

Research Article

Databases: Accuracy and readiness for use

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Abstract

Decisions for improving health care rely on data often contained in databases. A database is a compilation of information, often a group of variables, that is stored electronically in a computerized system. It can be specific to one organization, a group of several facilities, or a nationwide effort. Databases comprise elements specific to the endeavour. Types of databases include clinical, administrative, research, or combinations of these. The purpose of electronic storage of specific data and the uses for the results of database analyses need consideration regarding accuracy, validity, and reliability. All databases are accurate to the extent that each element and each point of data collection and entry are valid and reliable. The purposes of this paper are to explore methods for determining accuracy of the data in a database, reliability and validity of database elements, and to determine when a database is ready for use.

Key words

database management systems, management information systems.

INTRODUCTION

Decisions and policies for improving health care rely on data often contained in a database. Consumer demand in a competitive, cost-focused, health-care market impacts on the urgency for establishing best practices and optimal patient outcomes. The use of databases filled with large amounts of patient information is growing increasingly popular for deriving data to respond to consumers' demands and to influence decision-making. Data mining from databases includes the search for associations between variables, such as associating the number of nursing staff with patient outcomes or a certain procedure with hospital length of stay. In eagerness to make decisions, interpretation of the associations can inadvertently and prematurely become causal linkages. Hence, considerable scrutiny of the database methodology should play a role in utilizing any clinical, administrative, research, or combination of these types of databases for changing policy and clinical practice. The purposes of this paper are to

explore methods for determining accuracy of the data in a database, reliability and validity of database elements, and to determine when a database is ready for use.

DATABASES AND THEIR ELEMENTS: CLINICAL, ADMINISTRATIVE AND RESEARCH

What is a database?

A database is a compilation of information, often a group of variables with their definitions and values, that is stored electronically in a computerized system (Wolfe, 1995). It may be specific to one organization, a group of the same organizations or, perhaps, part of a national endeavour. Databases are as varied as their creators. Some databases provide aggregated, or group variables, such as: *The United Nations Demographics Yearbook* (United Nations, 1986); *Vital Statistics of the United States* (National Center for Health Statistics, 1980); and the disease incidence by geographic areas from the Centers for Disease Control (1986). Other databases comprise individual data such as: the National Death Index (National Center for Health Statistics, 1981); hospital discharge data for specific hospitals in some states (California

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Health Facilities Commission Discharge Data Program, 1985); military data; and third-party payers such as Medicare, Medicaid, and private insurance companies (Hearst & Hulley, 1988). The elements comprising a database vary with the topic. In short, a database can be created from any data collection effort and comprises elements that are the variables of interest. For this paper, the categorization of databases will be limited to clinical, administrative, research, or a combination of these.

Clinical databases contain elements that are derived from usual clinical practice such as: specific lab values; complete medication information (drug, dose, frequency); presence and type of advance directive; and perhaps risk, identified at admission such as fall or violence. Administrative databases include data collected from clinical sources but may also include more general information such as: type of insurance; discharge diagnoses; procedures done during hospitalization; length of stay; and type of medication. Clinical data can feed an administrative database if information is simplified. Research databases are protocol driven and include demographic information and all other data about variables. Instruments selected for data collection in research are expected to be valid and reliable with high levels of sensitivity and specificity already established. Further, the timing of instrument administration is systematically implemented, with interrater reliability and responsiveness to times of testing established. Research databases are used to test hypotheses.

All of the different types of databases may extend from local to international data sets. Examples of administrative databases include Health Care Financing Administration (HCFA) and the American Hospital Association (AHA). Extremely large databases that span the United States for hospital characteristics, patient mortality, and nursing staffing mix might be contained in the HCFA and AHA databases.

A combined clinical/administrative database that is required by HCFA is the Resident Assessment Instrument (RAI), also known as the Minimum Data Set (MDS) (Morris *et al.*, 1990; Hawes *et al.*, 1995; Phillips *et al.*, 1997). This database is particular to long-term care assessments at admission for stays planned beyond 14 days. Some of the RAI/MDS contains elements such as patient demographics, measures of physical and cognitive functions, psychosocial assessment, pain, sensory acuity, and behaviour. Much work has been done to improve this database, including establishing validity, training data gatherers, and ensuring accurate data entry.

Another combined clinical/administrative database is the Outcomes Assessment and Information Set (OASIS), a survey designed for nurses to use in home-care practice with data elements expected to lead to cost containment and quality enhancement (Schroeder, 2000). Developed over 10 years, and released in summer 1999, the database elements include: demographic data; current illness status; health history; prognosis; allergies; immunizations; risk factors; environmental issues; caregiver information; physical assessment; nutritional, social, emotional, behavioural, and hygienic factors; activities of daily living; self-care assessment; patient equipment needs; safety concerns; and patient's emergency plan. The OASIS survey became a required activity when HCFA added its use to conditions of participation in Medicare-certified home health-care agencies. This particular database has administration elements such as admission to home care, transfer or discharge during hospitalization, status change, and services requested. Further, OASIS has required that only professional health-care providers administer the 79-item questionnaire.

A clinical database may be particular to a hospital or hospital system that extends regionally or nationally. Depending on its variables, a database from hospital-wide data allows viewing patterns of care, provider-specific processes, and patient and organizational outcomes. A specific database in a hospital might contain all adverse drug events with elements including patient demographics, drug, dose, frequency, reaction, and patient outcome. Alternatively, a clinical database can be extracted from existing elements in an electronic system. For example, each Veterans Affairs Medical Center has an electronic system of documenting all clinical activities and the capability of creating a database from variables in the progress notes. Some of these data go to the Veterans Health Administration national database.

Finally, an example of a research database is the Breast Cancer Detection Demonstration Project (BCDDP), a nationwide breast cancer screening program conducted between 1973 and 1980 (Schairer *et al.*, 2000). Another example is the Health and Nutrition Examination Survey (HANES), a cross-sectional study of a selected representative USA sample for interviewing and examining health and habits (National Center for Health Statistics, 1973). Research databases are specific to the topic under investigation and the procedures for data collection are carefully controlled. They can range from a small database that is unique to one study to a very large database where data are collected from multiple sites and over a long period of time.

Combining administrative, clinical and research databases

Efforts are being made to combine the administrative, clinical, and research databases. If done using research methodology, clinical data could be of high enough quality to qualify for research purposes. Likewise, highly refined clinical data could improve the quality of administrative databases. Phillips and Morris (1997) compared RAI/MDS data elements (cognitive assessment and activities of daily living assessment in cognitively impaired residents of nursing homes) from administrative, clinical, and research databases in a multi-state research endeavour. They found that the assessments from the clinical and administrative databases were as valid and reliable as those obtained from the research database. Testing elements of clinical and administrative databases for validity and reliability will strengthen their uses for research and credibility for policy or decision-making.

PURPOSES OF DATABASES

A common purpose of databases is the compilation of large amounts of data on a large group of persons with similarities. Purposes are particular to the topics. That is, insurance companies may want very specific data about their insured populations, the services needed, and specifics about the claims such as persons, providers, organizations and expenditures. Similarly, the RAI/MDS involves data collection about the population entering nursing homes. The benefit of having large numbers of cases is that patterns, trends, and interrelationships between population variables can be explored.

Databases can be created with the specific purpose of trending or exploring interrelationships between parts of an organization (or elements within the database). They may be created from actual clinical observations, such as incident reports from falls or adverse medication reactions. Alternatively, databases can be created from patient records and other organizational elements that are part of routine data collection and storage, such as pharmacy and laboratory records.

A critical point in thinking about the purpose of a database is the desired use of the results. Several questions then arise, as follows. Will data be used to test hypotheses? Will data be used as evidence that one treatment is better than another? Will the data be used to make treatment or policy decisions? Will data be used to determine resource allocation such as staffing for particular units? To whom will data be

Table 1. A list of questions for evaluating database readiness for use

| Questions |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| What is the intent of the database? Administrative? Clinical? Research? Clinical/administrative? Is information in aggregate or individual form? |
| How are data gathered? Was a study design utilized? Who does the data collecting? Were the data collectors trained? |
| What variables are measured? Are variables operationally defined? Are the methods standardized? |
| What is the nature of the measurements? Are measures subjective? Objective? Is there more than one method of measurement? Is there calibration of any mechanical instruments? Is there standardization of any lab tests/values? |
| What is the established documentation about reliability, validity, specificity, sensitivity, responsiveness of any instruments? |
| Is there capability of risk adjustment through variables about severity of illness? |
| What further validation or statistical adjustment needs to be done to use the database with confidence? |

distributed? Is the database analysed for its intended purpose? Are the analyses appropriate to the data collection methods and procedures? Table 1 lists questions that should be asked to determine whether the database is ready for a specified use.

DETERMINING RELIABILITY AND VALIDITY OF THE ELEMENTS

Clinical, administrative, and research databases have issues of data integrity that include consistency and accuracy of measurement and indicator validity, reliability, and responsiveness (Booth & Collopy, 1997; Iezzoni, 1997; Phillips & Morris, 1997).

For beginning evaluation and critique, a database must be broken down into its elements or specific variables. The database can only be as good as each of its parts, and threats to integrity can emerge from all aspects of the data management. Evaluation should include all aspects that would be used to critique a research investigation, as follows: study design, methods of data collection, instrumentation (validity of instruments, interrater reliability, timing of data collection, sensitivity and specificity), and management of data (chances for error). This section presents the impact of these aspects on a database.

DESIGN FOR DATA COLLECTION

The 'gold standard' for research is the experimental design—the randomized controlled clinical trial (RCT). Random assignment controls bias through single or double blinding and controls confounding through the chance creation that all participant groups will be similar. Random assignment to interventions that may not be equally beneficial or efficacious poses ethical concerns and is a major weakness of the randomized controlled clinical trial. The RCT answers a question about what effects the intervention has on selected outcomes. For example, it could answer the effect of oestrogen on breast cancer development in postmenopausal women. A database containing data obtained from one or more studies of single or multi-site RCT is considered worthy of deriving causal linkages. The findings can be attributed to treatment based on group assignment, that one treatment really is better than another. However, not all databases comprise RCT.

Cross-sectional data collection captures information at one point in time. Similar to a cross-sectional study, the findings are exploratory, descriptive, observational, and non-generalizable. This type of design provides the prevalence of a certain disease or condition at one point in time. For example, a prevalence study is commonly done for pressure ulcers in acute care settings. Some strengths of the cross-section design are: ability to draw a representative sample, opportunity to standardize methods of collecting data for repeated use, and efficiency of data collection labour if prevalence is high. Some limitations of the cross-section design are: the lack of a time dimension prevents causal linkage or interpretation, and a small prevalence of the condition in question makes the method inefficient (Elwood, 1998). Examples of a cross-sectional design include hospital prevalence studies (i.e. for restraints or pressure ulcers) and surveys such as the USA Census. From a database created from cross-section data, associations—not causation—can be identified between items, and these associations must be made cautiously. An example is a database that includes a quarterly average number of RN staff and a 1 day restraint prevalence rate during that quarter. These two variables should not be causally linked. Further, an association between them could be made but would lack clinical meaning because the time measurements differ. An association would be more credible if both items are averaged from the same monthly sums.

The usefulness of a cross-section database is quality measurement over time with repeated measures.

Prevalence rates and frequencies can be obtained from such a database. A prevalence rate is the number of people with the condition divided by the number of people at risk (Newman *et al.*, 1988). For example, the calculation for pressure ulcer prevalence is the number of persons with ulcers divided by the total number of persons in the hospital at that particular point in time. The calculation of frequency of falls incidents, for example, is simply the total of episodes of falling that are reported. In both examples the monitoring over time in a database could reveal changes sensitive to new interventions. Monitoring skin or fall rates over time provides an ideal opportunity to implement a RCT in which patients are randomly assigned to intervention groups and the outcome measured at specified time intervals. From a cross-sectional database, variables cannot be controlled, but findings can be applied to practice improvements and data collection methods can be perfected.

An important aspect of analysis is risk adjustment, a form of stratifying cases or participants based on acuity or some other confounding variable. For example, if the database includes variables that address severity of illness, the analyses can include statistical control for the impact of grave illness on other outcomes of interest. In this manner (and with the help of a statistician) several confounding variables can be controlled to remove their effects on outcomes.

Analysing data from existing databases, known as secondary analysis, can produce meaningful results and should be considered if the question is appropriate to the specific database. Hornberger and Wrone (1997) highlight the differences between policy making based on observational versus randomized trial data. These authors note that less than 20% of clinical policies are based on findings from randomized trials! Considerations in favour of decision-making from large observational databases include: (i) costs are considerably less in time and funds; (ii) physicians may not want to enter patients into a study because of lack of benefit or belief that the expense would be better spent on existing therapy evaluation; and (iii) data already exist that may be compelling enough to resist a RCT on ethical grounds. Considerations in favour of starting a randomized trial include: (i) variables such as comorbidity or uses of certain medications are not controlled in observational databases; (ii) clear delineation of treatment effect is based on assignment to group; (iii) patient selection is more specific and treatment benefit can be generalized to the same type of patient; and (iv) historical evidence of error exists

in relying on observational data because of lack of clinical depth. There is no conclusive answer to the best way to use data for decision-making; each type of data capture is important for specific purposes.

METHODS OF DATA COLLECTION

All aspects of data collection involve chance of error. Chances for error can occur throughout data gathering by the collector, the participant, the instruments, data coding and recording, and data entry. This section will discuss possible areas where data collection errors can occur.

Instrumentation

Ideally, instruments or tools should be valid and reliable. They should have documented psychometric maturity as established from prior studies with similar populations. There should be explanations about validity, reliability, sensitivity and specificity, and scoring schema. When mechanical instruments are used for measures, such as blood pressure monitoring, calibration becomes essential for each machine used in the study. Further, if possible, participants' subjective responses should be validated with objective measures. For more detailed reading about measurement issues, the reader is referred to Hulley and Cummings, *Designing Clinical Research* (1988).

Generally, validity means that an instrument measures what it purports to measure. Validity has three main aspects (Hulley & Cummings, 1988): (i) face (content) validity is the investigator's and consultants' subjective and intuitive appraisal that the instrument measures the phenomenon of interest; (ii) criterion-related validity (convergence) is the matching of responses on the instrument to another measurement method (e.g. a psychiatric diagnosis in DSM-IV matches relatives' descriptions of behaviours); and (iii) predictive validity is the degree of precision with which the instrument can successfully predict an outcome of interest (e.g. an assessed risk for fall predicts a fall). Precision is determined when the same value can be achieved several times, as with repeated measures.

Reliability refers to the tool's consistency within itself, consistency in repeated testing, and consistency across users. Consistency measures are established with interrater reliability, test-retest methods and split-half reliability. The internal consistency of the instrument is measured using Cronbach's alpha, and an alpha of 0.8 and higher is considered adequate for psychosocial instruments.

The responsiveness of the instrument is revealed in its repeated measurement. Questions arise as to the timing of administration. Are the times selected appropriate? Will the score change if the test is administered at the intervals determined in the database? Has prior work demonstrated learning from testing? When are the times that the tool will demonstrate responsiveness to changes? Do persons taking the test tire of it?

Sensitivity of an instrument refers to the degree of ability to detect persons with a condition. Specificity means the instrument can detect persons without the condition. High percentages in both of these areas mean that the instrument can successfully discriminate between affected and unaffected persons.

Management of data

The management of data includes collecting, coding, and entering data. Depending on the variable or indicator, the person(s) collecting the data introduces bias. Collection involves administering tests and coding the information or responses. For example, if an indicator requires interviewing for its data, training with a script should be included so that all persons doing the same interview say the same things and that the same person repeating an interview says the same things. Interrater reliability, a method for establishing uniformity and consistency in raters' administration of any tests, should be done for each tool in a database. Timing of the data collection is also important for consistency of measurement across individuals in the database.

Coding converts the information into a form ready for data entry, and it may be done at the time of collecting data or at the time of entering data. There are many chances for error. The codes must be clear so that even the same person can be consistent with him/herself on repeated coding episodes. Coding errors can occur if the data are being transferred from an existing standardized clinical form to a database with its own standardized format, and the codes do not match; the coder must make an interpretation from a present or even absent description. Questions to consider about coding errors include the following. Is the same person doing the coding as does the interviewer? Is the same person coding each time the test is administered? Are different coders trained to code consistently and similarly? The coding should be consistent and systematic and subjected to interrater reliability. For repeated measures, the same person should repeat the administration of the tests. Coding by the interviewer is not problematic unless a delay in

timing influences recall or if the interviewer makes interpretations from the interview.

Entering data introduces another opportunity for error. Transferring data from the data collection forms into an electronic spreadsheet or statistical package requires skills of speed and accuracy. Common practice in research is to enter the data twice and check consistency between the two files. Another method to reduce error is to use the software program's parameters on number values so that an alarm indicates an outlying number has been entered. Some organizations and research endeavours utilize scanners to eliminate human error. However, scanners sometimes misread photocopied alterations or written marks on the scannable forms. Another method to eliminate error is the transfer of data from electronic documentation, such as in a medical record, into a spreadsheet. The potential error here is that words taken out of context might change the entry into a data field (e.g. a note that has the word 'violence' in it may not necessarily mean that the patient is violent or a threat to others).

METHODS FOR IMPROVING ACCURACY, RELIABILITY AND VALIDITY OF DATABASES

Methods for improving research apply to database improvement efforts. That is, the above-mentioned chances for error and bias need to be addressed and corrected, if possible. Large, nationally recognized, databases often have published documentation about their accuracy of data, sources of and procedures for data collection, and validity and reliability of instruments. Several assessments can be made for determining validity for undocumented or newly created databases.

One method for determining accuracy is manual checking of retrievable data. For example, a database that lists causes of death can be manually checked by viewing patient records, assuming that patient identifiers are in the database or can be obtained. Likewise, discharge diagnoses can be checked for match with medical records. Privacy and confidentiality, a growing issue with using databases, may be protected in some databases by scrambling such unique identifiers as social security numbers.

Another method for determining accuracy is visual checking of data printouts. For example, the management of missing data must be consistent in the data entry process as either zero or blank. Also, numbers that are greatly increased or decreased in contrast with a prior measurement could be outliers or errors.

Comparison of findings with another database from the same region or a similar organization may validate findings. Also, re-analysis of the available biologic specimens will validate database values. For example, the Henrietta Banting Breast Center Database comprises details of diagnostic procedures, pathology, treatment, dates and sites of recurrence, and date of death, on 96% of the 1097 women diagnosed with breast cancer between 1997 and 1986 in one hospital in Toronto (Sawka *et al.*, 1995). The authors established that their database is valid because their findings compared closely to the Ontario Cancer Registry. They could also re-analyse biological variables and immunocytochemical hormone assays because the specimens were still effectively stored.

Another method for improving or checking validity of instrumentation is through the use of alternative instruments that test the same construct. Although seen more frequently in research, using a second tool allows correlation of results between the two instruments. For example, using two measures of functional status will strengthen the credibility of each of them. As mentioned above, use of an objective measure to match a subjective measure enhances validity.

When data are collected through reporting mechanisms, such as incident reports, observational checks can validate findings from the collected data. Traditionally, incident reports underreport actual adverse occurrences such as falls and medication errors. However, observations on one unit over time would validate frequency of incident reporting and actual occurrence of incidents.

GUIDELINES FOR USING DATABASES

The following guidelines offer suggested activities for determining a database's readiness for use in analyses that will be used for health-care decisions:

(1) Evaluate design of the database: RCT, cross-section, longitudinal cohort, case-control, database of quality indicators, or other.

(2) Determine intent of database development. Was it an individual researcher's study? Was it a national endeavour? Is it a clinical, administrative, research, or combined database?

(3) Assess data collection methods to ensure chances for bias and error are minimized and discussed. Determine whether variables or indicators have been operationally defined, whether the methods have been standardized, and whether observers or data gatherers have been trained. Determine management of missing data.

(4) Assess instruments for validity and reliability, sensitivity and specificity, subjectivity or objectivity, and responsiveness to timing of measurements. Determine whether alternative measurements have been done to validate subjective measures.

(5) When possible, find cross-validation methods from the literature or from independent study with manual chart checks, re-analysis of biological markers etc.

(6) When evaluating the utility of one tool, establish the use of two instruments of the same construct.

(7) When using cross-sectional data for testing hypotheses, causal relationships cannot be made. Consider that possible confounding variables may not have been included in the database, measured adequately, or analysed appropriately (e.g. risk adjusted).

(8) Exercise caution in using cross-sectional data for establishing meaningful associations. Are the times of data collection important for answering the question? Are the times of data collection the same for all data points?

(9) Determine whether the database development included acuity or severity of illness measures. Determine methods for risk adjustment or stratification in the data analyses.

CONCLUSIONS ABOUT READINESS FOR USE

In summary, databases offer an efficient means of analysing data to answer questions related to quality of health care, research, and administrative issues such as resource utilization effectiveness. Prior to use, database methodologies require scrutiny for determining accuracy and threats to validity and data integrity. Imperfections in databases may not preclude their use if their limitations are recognized and statistical efforts are directed at improving quality of the data. Interpreting findings from secondary data analyses must be carefully discussed, including making causal linkages from cross-sectional data.

Davidoff (1997) cautions clinicians in using large databases for quality improvement. As relatively new innovations, databases need time to evolve and users must be aware of the seductive nature of large amounts of data. Assumptions about the benefits of data-based systems can lead to inappropriate uses and interpretations. Technological developments enabling wide-ranged database access necessitates scrutiny in interpreting data for making health-care policy. Health-care quality management must work interactively with database development to ensure adequacy

of methods and with clinicians in conducting and interpreting analyses.

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