Collection of Data

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Inevitably, this paper must deal with its subject in a somewhat general way. Data collection methods cannot be presented as an exhaustive list since they often relate specifically to the design of an experiment or survey.

Research design has been addressed in the preceding paper, and most elementary statistical books include a chapter on experimental design.[1-3] Additionally, specific advice and assistance in this area can be obtained by consulting local statistical resource persons at the very beginning of a study. All or some of these resources should be used in addition to the content of this paper in addressing a data collection problem.

Philosophy of Data Collection in Family Medicine

At the outset one must ask some basic questions.

In a family practice environment:

1. What is the purpose of data collection?
2. If any data are collected, how are they used?
3. What difference would it make to the practice of family medicine and to the discipline if no data were collected?

Such questions are asked frequently by practicing family physicians and they deserve an answer. This answer may be provided by examining the daily practice of family medicine in the office or at the hospital bed. The one-to-one physician-patient relationship provides an environment in which data are collected from the patient about the problem, by subjective and objective examination.

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These data are processed by the physician through his/her preexisting data base developed in the context of his/her medical training and from previous knowledge of this patient. This results in an assessment of a differential diagnosis which, after appropriate tests and/or further investigations, results in a final diagnosis or another set of differential diagnoses. This process of clinical decision making is illustrated in Figure 1. And, in classical, scientific terms this process (A) is further represented by Figure 2. These two models represent the medical modification of the classical, scientific method to meet the needs of a patient care situation.

The process (B) expressed in Figure 1 is accepted by most physicians without question, because it is related to a patient. All accepted medical practice is a result of patterns of patient presentation and the response of these patterns to interventions based on the experience of many physicians with many patients with similar problems. The data concerning these patterns have been collected, recorded, and reconfirmed over many years until the patterns are accepted without question by every member of the caring professions and have become part of the armamentarium of cognitive knowledge for all physicians.

This data base has been over 200 years in development and most of that development has occurred during the last 60 years—the majority of it in the hospital environment.

Physicians, having concentrated on the individual patient in the hospital, have ignored to a relative degree, data on patients (or persons) in their normal environments in the community. Family medicine, having accepted the added responsibilities of "the continuing, comprehensive care of patients and families over time,"[4] can no longer continue such neglect.

These responsibilities require data to produce information which can be used to develop intelligence, allowing the formulation of decisions concerned with preventive and promotive medicine

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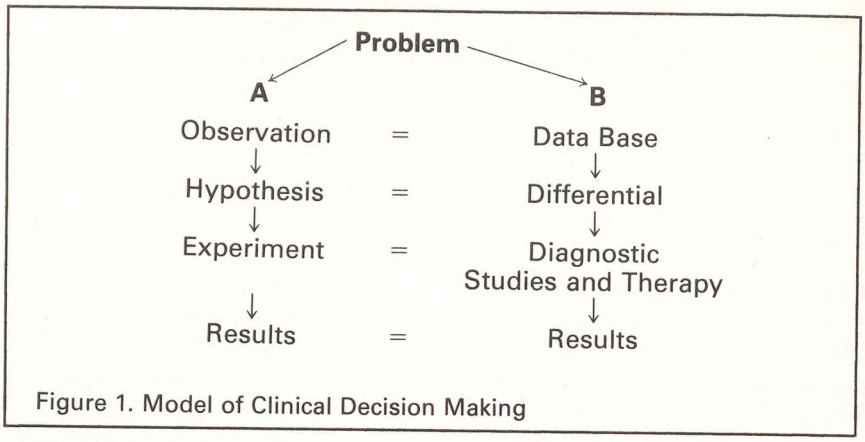

Figure 1. Model of Clinical Decision Making

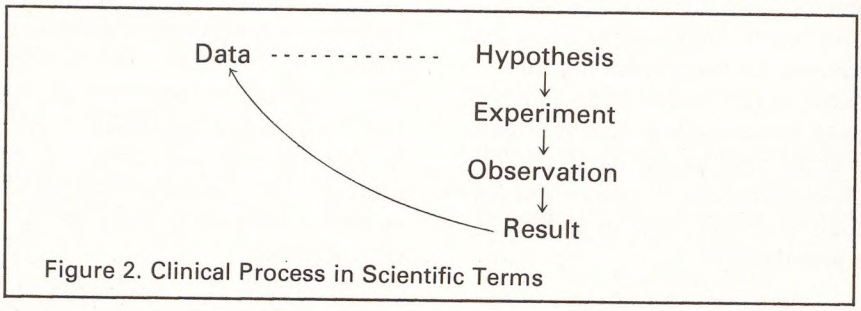

Figure 2. Clinical Process in Scientific Terms

for patients, families, and communities.

Such preventive and promotive medicine cannot be effectively developed on a personal or family basis until these data are available on each patient and each family in a practice. Inevitably, these data on many families lead to information and, therefore, intelligence about the community. A family practice patient population represents a microcosm of the community in which the physician, or physicians, live and work. The more the physician knows (data base) about his families and his community, the better his preventive and promotive medicine will be. A similar paradigm, which all physicians will recognize, is that the more the physician knows (data base) about the disease (problem), the better the standard of medical care will be.

Such logic reconfirms the absolute necessity of data collection in the family practice environment as an essential tool for the provision of the most appropriate patient and family care. As a byproduct, and coincidentally, it also provides a superb basis for research in family medicine as the family physician's office becomes a controlled environment in each community.

These data on patients, families, and communities will only become available if they are collected and recorded in family practice environments and so frequently reconfirmed that they become accepted without question as part of the data base of the family physician.

The above discussion answers our first two questions—(1) What is the purpose of data collection? and (2) If data are collected, how are they used? It leaves unanswered the third question—What difference would it make to the practice of family medicine and to the discipline if no data were collected? This question addresses a fundamental problem in family medicine—that of academic validity.[5,6] Without data there is no doubt that the practice of family medicine would continue as it has since World War II, but there would be no basis from which to teach its special philosophy, knowledge, skills, and attitudes to future generations of pre- and postdoctoral students except by the simple apprenticeship method. This approach would not allow the continuation of family medicine as an academic discipline for which there must be a literature based on facts, on data, derived from a family practice environment.

Without such an academic basis, the continued existence of family practice in medical schools as a discipline with a unique approach to caring would be in jeopardy. Students and residents might cease

to be attracted to its training programs and, without new generations of family physicians secure in the knowledge of their academic and practical validity, the discipline might follow the path of general practice into obscurity.

Data collection is only one part of a research process, but it is crucial. The most superbly designed study will fail if the data collection process does not have its own outcome, namely, valid and reliable data, ie, data which are what they purport to be (valid), and which are capable of being reproduced by the same data collection process in other settings (reliable).

A Minimum Data Set[7]

It is axiomatic that the larger the number of data elements, the larger the cost will be. It is, therefore, an essential requirement of every data collection system that the data set of items collected routinely and regularly, or on a sample basis, be the minimum necessary to allow the provision of patient care, and at the same time enable the definition of that controlled environment in the community.

This can be described as the concept of the *Minimum Data Set for Patient Care,* which postulates that in order to provide any patient care there must be available to the provider at least a minimal amount of demographic and clinical information about the patient; without this information, appropriate care is not possible. Furthermore, the minimum set of demographic and clinical information should be recorded in a clinical record to enable its use by several providers. Thus, the determination of a minimum data set and the agreement to record it, allows the development of a baseline for the measurement of both the process and outcomes of the care provided in that facility or organization.

It is not suggested that such a minimum data set represents all of the data necessary for appropriate patient care, or all that is required to meet the data needs of any particular study. Such data sets must be defined specifically by the responsible clinicians or researchers and will always contain within them the minimum data set of items previously defined.

The minimum data set can be determined by two methods: (1) by consensus between a group of peers; (2) by retrospective or prospective review of clinical records and abstraction of the relevant information; or by a combination of both of these.

The essential element is the acceptance of the minimum data set by all users and providers of care, and the agreement to record *at least* those items of information on all clinical records. Other items of information may be recorded and used in addition to the minimum data set, but the minimum data set items will invariably be present in the clinical record.

The use of a similar minimum data set at several sites will allow some comparison of the process and outcomes of care provided for particular problems at these sites.

The alternative to such an approach is the collection of all items of demographic and morbid information which might possibly be useful at the present, and in the future. This alternative is both prohibitively expensive and unnecessary. It results in the collection and storing of data in such quantities that they can never be used effectively. No data element should be collected unless it is required to meet a specific goal at that time.

The Minimum Data Set approach has many advantages, as the data set can be constructed to answer precisely the research question being asked and to avoid a "fishing expedition."

An excellent example of such an approach on a national scale is the National Ambulatory Medical Care Survey (NAMCS), which has been carried out regularly since 1973. This survey uses as a denominator all physicians in the United States providing ambulatory care, and selects a small but precise sample as a means of assessing the United States patient population. A simple encounter form is used to record the minimum data set at the time of contact with the patient.[8-10]

For the majority of the programs or practices wishing to record data, smaller denominators will be necessary, and, if the natural history of disease in the community is to be investigated, these denominators should be patient populations.

Today in the United States, it is possible to determine denominators of patients-at-risk and under care with variable degrees of accuracy by simply defining those denominators. Other approaches are under development.[11-13] Examples are: (1) current patients, (2) active patients, and (3) active families. Definitions of these terms have been published, and, if used, will allow comparison of data from different sites.[4]

General Principles of Data Collection in Family Medicine

There are several basic principles which can be applied to data collection in any primary care circumstance. Each circumstance will be uniquely different from all others, although there will be many similarities. These unique differences are mainly those of people, habits, routines, and facilities. Therefore, it is possible to divide the principles into three areas: (1) motivation of people; (2) definition of items; and (3) structure of the data collection process.

Motivation of People

Data are only as accurate as the recorders who do the collecting. All data on medical problems are the result of transactions between individuals. In such transactions one individual has to be committed and motivated to record certain elements to allow comparisons with similar transactions at a later point in time.

This commitment to accuracy requires a degree of persistence and motivation in the recorders which borders on the obsessional. It is not achieved without continuous communication throughout the period of a study. It invests all areas of data collection.

This first principle can then be stated as follows:

It is necessary to establish a commitment to accuracy in the recorders (collectors) by:

1. using the continuous process of communication about the goals and objectives of the study.
2. involving the recorders as equal partners in the study. This allows the development of enthusiasm and the sharing of the rewards produced by the achievements of the goals of the study.
3. stressing the advantages gained by the improvement in the standard of patient care.
4. stressing, in situations where the billing process is used as part of a data collection methodology, the economic advantages of accurate data for the purpose of producing more accurate billing.

Definition of Items

This principle is simply stated as follows:

Each data item must be defined specifically and justification given for its inclusion in the study. The definitions and justifications should be derived after discussion with all recorders over a sufficient period of time to allow each individual to understand clearly and agree upon what was involved in the decisions. This is time consuming, but it is vital to success and is an integral part of the communication and motivation process. It is of equal importance to use, as far as possible in any study, terms and definitions which are in common use in the literature of the discipline and which have been defined in print by previous workers. Such a glossary of common terms and definitions for primary care now exists and is available for use.[14] This glossary allows greater comparability between studies and improves the chances of replication of the results of a study in other populations. If it should be necessary to depart from the definitions quoted in such a glossary, it is still beneficial to state the standard definition and identify how it differs from the study definition.

Structure of the Data Collection Process

The essential principle here can be stated as follows:

Always develop protocols for the data collection process. These should address four components:

1. The process of collection of the data. The data item should be collected (recorded) at the moment and site of its development. The data item should be collected (recorded) by the, or one of the, responsible providers. Ideally, the data item should be collected once only. If several sites are being used for data collection, the data collection instruments should be incorporated into each practice organization on an individual basis. Although the organization at each site will be basically the same, there will be nuances of difference as a result of personalities and routines.
2. The flow of data after collection. This process requires a protocol to ensure that data elements which have been recorded on data gathering instruments such as encounter forms or worksheets are not lost because of casual or disorganized methods of collecting the forms during or at the end of the working day. The protocol should include the first of the validity checks, ie, to make certain that the number of encounter forms or entries on a worksheet matches the number of patient encounters during that recording period.

3. The handling of the data through validity and reliability checks at both manual and machine levels. In the same way, each step in a data handling sequence from collection to computer entry must be stated on a protocol and structured to allow validity and reliability checks to take place.

4. The storing structure should be that most appropriate for later retrieval, analysis, and interpretation of the data. Finally, the actual entry and sorting of the data in the machine requires special validation programs which automatically reject aberrant data produced by human or machine errors during input. Minutes taken to think through and write up such protocols in the beginning of a study will save hours of time and considerable frustration later.

Methods of Data Collection and Handling

Machine Collection

In machine collection there are two possible methods:

1. The patient (person) interacts with a visual display unit linked by direct line to a computer. The patient is asked to respond to questions and these responses trigger a preprogrammed series of algorithms, producing further questions. When these algorithms are completed, a printed statement is delivered to the physician who uses it as a history, an addition to his data base, during his encounter with the patient. This printed set of responses, after confirmation by the physician, represents the process of data collection and recording.

2. The physician (provider) interacts with the patient, asking the questions and putting the patient's responses directly into the machine for tape, disc, or card storage or perhaps a direct real-time link to a previously developed clinical record for this patient.

In the first method, the validity and reliability problems are concerned with the patient's understanding of the questions and the accuracy of the responses provided by the patient. In the second method, the problems are mainly those of the accuracy of the data input by the physician.

Checks at the machine level are possible; for example, the rejection of inappropriate combinations of morbidity with age and sex. Furthermore, if a real-time interactive capability with a preexisting clinical record for the patient is available, then it is possible to confirm the identity of the patient and perhaps the content of the record prior to the data input.

Such methods are popular with large medical organizations and may have the advantage of reducing the personnel time needed to interface with the patient. Acceptance by the patient of direct interaction with a visual display unit has been variable and there is no indisputable evidence of advantage or disadvantage.[15]

The costs of such programs are considerable because of the high cost of the equipment, which necessitates high usage. Large medical organizations involving many providers are able to justify such expense at the present time, but as the cost of this and other computer equipment steadily diminishes, this capability will become available to more and more providers.

Manual Collection

The principles previously expressed are particularly important in direct manual recording of data. There are several physical methods of recording (collecting) these data and they can be listed as follows:

Direct Methods

1. Written by hand in a clinical record or on a special encounter form.
2. Typed directly into a clinical record or an encounter form.
3. Recorded by edge punching a specially prepared card, ie, a Hollerith Card.[16]

Indirect Methods

1. Voice recorded onto a magnetic tape for later transcription into a clinical record or encounter form.
2. Keypunched onto a card for later computer input.
3. Typed on paper tape for later transcription or transference to No. 2 (Indirect Method).
4. Mark sensing an encounter form for optical viewing and later input into a data bank.[17]

The direct methods of recording are usually cheaper because they can be incorporated into the usual process of patient care by the nursing and physician providers and with experience take little time and interfere minimally with that process.

Also, the "instruments" used are inexpensive.

The indirect methods produce more interference with the process of patient care and, therefore, may involve a penalty in the motivation and accuracy of recording.

In family medicine, all methods of data collection will result in large numbers of data elements. In small or solo physician practices, using a minimum data set, it is possible to collect, record, and analyze these data manually and produce effective results. Without question, John Fry has shown what can be achieved by such methods.[16,18] With practices larger than three or four recorders, it is almost a requirement to have access to a computer for the filing, storage, retrieval, and analysis of data, but the initial data collection can be manual.

Development of Data Collection System

Below is presented a series of steps which can be applied to the development of a *data collection system* required to solve a data collection problem. The suggested steps are as follows:

1. *Develop goals and objectives for the data collection process, defining the data product expected.*

2. *Describe the data to be collected.*

   a. Where does it fit into the patient care system?

   b. Where best can it be collected?

Both questions may be answered by the design or redesign of the clinical record, by the addition of a flow sheet, or by a change in the progress notes. Any design change in a clinical record requires a dynamic process, that is, one of design, field trial for a period in patient care, feedback of the results of use, and then redesign. Flow sheet design and recording formats should respond to the demands of patient care.

3. *Describe the data collection process in the patient care system.*

This is best done by drawing a system flow chart and showing the steps, required procedures, and branches in the logic system. This will enable the recorders to think themselves through the data flow, improving their understanding of the problems and areas of difficulty. An example of such a flow chart is presented in Figure 3.

4. *Describe the classification and coding of the data.*

   a. What classification will be used?

   b. Who will classify and code the data?
      Self-coding (by the recording provider)
      Professional coding (by the medical record staff)

This step involves not only the application of the principles of data collection previously stated, but also (1) the definition of rubrics, names, labels, and diagnoses using, wherever possible, standard terms and definitions; and (2) the production of a manual of instructions which includes reference to such a standard glossary of terms and definitions, and protocols for classifying and coding unusual problems, perhaps with examples given. Common problems, ie, those representing the top 50 percent of the Content of Family Practice,[19,20] will be seen so frequently in practice that their classification and coding by recorders or professional coders will cause only temporary difficulty in the beginning of a study.

5. *Describe the entry of the raw data into the computer.*

What form of entry will be used? Card, tape, optical viewing, or direct on-line entry by CRT (cathode ray tube terminal). Indicate the validation methods. Describe how entry and recording errors are identified and corrected.

6. *Describe the data storage system in the computer.*

Indicate the form of data storage and the type of access by file, disc, or other system.

7. *Describe the sequence and order of the data items in the files or discs.*

This information will help recorders understand the scope of the system and allow them to identify the types of data presentation available to them as feedback.

8. *Describe the retrieval capability of the system.*

What routine presentations of data will be available?

How will the data be laid out? Show examples.

What special reports or displays will be available?

If limits must be set for special displays because of the resources available, these limits must be explicitly defined.

If a regular standard computer printout is offered to help motivate recorders, it is essential to keep the reports pertinent to the recorders' needs. Such a process must be dynamic and the following

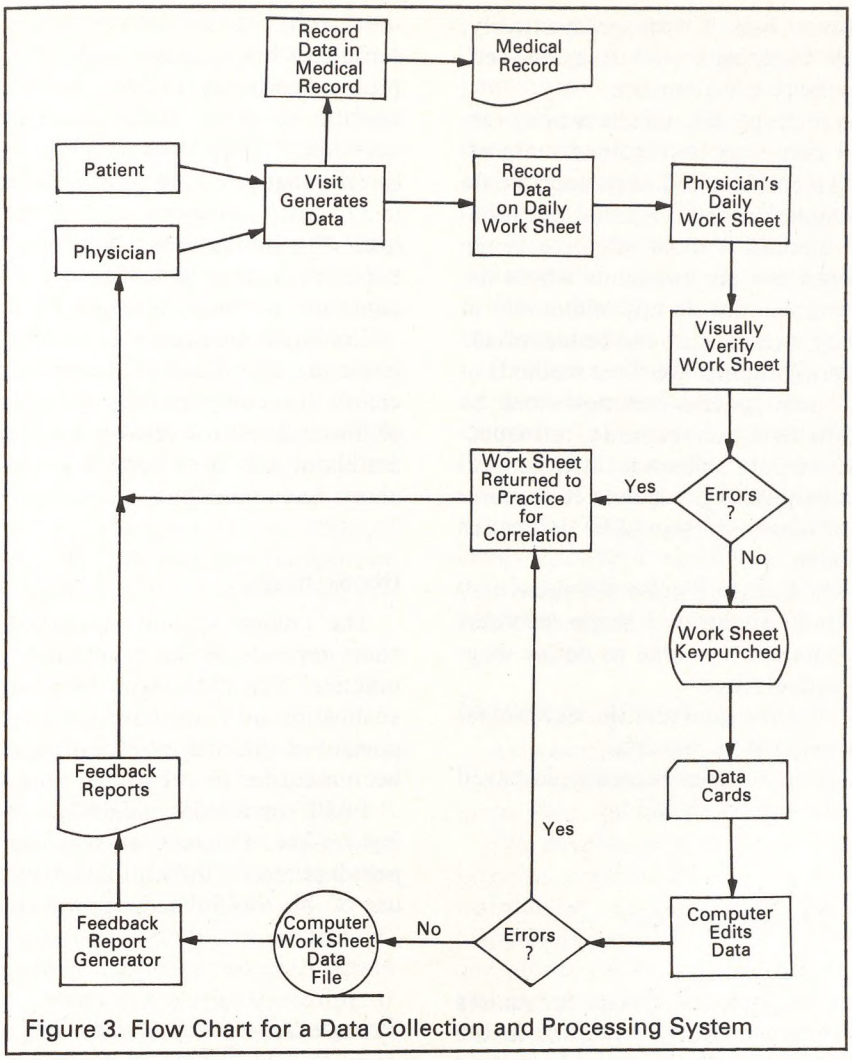

Figure 3. Flow Chart for a Data Collection and Processing System

suggestions may be helpful in achieving this:

- Design or redesign the display with the help of the recorders.
- Highlight the most significant items of data in the presentation format.
- Suppress redundant information; for example, columns of zeroes, extremely small percentages, and figures beyond the first or second decimal point.
- Prepare an explicit introduction describing what is presented in the report.
- Program regular meetings of the recorders with the design group to review each display after production, and recommend improvements in presentation or changes in format.
- If special reports are offered, make certain they can be provided, and above all, on time.

Specific Methods of Data Collection in a Patient Care Environment

Three such methods are described as (1) Retrospective Data Collection from the Medical Record; (2) Prospective Data Collection by Study Protocol and Predetermined Criteria; and (3) Survey by a Special Questionnaire.

The first two methods are only used in medically controlled environments, whereas the third method is also effective in assessing samples of the denominators (patients, problems, procedures, etc) in use in the practice environment.

Subjective assessments by patients of services and resources provided to them, which are impossible to abstract directly from a clinical record retrospectively, and which may be subject to con-

siderable interviewer bias if done prospectively, may be accessible by using a well-designed, self-completed anonymous questionnaire.

Objective data on large denominators in a practice environment may well be obtained more effectively by using a combination of an appropriate sample of the population and a special questionnaire. The third method is most effective in the field, ie, in uncontrolled environments where denominators of persons who do not relate only to one setting for their medical care can be identified.

Before considering each of the three methods of data collection, some general comments can be made regarding the first two methods, retrospective and prospective data collection, with respect to their use for individual or group data collection.

1. Problems or diagnoses should be defined as precisely as possible.
2. Problems which resist precise definition may be incapable of study except by a single recorder. Groups of recorders are less able to define diagnostic entities satisfactorily.
3. The data collection goal and the question(s) asked must be as simple as possible.
4. The larger the number of recorders involved the simpler the question(s) should be.

Retrospective Data Collection

Advantages

This technique is quick and cheap. It requires only an index to the morbidity identified in the patient population in the practice to allow chart identification by problem or dis-ease. Review and audit of the chart with abstraction and recording of the data expressed in the clinical notes provides baseline measures of the process of care for a particular problem and, perhaps, some data on outcomes.

Retrospective data collection is a most appropriate method for individual physician or individual practice studies and particularly for auditing the process of care. In these settings, either the diagnosis or management of a problem as expressed in the clinical record can be compared with previously established criteria or protocols. It is a useful method for refining a question to be asked. During his practice, a physician may develop an awareness of the association of various factors in patients with a particular problem. The data collected from a retrospective review of a sample of the clinical charts of patients with that problem may confirm the association in terms of specific numbers. These data will raise a "why" question. "Why does this association occur so (in)frequently in the presentation of this problem?" Such questions, after further refining, may lead to a hypothesis which can be subjected to experiment at a later date by means of a well-constructed prospective study.

Common, frequently presenting problems may cause the identification of large numbers of clinical charts. It is comparatively easy to identify samples of these charts for retrospective review. Detailed methodologies for identifying and accessing such charts have been published.[21]

Disadvantages

The amount of data recorded in the clinical chart depends on the standard of recording in the practice. The data elements required for the investigation may not have been recognized as important at the time of recording or may not have been recorded as present or absent.

Badly written data might be misinterpreted during review. Because of this, the application of preset criteria is difficult and usually precludes the use of this tool for large group studies.

Prospective Data Collection

The Minimum Data Set approach can be used to identify samples of the denominator of patients to be followed prospectively for variable periods of time. Recording formats can be developed which will allow access to this sample of patients to provide more detailed demographic, morbid, social, or psychological data elements than are available in a minimum data set. These additional data elements will be those required to answer specific research questions.

Advantages

Precise definitions of diseases and problems can be made prior to the study. The criteria can be made as detailed as the recorders wish, or have time and interest to apply to the task.

Large numbers of recorders and, therefore, cases (numerator) in a total population (denominator) can be followed. These data may be used to show regional, geographic, or factual similarities or differences which will answer research questions and, in so doing, may raise other research questions.

Prospective studies make it possible to develop matched cohorts of individual patients who can be followed during intervention studies; furthermore, the appropriate selection of cohorts may help the researchers control some of the many variables present in community practice populations.

Prospective data collection is a method which allows the controlled examination of the natural history of the presentation of diseases and problems in the community situation. Such patterns of early presentation of disease are particularly prone to inaccurate description if they are observed retrospectively.

Disadvantages

Problems or diseases which present very commonly are difficult to follow because of the time necessary to record the data identifying them. It may only be possible to follow one facet of such a problem and, thus, both the problem and the question asked require precise definition.

Rare and very uncommon problems are also difficult to follow as they may never be seen within the time frame of a study in a particular setting. If the problem, disease, or that facet which is followed must be defined very precisely, it follows that all recorders must be involved in creating, or must at least concur with, the definition used. It is necessary to work, as always in research, at the simplest possible level of question, protocol, or criterion, and each definition should undergo pilot study and field testing at the recording sites.

An example of such a definition might be as follows: "For the purpose of this study, a case of acute tonsillitis will be defined by the following symptom/sign complex:

A person of either sex, above the age of five years, who has complained of sore throat, difficulty of swallowing with malaise for at least 48 hours, and has sustained a temperature of at least 100 F for a minimum of 12 hours. Examination shows large infected tonsils with palpably enlarged neck glands."

Such prospective studies are difficult and time consuming to establish, and if large numbers of patients are required and large numbers of sites are to be used in a collaborative study, local conveners may be necessary to effect the appropriate communications. It is extremely difficult to collect data on poorly defined entities, and it is often impossible to repeat individual recording effort in collaborative studies. However, the best data collection method for collaborative studies is the prospective method.

Examples of the application of such methods are numerous in the literature and one of the best examples in the family practice discipline is the Oral Contraceptive Study organized by the Royal College of General Practitioners in the United Kingdom. This is now in its ninth year and has recently produced significant new information on the risks of the contraceptive pill for women beyond the age of 35 years.[22]

Survey by Special Questionnaire

As previously stated, this methodology can be used both in a controlled practice environment and in the field.

The development of these survey instruments involves considerable skill and experience. The instruments are required to be simple, reliable (capable of being repeated in other environments and producing the same results), and valid (capable of measuring what they were intended to measure). This technique is the tool of the social scientist, who depends very heavily on questionnaires, both the self-completed and the interviewing type, for his data. There are many excellent books and monographs available, and these should be referred to for a more complete description of the technique.[23-25]

Some general comments can be made on the development and use of questionnaires.

1. Questionnaires are appropriate for undertaking multiple observations. The questions asked should be standardized, with the wording developed with care and subjected to repeated review and, above all, tested by pilot survey. The questions should be short and should follow one another logically through the questionnaire. Their presentation should be varied to avoid monotony, and a layout must make it obvious that, at the end, all of the questions have been completed.

2. The questionnaire should not be overlong as compliance diminishes rapidly with length.

3. Instructions for completion of the questionnaire should be precise and unequivocal. If the survey is to be self-completed and anonymous, this fact must be stated and some numbering system used which will not identify the recorder.

4. If an interviewer is involved in collecting the data, an adequate briefing of both the interviewer and the interviewee is necessary. A standard introductory briefing letter provides a basis for further explanation by the interviewer. Explanations of common questions asked by interviewees should be explicit, and, as far as possible, be presented in a standard format. As is so in other data collection methods, considerable time must be spent in motivating, briefing, and debriefing the interviewers. Interviewer bias is a considerable problem and must be guarded against constantly by using various feedback and debriefing techniques.

Comment

This review of data collection methods cannot be comprehensive as it is impossible to address every situation and circumstance. However, it is hoped that the principles and examples presented will help when a solution to a difficult data collection problem is sought.

Some final thoughts—all survey methods are an essential part of the process of analysis. They depend heavily on numbers, and care and attention to detail in developing the data collection techniques are vitally necessary if these data are to be valid and reliable. No matter how inspired the subsequent stages of analysis and interpretation, they will be of no avail unless that data collection process has been well conceived, well designed, and well constructed.

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