given to patients. We are asking your help in carrying out this vital study. For the patient listed above, we are requesting information regarding all cancer treatment actually received by the patient.

If you cannot provide complete information, please give us what you can, and let us know as soon as possible. Your cooperation in improving our cancer therapy information is greatly appreciated.

Sincerely yours,

Grace Abounding
Title

PHYSICIAN QUESTIONNAIRE

Patient Identification:

CCPDS Identification Number:

Physician:

Date of Diagnosis:

Type of Cancer:

Please enter all cancer-directed therapy information known to you which has been given to this patient within one year of diagnosis date, regardless of where or by whom administered. Please indicate if treatment was given for another cancer.

For surgery, give date and type of surgery.

For radiation or drug therapy, give beginning and ending dates, and type of radiation or specific drugs given.

Date(s)   Type of Therapy   Where Given

Was therapy changed in response to recurrence, metastasis, or other progression of disease? ____Yes ____No

If yes, give date of progression: _____

Do you believe that this information is complete? ____Yes ____No ____Doubtful

If not sure, from whom might we obtain better information?

Comments:

____I would like to see the results of this study.

Signed_____

CCPDS/SAQC
Centralized Cancer Patient Data System
Statistical Analysis and Quality Control Center
1124 Columbia Street
Seattle, Washington 98104

CCPDS Therapy Reporting Study: SUMMARY FORM

CCPDS Patient ID: | 99 123-456-789 1 | Birthdate: 99-99-9999

Center: 99 XYZ Cancer Center

Date of Admission: JUL 1980 | The information in
                                                | this part of the form
Date of Diagnosis: MAY 1980 | will be pre-printed
                                                | by SAQC.
Primary Site: 199.9 Unknown Primary Site

Histology: 8000/3 Carcinoma, NOS

Date First Therapy at Center: AUG 1980

Date of Last Contact: SEP 1981

TO BE COMPLETED BY THE CENTER:

Date(s)   Type of therapy   Where given

Date of first recurrence, metastasis, or other progression
of disease following initiation of therapy: ____ - ____ - ____
    (code zeroes if no recurrence)   Month Day Year
    (code nines if unknown)

Treatment Codes: ___ ___ ___ ___ ___ ___
                      S   R   C   E   I   O

SAQC VERIFICATION CODES

                     ___ ___ ___ ___ ___ ___   By: ___ ___
                      S   R   C   E   I   O

SAQC FORM DP/94 3-2-82   182

APPENDIX 18

Examples of Outpatient Data Forms

These forms were used in a study evaluating patterns of patient care in which obtaining complete treatment information was considered essential. This study was conducted by the Statistical Analysis and Quality Control Center (SAQC), Fred Hutchinson Cancer Research Center, 1124 Columbia Street, Seattle, Washington 98104.

PHYSICIAN QUESTIONNAIRE

Patient Name: _____

Patient Identification Number: _____ Physician: _____

Date of Diagnosis: _____ Type of Cancer:_____**BREAST**_____

PLEASE DESCRIBE ALL NON-SURGICAL CANCER-DIRECTED THERAPY WHICH HAS BEEN GIVEN TO THIS PATIENT, REGARDLESS OF WHERE ADMINISTERED OR BY WHOM.

1. Were specialists in either of the following disciplines consulted or involved in the management of this patient?

   MEDICAL ONCOLOGY   ☐ No ☐ Yes, Dr. _____ ☐ Unknown

   RADIATION ONCOLOGY ☐ No ☐ Yes, Dr. _____ ☐ Unknown

2. Did this patient receive RADIOTHERAPY within four months after_____?

   ☐ No   ☐ Yes   ☐ Unknown   (Date First Rx)

3. If yes, what type(s) of RADIATION was administered?

   ☐ External Beam

   ☐ Interstitial Radiation

   ☐ Other, specify _____

4. Did this patient receive CHEMO/HORMONAL therapy within four months after _____?

   ☐ No   ☐ Yes   ☐ Unknown   (Date First Rx.)

5. If yes, which CHEMO/HORMONAL therapy agents were administered?

   ☐ Cyclophosphamide (Cytoxan)   ☐ L-PAM (Melphalan, Alkeran)
   ☐ 5 Fluorouracil (5-FU)   ☐ Tamoxifen (Nolvadex)
   ☐ Methotrexate   ☐ Prednisone, Halotestin
   ☐ Doxorubicin (Adriamycin)   ☐ Oophorectomy
   ☐ Vincristine (Oncovin)   ☐ Other, specify _____

6. Was this patient clinically free of disease when radiotherapy and/or chemo/hormonal therapy was initiated?

   ☐ No   ☐ Yes   ☐ Unknown

7. Was any of the therapy documented above administered in response to recurrence, metastasis, or other progression of disease?

   ☐ No   ☐ Yes, specify: _____

8. IF YOU BELIEVE THIS INFORMATION TO BE INCOMPLETE, ARE THERE OTHER PHYSICIAN(S) WE COULD CONTACT WHO MIGHT HAVE BETTER INFORMATION?

   DR: _____ ADDRESS: _____

   DR: _____ ADDRESS: _____

   RETURN TO: _____

                                           (Physician Signature)

FH-D007

PHYSICIAN QUESTIONNAIRE

Patient Name:_____

Patient Identification Number: _____ Physician: _____

Date of Diagnosis: _____ Type of Cancer: __COLON/RECTUM__

PLEASE DESCRIBE ALL CANCER-DIRECTED THERAPY WHICH HAS BEEN GIVEN TO THIS PATIENT, REGARDLESS OF WHERE ADMINISTERED OR BY WHOM.

1. Were any specialists in the following disciplines consulted or involved in the management of this patient?

   MEDICAL ONCOLOGY ☐ No ☐ Yes, Dr. _____ ☐ Unknown

   RADIATION ONCOLOGY ☐ No ☐ Yes, Dr. _____ ☐ Unknown

   SURGERY ☐ No ☐ Yes, Dr. _____ ☐ Unknown

2. Did this patient receive RADIOTHERAPY within four months after _____?
   ☐ No ☐ Yes ☐ Unknown (Date First Rx)

3. If yes, when was RADIATION administered?
   ☐ Pre-operative
   ☐ Post-operative
   ☐ Pre- and Post-operative
   ☐ Other, specify _____

4. Did this patient receive CHEMOTHERAPY within four months after _____?
   ☐ No ☐ Yes ☐ Unknown (Date First Rx)

5. If yes, indicate the type of CHEMOTHERAPY administered:
   ☐ Portal vein infusion
   ☐ Hepatic artery infusion
   ☐ Chemotherapy, not otherwise specified

6. Was this patient clinically free of disease when radiotherapy and/or chemotherapy was initiated?
   ☐ No ☐ Yes ☐ Unknown

7. Was any of the therapy documented above administered in response to recurrence, metastasis, or other progression of disease?
   ☐ No ☐ Yes, specify: _____

8. IF YOU BELIEVE THIS INFORMATION TO BE INCOMPLETE, ARE THERE OTHER PHYSICIAN(S) WE COULD CONTACT WHO MIGHT HAVE BETTER INFORMATION?

DR: _____ ADDRESS: _____

DR: _____ ADDRESS: _____

RETURN TO:

_____
(Physician Signature)

186

FH-D006

PHYSICIAN QUESTIONNAIRE

Patient Name:_____

Patient Identification Number: _____ Physician: _____

Date of Diagnosis: _____ Type of Cancer: __OAT CELL, LUNG__

PLEASE DESCRIBE ALL CANCER-DIRECTED THERAPY WHICH HAS BEEN GIVEN TO THIS PATIENT, REGARDLESS OF WHERE ADMINISTERED OR BY WHOM.

1. Were any specialists in the following disciplines consulted or involved in the management of this patient?

   MEDICAL ONCOLOGY   ☐ No ☐ Yes, Dr. _____ ☐ Unknown

   RADIATION ONCOLOGY ☐ No ☐ Yes, Dr. _____ ☐ Unknown

   SURGERY   ☐ No ☐ Yes, Dr. _____ ☐ Unknown

2. Please indicate if any of the following tests for metastatic evaluation were performed while the patient was an outpatient:

   BRAIN SCAN/CT SCAN BRAIN   ☐ Not Done   ☐ Done   ☐ Unknown

     If done, specify: Date: _____, Results: _____

   LIVER SCAN/CT SCAN LIVER   ☐ Not Done   ☐ Done   ☐ Unknown

     If done, specify: Date: _____, Results: _____

   BONE SCAN (RADIOISOTOPE)   ☐ Not Done   ☐ Done   ☐ Unknown

     If done, specify: Date: _____, Results: _____

   BONE MARROW BIOPSY ASPIRATION ☐ Not Done   ☐ Done   ☐ Unknown

     If done, specify: Date: _____, Results: _____

3. Did this patient receive RADIOTHERAPY within four months after _____?
   (Date First Rx)

   ☐ No radiation therapy

   ☐ Yes, radiation to primary site and or nodes

   ☐ Yes, radiation to distant metastatic site(s)

   ☐ Yes, prophylactic CNS radiation therapy

   ☐ Unknown

4. If patient received RADIATION to his her PRIMARY TUMOR, indicate:

   # Rads:_____ # Fractions _____ Date started _____ Date completed _____

5. Did this patient receive CHEMOTHERAPY within four months after _____?
   (Date First Rx)

   ☐ No

   ☐ Yes, single agent

   ☐ Yes, combination

   ☐ Yes, other

   ☐ Unknown

6. Was any of the therapy documented above administered in response to recurrence, metastasis, or other progression of disease?

   ☐ No   ☐ Yes, specify: _____

7. IF YOU BELIEVE THIS INFORMATION TO BE INCOMPLETE, ARE THERE OTHER PHYSICIAN(S) WE COULD CONTACT WHO MIGHT HAVE BETTER INFORMATION?

   DR: _____ ADDRESS: _____

   DR: _____ ADDRESS: _____

RETURN TO:
HD008   _____
               (Physician Signature)

<u>SAMPLE LETTER TO PHYSICIANS</u>

(Community Hospital Program Letterhead)
XXXXXXXXXXXXXXXXXXXXXXXXXXXX
YYYYYYYYYYYYYYYYYYYYYYYYYYYY
ZZZZZZZZZZZZZZZZZZZZZZZZZZZZ

June 1, 1984

Homer A. Hippocrates, M.D.
1253 Acropolis Road
Athens, Georgia 05263

RE: Alice B. Patient
        1200 Malaise Lane
        Athens, Georgia 05263
        DOB: 01/01/1920

TYPE OF CANCER: _____

Dear Dr. Hippocrates,

Our hospital is participating in a Patterns of Care Study, as a part of the three-year Community Cancer Care Evaluation. To document changes in cancer patient management in our community, it is necessary to collect complete and accurate data concerning first course of cancer treatment delivered to our patients.

We request your assistance in carrying out the Patterns of Care Study. Vital information is needed concerning the cancer treatment regimen of the patient listed above. Please complete the enclosed questionnaire and return it as soon as possible.

If you cannot provide complete information, please give us what you are able. Your cooperation in improving our record of cancer therapy data information is greatly appreciated.

Sincerely,

Grace Abounding
Title

APPENDIX 19

Examples of Site/Stage/Histology Coding Exercises

Additional "Summary Coding Exercises" are available upon request from SAQC, Fred Hutchinson Cancer Research Center, 1124 Columbia St., Seattle, Washington, 98104.

PHYSICAL EXAMINATION: 2-10-73 Chief complaint: Bright red blood per rectum. Chest clear. Lymph nodes negative. Breasts negative. Abdomen liver 2 finger breadths below right costal margin. On pelvic exam there appeared to be adherence of the colon to the vagina at the level of 5-6 cm.

X-RAYS: 2-17-73 Chest x-ray negative. 2-20-73 Barium enema: large annular irregular mass lesion in the distal rectum which is compatible with a primary rectal carcinoma. 2-20-73 Cystogram unremarkable. 2-20-73 IVP: No evidence of bladder invasion.

MANIPULATIVE PROCEDURES: 2-16-73 Sigmoidoscopy: 2 intraluminal masses at 7 cm. and 10 cm. biopsies taken.

SURGICAL OBSERVATIONS: 2-22-73 Abdominal-Perineal Resection: An exploration of the abdomen revealed there to be no abnormality aside from those associated with the sigmoid colon. Just at the peritoneal reflection, a tumor was felt intraluminally in the rectosigmoid colon. There were several palpable lymph nodes along the course of the superior hemorrhoidal artery and vein. The highest of these lymph nodes was located close to the bifurcation of the aorta. The posterior vaginal wall was removed in the area where it was contiguous with the tumor. No gross involvement of the vagina was found.

PATHOLOGY: 2-16-73 Rectal biopsy at 10 cm. Mixed colonic polyp. Biopsy at 6 cm. Adenocarcinoma, Moderately differentiated. 2-22-73 Abdominal Perineal Resection: Poorly Differentiated Adenocarcinoma of the rectum with invasion of perirectal fat, veins and nerves with metastasis to 5/16 lymph nodes. Mixed villous and adenomatous polyps of the colon. GROSS: Received is 43 cm. of terminal colon and rectum. A lesion is present 6 cm. from the distal surgical margin It is a large ulcerating almost annular lesion measuring 7 cm x 3 cm. The margins are free of tumor. MICROS: Tumor glands invade muscularis and extend into perirectal fat. The squamous epithelium of the vaginal margin is not invaded by tumor. However invasion of perirectal fat veins and nerves are noted. Of distal lymph nodes 3/4 are involved with tumor. Of the proximal lymph nodes 1 of 12 shows tumor. Polyps show no evidence of malignancy.

THERAPY: 2-22-73 Abdominal-perineal resection.

9	DATE ADMITTED		
10		SEQUENCE	
11	DATE DIAGNOS.		
12	PRIMARY SITE		
13		LATERALITY	
14	HISTOLOGY		
15		GRADE	
		DIAGNOSTIC CONFIRMATION	
16	DATE BEST CONFIRMATION		
17		STAGE	
18	PRIOR THERAPY:	SURGERY	
19		RADIATION	
20		CHEMOTHERAPY	
21		ENDOCRINE	
22		IMMUNOTHERAPY	
23		OTHER	
24	DATE OF INITIAL THERAPY:		
25		SURGERY	
26		RADIATION	
27		CHEMOTHERAPY	
28		ENDOCRINE	
29		IMMUNOTHERAPY	
30		OTHER	
31	STATUS LAST CONTACT		
32	DATE LAST CONTACT		
33		AUTOPSY	
34	CANCER/TREATMENT RELATED TO DEATH		

SAQC NUMBER 13

191

PHYSICAL EXAMINATION: 3-11-75 Three to four weeks ago the patient had right face and hand seizures. HEENT: Negative. Chest clear. Neurological: Right facial sag, probable papilledema. Impression: Left frontal mass--probable glioma, hopefully meningioma.

X-RAYS, SCANS: PTA: EMI shows left frontal lesion. 3-11-75 Left carotid angiogram: large avascular left sided posterior frontal tumor mass lesion. 3-11-75 Cerebral circulation study/brain scan: Large area of increased uptake in the left frontal region consistent with a large space occupying lesion 2-6-76 EEG: possibly abnormal. 2-6-76 EMI No recurrent tumor noted.

SURGICAL OBSERVATION: 3-14-75 Frontal craniotomy and excision of tumor. Upon elevating the bone flap, there was no frank erosion of tumor through the dura, but the dura at the level of the erosion did appear infiltrated with tumor. The tumor was readily visualized on the surface of the brain and the tumor demarcations from normal brain tissue was quite clear cut. The tumor was grossly entirely removed. The bone flap was examined and the defect in the center of the bone was enlarged in order to be sure that any bone infiltrated with meningioma had been removed.

PATHOLOGY: 3-14-75 Left frontal brain tumor and remaining tumor and dura: Cellular tumor of uncertain histogenesis. Final diagnosis deferred until further study. 4-7-75 Letter from Professor of Neuropathology: The microscopic appearances of this tumor are classically those of oligodendroglioma. There is no doubt that this tumor is a primary glial tumor. Oligodendrogliomas are known to be sometimes unusually well-defined, so that they may appear not to originate from the parenchyma of the brain. However, the microscopic appearances are quite unequivocal in indicating a tumor of primary neuroectodermal origin. No invasion of dura or bone are noted in the specimens.

THERAPY: 3-14-75 Left frontal craniotomy and excision of tumor.

SAQC NUMBER 28

192

9	DATE ADMITTED			
10	SEQUENCE			
11	DATE DIAGNOS.			
12	PRIMARY SITE			
13	LATERALITY			
14	HISTOLOGY			
15	GRADE DIAGNOSTIC CONFIRMATION			
16	DATE BEST			
17	CONFIRMATION STAGE			
18	PRIOR THERAPY: SURGERY			
19	RADIATION			
20	CHEMOTHERAPY			
21	ENDOCRINE			
22	IMMUNOTHERAPY			
23	OTHER			
24	DATE OF:			
25	INITIAL THERAPY: SURGERY			
26	RADIATION			
27	CHEMOTHERAPY			
28	ENDOCRINE			
29	IMMUNOTHERAPY			
30	OTHER			
31	STATUS LAST CONTACT			
32	DATE LAST			
33	CONTACT AUTOPSY			
34	CANCER/TREATMENT RELATED TO DEATH			

PHYSICAL EXAMINATION: 12-10-74 3 cm. mass in the bottom, mid and posterior tongue. The tongue has early fixation to the floor of the mouth. There is a 1 cm. submental mass; a 2 cm. mid-neck mass without evidence of left neck disease. Biopsy one month prior to admission showed carcinoma. 12-19-74 Admitted for surgery for carcinoma of tongue. Oral examination: 2 x 1 cm. lesion right lateral surface midlingually with extension to the lingual sulcus and adjacent gingiva. Neck: one large node high and near the mandibular angle and other node anterior cervical chain. No supraclavicular lymph nodes. No other oral lesions.

MANIPULATIVE PROCEDURES: 12-14-74   Exam anesthesia and with preparation of delayed forehead flap. There is a 3 cm. mass in the bottom, mid and posterior tongue on the right side. There is a 2 cm. mass in the mid right neck and a one cm. mass in the submental area. No biopsy done.

SURGICAL OBSERVATION: 12-20-74 Right neck dissection, right hemiglossectomy: There is an infiltrating lesion involving most of the right mid-tongue, extending post- erior to involve part of the base of the tongue. The tumor extends deep into the musculature of the tongue and extends behind the mandible. Does not involve the mandible proper. There is metastatic deposit in the high right digastric triangle. It was apparent the hypoglossal nerve was invaded by tumor.

PATHOLOGY: 12-20-74 Right tongue and neck dissection: Well differentiated infiltrating squamous cell carcinoma extending to the anterior-lateral surgical margin of the tongue resection and metastatic to 4/33 cervical nodes with perinodal soft tissue extension. GROSS: In the center of the mucosal surface there is an ulcer- ated neoplasm 1.2 cm. in depth surrounded by a layer of uninvolved muscle tissue. Within the muscle of the anterior lateral portion is a 3 mm. white nodule, well circumscribed, but not encapsulated. This nodule has no visible connection with the main tumor mass. MICRO: 2/6 submaxillary nodes and 1/5 lower jugular and 1/22 mid and upper jugular nodes harbor metastases with extension out of the nodes into the surrounding soft tissue in all 3 areas. The nodule deep in the antero- inferior portion of the tongue is tumor. (No mention of hypoglossal nerve in path report)

THERAPY: 12-20-74 Right neck dissection, right hemiglossectomy

SAQC NUMBER 35

193

9	DATE ADMITTED	
10	SEQUENCE	
11	DATE DIAGNOS.	
12	PRIMARY SITE	
13	LATERALITY	
14	HISTOLOGY	
15	GRADE	
	DIAGNOSTIC CONFIRMATION	
16	DATE BEST	
17	CONFIRMATION	
	STAGE	
18	PRIOR THERAPY: SURGERY	
19	RADIATION	
20	CHEMOTHERAPY	
21	ENDOCRINE	
22	IMMUNOTHERAPY	
23	OTHER	
24	DATE OF INITIAL THERAPY:	
25	SURGERY	
26	RADIATION	
27	CHEMOTHERAPY	
28	ENDOCRINE	
29	IMMUNOTHERAPY	
30	OTHER	
31	STATUS LAST CONTACT	
32	DATE LAST CONTACT	
33	AUTOPSY	
34	CANCER/TREATMENT RELATED TO DEATH	

PHYSICAL EXAMINATION: 10-8-73 Mass in right breast approximately 2 years ago. This became larger and two months PTA pain was noted when lifting. Right breast: lesion with darkened peau d'orange appearance. 4 cm. diameter, medial with firm area beneath and firm tissue in right upper quadrant. No palpable axillary nodes. Left breast negative. Abdomen no masses. No supraclavicular nodes palpable.

X-RAYS: 10-8-73 Chest: Solitary pulmonary nodule noted at anterior basilar segment of the left lower lobe. This may represent a granuloma, primary neoplasm, and in view of the breast changes on the right side, metastatic involvement is a consideration. 10-9-73: Bone survey. No evidence of osteolytic or osteoblastic metastases.

OPERATIVE FINDINGS: 10-9-73 Excisional biopsy of right medial breast mass. No description other than this. Right radical mastectomy was done at this time.

PATHOLOGY: 10-9-73: Right radical mastectomy: Infiltrating ductal carcinoma with skin involvement. Metastatic carcinoma in lymph nodes from axillary level I. Levels II and III are negative. GROSS: Skin over tumor mass is puckered and shows an orange-peel appearance. Tumor mass is 2.5 x 4 x 4 cm. extending diffusely into surrounding fatty tissue. In addition in the upper outer quadrant there is another firm tan tumor nodule approximately 2 x 2 x 2 cm. MICRO: Sections from the mass in UIQ show infiltrating ductal carcinoma with focus of vascular invasion. Sections from the UOQ also show infiltrating ductal carcinoma. Sections of the skin overlying mass in the UIQ show extensive infiltration of the skin by invasive carcinoma. Focus of carcinoma is seen in a section of the nipple and random sections from the upper inner quadrant and upper outer quadrant of the breast. Level I nodes with 3/5 with metastatic carcinoma. Focus of metastatic carcinoma is also in adipose tissue. Level II and III nodes are free of metastases.

THERAPY: 10-9-73 Radical Mastectomy, right. 11-26-73 to 12-14-73 Cobalt 60 therapy to chest, axilla, internal mammary nodes and supraclavicular areas 4000 rads.

9	DATE ADMITTED					
10			SEQUENCE			
11	DATE DIAGNOS.					
12	PRIMARY SITE					
13			LATERALITY			
14	HISTOLOGY					
15			GRADE			
			DIAGNOSTIC CONFIRMATION			
16	DATE BEST CONFIRMATION					
17			STAGE			

18	PRIOR THERAPY:	SURGERY	
19		RADIATION	
20		CHEMOTHERAPY	
21		ENDOCRINE	
22		IMMUNOTHERAPY	
23		OTHER	

24	DATE OF INITIAL THERAPY:					
25		SURGERY	
26		RADIATION	
27		CHEMOTHERAPY	
28		ENDOCRINE	
29		IMMUNOTHERAPY	
30		OTHER	

31	STATUS LAST CONTACT	
32	DATE LAST CONTACT					
33		AUTOPSY	
34	CANCER/TREATMENT RELATED TO DEATH	

CENTRALIZED CANCER PATIENT DATA SYSTEM

ICD-O AND STAGING CODING EXERCISES

EXERCISE 1

PRIMARY SITE: Endometrium

HISTOLOGY: 11-24-76 Uterine curettings: adenosquamous carcinoma, intermediate
differentiation, consistent with endometrial origin.

12-7-76 Uterus, bilateral oviducts and ovaries: Poorly differentiated adenoacan-
thoma with superficial myometrial invasion.

ASSESSMENT OF STAGE: Chest x-ray normal. Physical examination within normal
limits.

CODE THE FOLLOWING INFORMATION

PRIMARY SITE: __ __ __.__

HISTOLOGY: __ __ __ __/__ __

STAGE: __

EXERCISE 2

PRIMARY SITE: Left breast

HISTOLOGY: 12-11-76 Needle biopsy of left breast mass: Poorly differentiated
carcinoma, infiltrating, left breast.

ASSESSMENT OF STAGE: Physical examination: 5 cm. mass in the UOQ of the left
breast, peau de orange of the left breast is present, multiple firm, fixed nodes
are present in the left axilla. Rest of the physical examination is within normal
limits.

PRIMARY SITE: __ __ __.__

HISTOLOGY: __ __ __ __/__ __

STAGE: __

EXERCISE 3

PRIMARY SITE: Right tonsillar fossa

HISTOLOGY: 12-13-76 1) Biopsy, base of tongue: Infiltrating squamous carcinoma
moderately differentiated. 2) Biopsy of right tonsillar fossa: small separate
fragments of squamous epithelium with neoplastic change.

ASSESSMENT OF STAGE: The tumor extended into the retromolar trigone, right
soft palate, right pharyngeal and oral tongue posteriorly--extended into the
hypopharynx; middle and anterior two-thirds of the tongue on the right side
was also involved. The origin of the tumor was felt to be the right tonsillar
fossa.

PRIMARY SITE: __ __ __.__

HISTOLOGY: __ __ __ __/__ __

STAGE: __

EXERCISE 4

PRIMARY SITE: Bladder neck

HISTOLOGY: 10-4-76 Transurethral resection of bladder tumor: papillary
transitional cell carcinoma, grade III, urinary bladder. Invasion into the
superficial muscle is noted.

ASSESSMENT OF STAGE: Bone scan and chest x-ray were within normal limits.
On examination under anesthesia the mass was determined to be fixed and extension
into the prostate was noted.

PRIMARY SITE: __ __ __.__

HISTOLOGY: __ __ __ __/__ __

STAGE: __

EXERCISE 5

PRIMARY SITE: Left parietal lobe of brain

HISTOLOGY: 10-26-76 Excision of brain tumor: Glioblastoma multiforme, left parietal area. No invasion of the dura is noted.

ASSESSMENT OF STAGE: Brain scan showed only one lesion which was confined to the left parietal lobe.

PRIMARY SITE: ___ ___ ___.___

HISTOLOGY: ___ ___ ___ ___/___ ___

STAGE: ___

EXERCISE 6

PRIMARY SITE: Right lower lobe, lung

HISTOLOGY: 10-17-76 Bronchoscopy with biopsy: bronchoalveolar cell carcinoma of right lung. 10-20-76 Right lower lobectomy: Bronchoalveolar cell carcinoma in right lower lung with metastases to hilar lymph nodes and mediastinal lymph nodes.

ASSESSMENT OF STAGE: Chest x-ray revealed a 3 cm. mass in the right lower lung. Some hilar and mediastinal adenopathy was noted. 10-20-76 At surgery there was noted to be extension of the tumor mass into the pericardium.

PRIMARY SITE: ___ ___ ___.___

HISTOLOGY: ___ ___ ___ ___/___ ___

STAGE: ___

EXERCISE 7

PRIMARY SITE: Prostate

HISTOLOGY: 10-5-73 Transurethral resection of prostate: Adenocarcinoma of prostate, grade III.

ASSESSMENT OF STAGE: Bone scan revealed several areas of osteolytic lesions within the pelvis and skull. Examination under anesthesia revealed hard, firm prostate with extension into the adjacent tissues.

PRIMARY SITE: __ __ __.__

HISTOLOGY: __ __ __ __/__ __

STAGE: __

EXERCISE 8

PRIMARY SITE: Cecum

HISTOLOGY: Right colectomy: Adenocarcinoma, grade I with submucosal extension. No regional lymph nodes were involved with tumor.

ASSESSMENT OF STAGE: Chest x-ray, liver scan normal. Physical examination within normal limits. Exploration at time of surgery revealed no abnormalities other than mass within the cecum.

PRIMARY SITE   __ __ __.__

HISTOLOGY: __ __ __ __/__ __

STAGE: __

EXERCISE 9

PRIMARY SITE: Lung

HISTOLOGY: 10-2-76 Bronchial biopsy with evidence of undifferentiated small cell carcinoma, fusiform cell type.

ASSESSMENT OF STAGE: At bronchoscopy extension of the tumor across the carina into the left mainstem bronchus was noted. Liver scan was normal. Brain scan normal. Chest x-ray: There was a mass noted in the right upper lobe as well as masses scattered throughout the left lung field.

PRIMARY SITE: __ __ __.__

HISTOLOGY: __ __ __ __/__ __

STAGE: __

EXERCISE 10

PRIMARY SITE: Stomach.

HISTOLOGY: 11-7-76 Partial gastrectomy: Signet ring adenocarcinoma, primary stomach. 0/6 lymph nodes involved with tumor. Invasion into muscularis noted.

ASSESSMENT OF STAGE: At surgery there was noted to be a 3-4 cm. mass located on the lesser curvature of the stomach. Several lymph nodes were noted. Partial gastrectomy with Bilroth II anastomosis done.

PRIMARY SITE: __ __ __.__

HISTOLOGY: __ __ __ __/__ __

STAGE: __

EXERCISE 11

PRIMARY SITE: Pancreas

HISTOLOGY: 10-9-76 Biopsy of peripancreatic lymph node; Islet cell carcinoma.

ASSESSMENT OF STAGE: Chest x-ray within normal limits. At exploratory laparotomy a small mass was noted in the tail of the pancreas; some attachment of the pancreas to the surrounding structures was noted. One enlarged lymph node was biopsied and frozen section revealed carcinoma. The liver was free of disease as was the rest of the abdominal examination.

PRIMARY SITE: __ __ __.__

HISTOLOGY: __ __ __ __/__ __

STAGE: __

EXERCISE 12

PRIMARY SITE: Cervix

HISTOLOGY: 9-29-76 Biopsy of cervix: Squamous cell carcinoma, keratinizing type, large cell.

ASSESSMENT OF STAGE: On bimanual examination there was noted to be extension of the tumor into the parametrium. Extension was also noted onto the vaginal wall on the left side.

PRIMARY SITE: __ __ __.__

HISTOLOGY: __ __ __ __/__ __

STAGE: __

CENTRALIZED CANCER PATIENT DATA SYSTEM

ICD-O Coding Exercise

Topography		Morphology
__ __ __.__	1. Adenosquamous carcinoma, endometrium	__ __ __ __/__ __
__ __ __.__	2. Embryonal carcinoma, right testis	__ __ __ __/__ __
__ __ __.__	3. Squamous cell carcinoma in-situ, squamo-columnar junction, cervix uteri	__ __ __ __/__ __
__ __ __.__	4. Poorly differentiated clear cell carcinoma left kidney	__ __ __ __/__ __
__ __ __.__	5. Bronchioloalveolar carcinoma, moderately well differentiated, lingula left lung	__ __ __ __/__ __
__ __ __.__	6. Papillary serous cystadenocarcinoma, right ovary	__ __ __ __/__ __
__ __ __.__	7. Lobular carcinoma, upper outer quadrant right breast	__ __ __ __/__ __
__ __ __.__	8. Superficial spreading malignant melanoma, left scapular area	__ __ __ __/__ __
__ __ __.__	9. Well differentiated adenocarcinoma, descending colon	__ __ __ __/__ __
__ __ __.__	10. Osteogenic sarcoma, left femur	__ __ __ __/__ __
__ __ __.__	11. Nodular sclerosing Hodgkin's disease, cervical lymph nodes	__ __ __ __/__ __
__ __ __.__	12. Acute leukemia	__ __ __ __/__ __
__ __ __.__	13. Chronic myelogenous leukemia	__ __ __ __/__ __
__ __ __.__	14. Oat cell carcinoma, right upper lobe lung	__ __ __ __/__ __
__ __ __.__	15. Oligodendroblastoma, frontal lobe	__ __ __ __/__ __
__ __ __.__	16. Well differentiated squamous cell carcinoma, left false cord	__ __ __ __/__ __
__ __ __.__	17. Retinoblastoma, right eye	__ __ __ __/__ __
__ __ __.__	18. Moderately well differentiated adenocarcinoma, body of pancreas	__ __ __ __/__ __
__ __ __.__	19. Hairy cell leukemia	__ __ __ __/__ __
__ __ __.__	20. Adenofibroma, malignant, left ovary	__ __ __ __/__ __
__ __ __.__	21. Malignant lymphoma, mixed lymphocytic-histiocytic, cervical and axillary lymph nodes	__ __ __ __/__ __

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ICD-O Coding Exercise

Page 2

Topography   Morphology

___ __ __.__   22. Carcinoma, undifferentiated type from   __ __ __ __/__ __
                     pelvic mass biopsy

__ __ __.__   23. Pleomorphic carcinoma of the posterior   __ __ __ __/__ __
                     wall of the stomach

__ __ __.__   24. Small cell carcinoma of main stem bronchus   __ __ __ __/__ __

__ __ __.__   25. Malignant lymphoma convoluted cell type   __ __ __ __/__ __
                     of supraclavicular nodes

__ __ __.__   26. Pseudomyxoma peritonei   __ __ __ __/__ __

__ __ __.__   27. Pleomorphic adenoma of the parotid gland   __ __ __ __/__ __

__ __ __.__   28. Papillary transitional cell carcinoma   __ __ __ __/__ __
                     Grade III of posterior wall of urinary
                     bladder

__ __ __.__   29. Poorly differentiated lymphocytic lymphoma   __ __ __ __/__ __
                     nodular arising in retroperitoneal nodes

__ __ __.__   30. Non-infiltrating intracystic carcinoma   __ __ __ __/__ __
                     from midline of breast

__ __ __.__   31. Malignant meningioma of the R parietal   __ __ __ __/__ __
                     lobe

__ __ __.__   32. Histiocytic medullary reticulosis from   __ __ __ __/__ __
                     bone marrow biopsy

__ __ __.__   33. Paget's disease and infiltrating duct   __ __ __ __/__ __
                     carcinoma of UOQ of breast

__ __ __.__   34. Malignant lymphoma of undifferentiated   __ __ __ __/__ __
                     cell type, non Burkitts, arising in
                     inguinal & axillary nodes

__ __ __.__   35. Leiomyosarcoma of retroperitoneum   __ __ __ __/__ __

__ __ __.__   36. Germinoma of anterior mediastinum   __ __ __ __/__ __

__ __ __.__   37. Adenocarcinoma, Grade I with apocrine   __ __ __ __/__ __
                     metaplasia of the inner breast

__ __ __.__   38. Malignant histiocytosis   __ __ __ __/__ __

__ __ __.__   39. Liposarcoma, well differentiated type   __ __ __ __/__ __
                     of L thigh

__ __ __.__   40. Spindle cell melanoma, type A of the   __ __ __ __/__ __
                     choroid of the eye

APPENDIX 20

Centralized Follow-up as Exemplified by the SEER Program

By
Young, J.L., Ries, L.A., Pollack, E.S.

This paper was presented at a meeting of the International Association of Cancer Registries in September 1982, Seattle, Washington. It is reprinted here with permission of the senior author.

CENTRALIZED FOLLOW-UP AS EXEMPLIFIED BY THE SEER PROGRAM

John L. Young, Jr., Lynn A. Ries, Earl S. Pollack

Abstract

The SEER Program requires active follow-up of all patients not known to be dead, on an annual basis. While active follow-up implies contact with the patient by a hospital or physician, non-medical sources are utilized to determine patient vital status. These include motor vehicle records, voter registration records, and records of Medicare and Social Security. Six methods of measuring successful follow-up can be defined. During the most recent follow-up year, 85% of alive patients were successfully followed. Comparison of 4-year relative survival rates based on active versus passive follow-up procedures revealed that in areas with large out migration, passive follow-up overestimates survival. A test of the National Death Index (NDI) in two SEER areas resulted in a false negative rate of 8%. Thus, the NDI is a less viable alternative to active follow-up at present. Hospital cooperation is often dependent on assistance by the central registry in maintaining hospital follow-up for accreditation by the American College of Surgeons. Follow-up accounts for only 8% of the NCI dollars expended on the SEER Program. If the total costs of the program are considered, follow-up accounts for 14%. Active follow-up of all patients, with the exception of those with in situ carcinoma of the uterine cervix, will be continued into the near future.

The United States Surveillance, Epidemiology, and End Results (SEER) Program is, in effect, a network of ten population-based centralized cancer registries. As the name implies, one major goal of this program is the monitoring of cancer patient survival (end results). This goal can only be achieved through annual follow-up of all cancer patients included in the various registries.

The SEER Program requires each of its ten central registries to follow its patients on an active basis. The actual contract requirement is stated as follows:

> "With the use of all available methodologies, obtain active follow-up on all cases resident in the area. Maintain reporting and data processing procedures so as to provide current active follow-up on all living patients within 18 months of the date of diagno-
> sis or the date of last contact, whichever is later."

Unfortunately, while the terms active and passive follow-up are frequently used in discussion of tumor registry methodology, neither term has been defined in the cancer literature. The term "active" follow-up probably arises from the hospital-based setting where someone at the hospital level, either a physician or a hospital registrar, initiates a direct contact with the patient. Thus, the connotation of active follow-up involves contact with the patient by a medical source. The term "passive" follow-up is generally understood to imply no direct patient contact and usually involves a simple match of all patients known to a registry against a list of patients known to have died during a defined time period with the assumption that any patient not matched is alive. Passive follow-up would not be acceptable to any registry interested in cancer status of patients not known to be dead, nor would it be particularly effective in areas with either large in and out migration or with incomplete ascertainment of all deaths.

The term active follow-up does not apply in its strictest sense to the SEER Program since many non-medical sources are used to ascertain that patients are indeed alive, if not well. These "subjective" sources (which will be discussed below) are acceptable as indicators of patient vital status because the Program does not place emphasis on determining tumor status. While the database in the past has attempted to determine whether a patient is alive with or without cancer, the data have not been readily available, and this requirement has been dropped. The use of subjective data, i.e., non-medical sources, would also not be acceptable to any registry whose goal was to determine quality of life.

METHODS EMPLOYED WITHIN SEER

Centralized follow-up within SEER is not easy to exemplify since the procedures vary widely among the ten centralized registries. Patient follow-up is sometimes made easier and sometimes more complicated by the presence of hospital-based registries within the catchment area. For hospitals who independently maintain their own tumor registry, it is often possible for the central registry to receive any follow-up information available at the hospital level free of charge. Data may be transmitted to the central registry via magnetic tape or on paper documents or may be recorded by central registry personnel during routine visits to the local hospital. Sometimes the data are given to the central registry by the hospital free of charge and sometimes for a fee. In some areas, because patient follow-up is often difficult as well as time-consuming, some hospital registries have elected to provide incidence data directly to the central registry expecting in return that the central registry will follow the patient on behalf of the hospital in a "you scratch my back, I'll scratch yours" arrangement.

For those unfamiliar with medical practice in the United States it should be pointed out that many hospitals maintain their own individual tumor registries in order to meet a necessary requirement for accreditation of their oncology program by the American College of Surgeons. These hospitals are generally large, 200+ beds, are often located in urban centers, and many serve as teaching hospitals for medical schools. A question often arises as to why the SEER Program requires follow-up on a population base rather than accepting only follow-up from hospitals with their own registries. It should be readily apparent that such a procedure would indeed be less expensive, but the data would also be open to considerable and unmeasurable bias since the experience of patients seen in "registry hospitals" might be vastly different from that of patients in non-registry hospitals. Further, the percentage of patients seen in registry hospitals varies greatly from one SEER registry to another. In one area, for example, only 3 of XX hospitals maintain their own registry.

It should also be pointed out that problems of patient confidentiality and also of "political turf" can arise when hospital registries and central registries interact. If a patient is seen in more than one registry hospital, the central registry has the option of assisting the two registries in the sharing of information. However, some central registries have opted to share only vital status since further diagnostic and/or treatment data may be considered privileged information by one or the other hospital.

With the above information as background, the most general method of operation within the central registry revolves around the preparation of individual lists of patients in need of follow-up during a given time frame — usually one month. For those central registries who are fortunate enough to have access to vital statistics data on a monthly (or at least a quarterly) basis, death clearance may take place prior to the preparation of the actual monthly lists. In any event, lists are prepared for a given month and are used either as a tickler for the local hospital registrar or for use by the central registry staff.

Central registry staff use the monthly follow-up lists in a number of ways. For those registries who have permission to routinely contact their patients, the lists are used to initiate contact. This may be via a telephone call to the patient (or the physician of record) or a direct letter, either individually typed or, as in the case of two central registries, computer generated. For those registries whose first attempt at follow-up is through the local (non-registry) hospital, central registry staff visit the hospital in an attempt to ascertain whether the patient has been readmitted or has visited the out-patient department since the time of last contact. If no further information is available within the hospital, several alternatives may be pursued, the most common of which is for the central registry staff to write the patient (or the physician of record) using local hospital stationery rather than that of the central registry. Or a telephone contact with the patient (or physician) may be attempted by the central staff but identifying his or herself as an employee of the local hospital. Either procedure is, of course, only attempted with the full knowledge and approval of the local hospital administration.

Once all permissible avenues of hospital/physician/direct patient contact have been exhausted, more subjective sources are pursued for those patients not known to be dead by periodic matches to death tapes and for whom date of diagnosis or of last contact has been at least 18 months. At least four (subjective, passive) sources have been utilized by the various central registries. The first of these are records available from the State Department of Motor Vehicles. Depending on the state, a variety of data may be available on magnetic tape for all licensed drivers in the state. At a minimum, the date of last renewal will be available and, in some states, the date of any moving or parking violation will also be available. It is felt that motor vehicle records are most helpful in locating lost patients under the age of 65 since many persons in their retirement years, particularly cancer patients, are no longer able to drive. A limitation to the motor vehicle files is that in most states the license renewal period is four to six years so that during any given year the chances of a more current follow-up date is greatly reduced.

A second source which has been utilized is the records of local election boards. These records contain the names of all persons who voted in the last election, generally held at least every two years, and can be of great assistance in finding lost patients, particularly during an election year. A third source which to date has become available to only one central registry is state Medicare (national insurance for the elderly) files. These files are most useful for persons over the age of 65 since relatively few persons qualify for Medicare coverage prior to that age. These files contain the most recent date of a visit to any physician or any hospital for any cause for which Medicare has been billed. Thus, especially for those patients with no evidence of active cancer but with other acute or chronic problems, Medicare files are an excellent source of information. In addition, for those patients for whom social security number is available, matching of registry records to Medicare files is extremely simplified since the social security number coincides with the Medicare claim number.

A fourth source, which again has been utilized by only one central registry, are the records of the national Social Security Administration (SSA). By submitting a roster of lost patients to the SSA, it is possible to learn which claimants are still being paid (although not where they are paid) and for any claimant who has died, the state of death. To date, however, only information on dead claimants has been released.

A fifth, but highly subjective source, which has been utilized by some registries are local telephone and city directories, the assumption that any one listed therein was still alive at the time the directory was prepared for publication, generally the previous calendar year. There are, of course, limitations to such assumptions.

All of the subjective sources are open to possible biases and limitations. There are always instances in which persons assume the identity of a decedant and continue to vote, drive, draw social security checks, and file Medicare claims in the name of the deceased. Hopefully, the number of such frauds is small. A more severe limitation to the use of such sources is the availability of a computer program to match two large data files without the presence of a common identity number and to correctly link every person common to the two files. Since each central registry has developed its own matching program, the degree of comparability from one registry to another is not known. Further, many central registries are limited by considerations of confidentiality in their ability to utilize the sources discussed above. For example, to utilize the files of the SSA, tapes must be provided to that federal agency, and the matching is carried out by the SSA rather than the cancer registry. Not all registries would be able to submit their files to an outside agency for such a procedure. Thus, the degree to which these sources are available or are accessible to the central registries varies widely throughout the program.

RESULTS OF ACTIVE FOLLOW-UP

One of the most difficult aspects of cancer patient follow-up is the evaluation of how good (or how successful) patient follow-up has been. Data submitted to the SEER program in December 1981 was supposed to contain active follow-up on all cases diagnosed 1973-79 through December of 1980. The goal which was established for each contractor was that 80% of the patients diagnosed 1973-75 should have been followed, 82.5% of the 1976 diagnoses, 85% of 1977 diagnoses, 87.5% of 1978 diagnoses, and 90% of 1979 diagnoses. However, at least six methods of calculating the percentage of patients followed are possible depending on the definition of the numerator and denominator. Results of these six methods of calculating percent of patients successfully followed are shown in Table 1. In each case the numerator is either patients "followed" at any time during 1981 or patients followed during or after their anniversary month during 1980. The denominator is based on either all patients ever to be followed, all patients alive at the beginning of the follow-up period (1980), or all patients alive at the end of the follow-up period. As can be seen, follow-up rates ranged from a low of 72% to a high of 92% depending on the method of calculation chosen.

Table 1: Percent of cases successfully followed during 1980 by year of diagnosis, USA SEER Program 1973-79

Year of Dx	Total in active follow-up	Alive as of last contact	Dead as of last contact	Alive 1980+	Dead 1980+	Alive 1980, but last contact before anniv. month	Percent follow-up based on cases alive as of last contact		Percent follow-up based on cases alive as of 1980		Percent follow-up based on all cases	
							yr	yr & mo	yr	yr & mo	yr	yr & mo
1973	43,281	18,208	30,073	10,079	1,369	1,065	76	68	79	71	93	90
1974	54,775	18,832	35,943	14,404	2,110	1,579	76	68	79	71	92	89
1975	60,793	22,679	38,114	17,626	2,905	1,949	78	69	80	73	92	88
1976	66,946	27,408	39,538	21,657	3,918	2,304	79	71	82	74	91	88
1977	68,234	30,060	38,174	24,318	5,303	2,520	81	73	84	77	92	88
1978	69,322	33,642	35,680	28,048	8,162	2,834	84	75	87	80	92	88
1979	71,325	39,112	32,213	33,942	16,831	4,211	87	76	91	83	93	87
1973-79	434,676	184,941	249,735	150,074	40,596	16,462	81	72	85	77	92	88
	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)

In the first set of calculations, columns 7 and 8, the denominator was the number of persons alive (not known to be dead) as of the last date of contact (column 2). The numerator was all alive patients with a date of last contact at any time during 1980 or 1981 (results shown in column 7) or all alive patients with a date of last contact during or anytime after their anniversary date during 1980. The anniversary month in this case was the month of diagnosis. Thus, for the calculations shown in column 8, a patient diagnosed in June of any years, 1973-79, would be considered to be successfully followed only if the date of last contact were June 1980 or later. A patient diagnosed in June but followed in May 1980 would be considered lost. Considering month of last contact rather than year reduces the percent followed by 8-9 percentage points for each diagnosis year.

In the second set of calculations (columns 9 and 10) all persons who died during 1980 or 1981 were added to both the numerator and the denominator previously described, the thought being that these deaths were actually successful follow-ups for the period being evaluated, namely, 1980. I.e., these patients were alive at the beginning of the year and the fact that their death was discovered could and should be considered as a successful follow-up. As can be seen, adding these deaths to both the numerator and the denominator improved follow-up rates by 4-5 percentage points. Considering month of follow-up reduced the percent successfully followed by 7-8 percentage points.

The third set of calculations were based on considering any death (regardless of year) as a successful follow-up so that all deaths were added to the numerator and all persons ever in active follow-up were used for the denominator. This resulted in follow-up rates which were 11-16% higher than those calculated by the first method with the difference considering anniversary month being only 3-4% lower than when only year is considered. This third method of calculating follow-up rates has been the one traditionally used by the American College of Surgeons. However, it should be readily apparent that as a registry ages, high follow-up rates can be achieved regardless of how many alive patients are actually followed since adding large numbers of deaths to the numerator will automatically yield high rates. The first method of calculation is also an unfair measure of follow-up since registries are actually punished rather than credited for finding cancer deaths. It is therefore suggested that the best measure of how successful a registry has been in following patients during the most recent period of time is the second method. It is further suggested that it is also more appropriate to consider contact at any time during the year of follow-up as "success" rather than basing such a consideration on anniversary month, especially since anniversary month from the vantage point of the central registry is subject to change from year to year. Thus, column 9 of Table 1 is the recommended measure of success in evaluating how well a registry is following patients on an "active" basis. It is interesting to note that the percentages reflected in column 9 are almost exactly equal to those established as the SEER goal stated above.

In calculating survival rates via the actuarial method, not much has been written in regard to what percentage of patients lost to follow-up can be tolerated before the basic underlying assumptions of life table methodology are invalidated. In the first End Results Report, Dorn advised to have none. While a discussion of the underlying mathematics is beyond the scope of this presentation, suffice it to say that the percentages of patients successfully followed by the SEER Program are as high as any ever achieved in previous NCI-sponsored programs. Perhaps a future session of this organization could be devoted to a discussion of what percentage of lost patients is acceptable with the definition of "lost" being clearly defined.

One final issue which should be addressed is that of a totally passive follow-up system as defined above. In the passive follow-up methodology, all patients not found to be dead in a match against vital records are assumed to be alive at the end of the follow-up period (study cut-off date) and the concept of lost to follow-up is no longer a consideration. Acceptance of a passive follow-up system would of necessity be based on the presence of a proven computer (or manual) matching program. The opportunity to test passive versus active follow-up in the SEER Program can only take place when the National Death Index (NDI) becomes available for an extended period of time. A preliminary test of the NDI involving two SEER registries has indicated a high number of false negative matches (8%) because of the very stringent matching criteria used by the NDI. Thus, at the present moment, the NDI is not a feasible alternative to current procedures.

In an attempt to measure the difference between active and passive follow-up in the SEER Program, a small scale study utilizing only 1976 diagnoses was undertaken by the SEER staff. Each central SEER registry was asked to submit data for the diagnosis year 1976 with only follow-up information obtained by matching 1976 data against the state vital statistics tape for the years 1976-80. Follow-up results were then compared to previously submitted data containing active follow-up from any and all available sources for the same time period. For a variety of technical reasons, four of the ten registries had to be excluded from the analysis. Comparative results for the other six registries are shown in Table 2. The 4-year relative survival rates are shown for sites with poor (lung), intermediate (colon), and good (breast) survival. The six registries have been divided into two groups, those which, at that time, had poor active follow-up ((60%) and those which had good active follow-up (80+%).

As can be seen, the difference between the 4-year relative rates are larger for the registries with poor follow-up. It is interesting to note that the largest differences were those for colon cancer. It is clear that passive survival overestimates patient survival. However, on the other hand, active follow-up probably underestimates survival since (particularly in areas with very little out migration) persons lost to follow-up are more likely to be alive than dead. This assumption could only be made based on the proven efficiency of the computerized death matching program used to link the registry data with vital statistics records.

Table 2: Four-year relative cancer survival rates as measured by active and passive follow-up for white patients diagnosed during 1976 by registry and primary site, USA SEER Program

Registry	Percent patients followed in 1980	Lung		Colon		Female Breast	
		Active follow-up	Passive follow-up	Active follow-up	Passive follow-up	Active follow-up	Passive follow-up
A	55	10	17	34	48	67	77
B	59	8	11	29	44	58	69
C	81	10	13	34	43	67	70
D	89	20	31	63	67	75	80
E	80	9	13	41	49	71	75
F	80	11	17	41	46	71	73

If the assumption is made that all persons not found through active follow-up are alive, the resulting 4-year survival rates are intermediate to those shown in Table 2. Rates calculated under this assumption have been referred to as "optimum" survival rates. For registries with poor follow-up these "optimum" rates are very close to passive follow-up rates.

One difficulty in the United States in using only passive follow-up is the mobility of the people. It is clear from Table 2 that at least registry "D" has substantial out migration. Thus, passive follow-up based only on death clearance for a single state can lead to a sizeable overestimation of cancer patient survival (witness the 31% 4-year passive survival rate for lung cancer in Table 2). The presence of a national death index would make passive follow-up a much more feasible alternative. Such an index was begun in the United States for deaths occurring 1979 forward. A preliminary test of the index by two SEER registries indicated that at least 8% of the deaths known to the cancer registry were missed by the national index whereas the index was able to identify only a potential of 3% of deaths unknown to the SEER registry. The high number of false negative matches was due to the very strict matching criteria of the index, particularly with respect to date of birth for which an exact match on month, day, and year is required. Another problem making all matching difficult is the lack of a common identity number, the social security number being the closest surrogate. Thus, for the immediate future, the national index remains an unproven alternative to active follow-up.

The SEER program has made the decision to continue active follow-up into the near future. This decision has been made on the basis of considerations in addition to those discussed above. The exchange of information between the central registry and the local hospital registry is of benefit to the local hospital in maintaining accreditation by the American College of Surgeons and is often the price to be paid for the cooperation of the hospital in allowing central registry staff to gain access to the medical records for that hospital. It is felt that many hospitals would withdraw their cooperation with the central registry if "there were nothing in it for them". Further, active follow-up is a valuable source for completing information on first course of treatment. Also, one SEER registry which has permission to contact patients directly has used follow-up as a means of obtaining additional personal data (work history, water supply, etc.) for use in epidemiologic studies. Finally, the decision to continue active follow-up has been made on a consideration of cost. A recent analysis of the costs of the SEER Program by function revealed that only 8% of the SEER budget is expended for follow- up. If account is made of time contributed by individual hospital registrars, the percentage is increased to 14%.

One change which is being made within the Program concerns follow-up of patients with in situ carcinoma of the cervix uteri. In the past, follow-up was required for only five years for patients with this diagnosis who were treated by hysterectomy. However, in situ patients are young, mobile, and frequently change their name, making follow-up difficult. Further, many physicians resent having their in situ patients included in a cancer registry and particularly resent attempts at annual follow-up. Therefore, the requirement for annual follow-up of any in situ carcinoma of the cervix uteri only is being discontinued. Other in situ lesions will continue to be actively followed.

To summarize, the central registries participating in the SEER program attempt to actively follow all patients on an annual basis where active follow-up is understood to include a number of non-medical sources. In the most recent time period, 85% of patients were successfully followed. Tests of passive follow-up and the National Death Index, as well as considerations of hospital cooperation, additional treatment information, and costs, have resulted in a decision by the program to continue active follow-up of all patients with the exception of those with in situ carcinoma of the cervix uteri.

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