Administrative Databases and Outcomes Assessment: An Overview of Issues and Potential Utility

Sanjay K. Gandhi, J. Warren Salmon, Sheldon X. Kong, and Sean Z. Zhao

OBJECTIVE: To make health care researchers, clinicians, and managers who are relatively new to outcomes research using administrative databases more aware of issues to consider when planning or conducting studies, and to encourage improvement in the data quality and structure of administrative databases.

CONCLUSION: Administrative databases are being used more frequently in the assessment of health care interventions. Their increased popularity as a research tool can be attributed to timely availability, the large patient populations they cover, low cost, and applicability in the real world. However, there are limitations to their use as an outcomes assessment tool due to their structure, the data collection process, and the inherent nature of the U.S. health care delivery system.

KEYWORDS: Outcomes research, Outcomes assessment, Administrative databases

J Managed Care Pharm 1999: 215–222

Leaving an era of expansion in facilities and services, health care has now entered the era of outcomes assessment and accountability. This evolution has been driven in part by fears that cost-containment efforts may adversely affect the quality of services, as well as by documented widespread variations in medical practice, deficiencies in clinical decision making, and drug misadventuring, all of which highlight the need to reform professional activities.

Outcomes assessment provides those who finance health care with a new way to assess the accountability of those providing that care. Interdisciplinary approaches to assessing health care delivery outcomes therefore have gained nationwide and worldwide attention.

OUTCOMES ASSESSMENT

Outcomes assessment can be defined as the evaluation of the impact of medical and nonmedical interventions, the health care process, and the structure of the health care system on clinical, economic, and humanistic outcomes, such as patient health-related quality of life and patient satisfaction. Government and private providers have attempted to enhance patient outcomes by guiding medical practice decisions through practice guidelines, continuous quality improvement and quality assurance efforts, and clinical pathways to standardize and optimize the medical care process.

Guadagnoli and McNeil define outcomes research as linking the type of care received by a variety of patients who have a particular condition to positive and negative outcomes in order to identify what works best for which patient.

Outcomes research provides a means for evaluating different health alternatives in terms of their impact on the health status
of patients and on future resource consumption. Recently, economic and health-related quality of life (HQL), in addition to mortality, morbidity, and clinical variables, have been included in the assessment of health interventions.6-11

Several interest groups, including payers, providers, and patients, have a stake in the economic and HQL impacts of health interventions. Government is the single biggest payor of health services, purchasing more than 40% of all health care delivered in the United States through Medicare, Medicaid, Veterans Administration, CHAMPUS, Indian Health Service, and other programs. Outcomes research offers these programs the opportunity to select medical interventions that provide an optimal balance between cost and quality.6 Employers have become interested in outcomes research as a means to measure functionality and wellbeing in their efforts to maintain a high-functioning workforce. Managed care organizations (MCOs), recognizing the importance of outcomes research, have begun to demand that pharmaceutical companies submit pharmacoeconomic data in order to have their products included in formularies.12 Changes in the payment structure (prospective payment and capitation) provide incentives for clinicians to decrease costs. Outcomes research initiatives may help providers select the services they will provide under such restricted payment mechanisms.

Conducted appropriately, outcomes research shows tremendous potential for ensuring the effective and efficient use of health care services and appropriate allocation of resources. Considering its popularity and usefulness in health care delivery, we can conclude that outcome measures will provide significant directions in health care decision making.

Outcomes research can be conducted by a variety of means: clinical trials, observational studies, surveys, and administrative/clinical research database analyses. The conceptual design and methodologies used to conduct outcomes research can be quite sophisticated, mainly due to complexities and variables in the health care system, data sources, and patient and provider populations. Furthermore, outcomes research demands collaboration from experts in various disciplines.4 All members of the outcomes research team need a basic understanding of the process and the issues.

Several reported studies have used administrative patient databases to examine aspects of health care delivery, including practice patterns,2,3 quality of care,14 technology assessment,15 economics,16-20 and epidemiological studies.21-29 The use of large databases in outcomes research has gained increasing attention from researchers.5,27 An entire issue of *Annals of Internal Medicine* (October 15, 1997) has been devoted to the topic.

Our aim is to make health care researchers, clinicians, and managers who are unfamiliar with the process aware of the issues, potentials, and pitfalls to consider when planning or conducting studies using administrative databases in outcomes research. A basic comparison of different data sources used for outcomes research is provided in Table 1.

### CLINICAL TRIALS

Randomized controlled trials are the "gold standard" for establishing the therapeutic efficacy of health care interventions. Although these trials are widely accepted by scientists, the U.S. Food and Drug Administration, and practitioners, they are not without shortcomings as outcomes assessment tools.29 It is important to understand their advantages and disadvantages compared to administrative databases as tools for conducting outcomes assessment.

Clinical trials typically are designed to achieve internal validity—to establish a causal relationship between the intervention and the outcome in a controlled condition, achieved by strict patient inclusion criteria and close monitoring of the intervention, the health professionals, and the patients. The scientific community continues to debate the validity of clinical trial results in the real-world setting, with its diverse patient populations (including women, minorities, and children, often under-represented in controlled trials), elderly patients with several comorbid conditions and medications, and compliance issues.29,30

Other issues limit the ability to generalize the results of controlled clinical trials. The close monitoring of patients in clinical trials may lead researchers to detect adverse events that might go undetected in actual clinical practice (e.g., ulceration due to NSAID therapy).31 Due to liability issues, adverse events are more intensively treated in clinical trials (e.g., more lab testing is done) than in normal practice. These factors raise concerns about the applicability of controlled trial results to general clinical practice, where patients are not under constant and close scrutiny and may well have exposure to fewer re-resources than patients participating in clinical trials.

In most clinical trials, clinical variables are primary and humanistic and economic variables, are secondary, raising the question of power considerations (ability to detect differences if they exist) in the statistical tests involving secondary variables.32 Typically, clinical trials are very expensive to conduct, especially when the effect under consideration is small, which necessitates larger sample sizes. Considering the limited applicability of highly controlled clinical trial results to actual clinical practice, justification for high-cost, controlled trials may be open for argument.

Some of the disadvantages of controlled clinical trials in outcomes assessment can be overcome by the use of patient care databases, which are most often compiled for administrative purposes (i.e., claims payment) rather than for research purposes. However, this approach is not free of problems. Before we begin our discussion on the potential advantages and disadvantages of using administrative databases in outcomes research, it is important to make the distinction between administrative databases and databases specifically compiled for research purposes.33
### Table 1. Comparison of Major Popular Data Sources for Outcomes Research: A General Representation of Advantages (+++) and Disadvantages (---)

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<thead>
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<th>Desired traits for outcomes research activity</th>
<th>Prospective Data Collection</th>
<th>Analysis of Existing Database</th>
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<td>Controlled clinical trial*</td>
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<td>Actual practice research database†</td>
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<td>Nonintrusive</td>
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<td>Comprehensiveness of collected information**</td>
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<td>Ease of patient availability in rare conditions/exposure</td>
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<td>Diverse (heterogenous) patient groups</td>
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<td>Resemblance to the actual clinical practice</td>
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<td>Validity of information</td>
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<td>Actual practice research database†</td>
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<td>Nonfragmented</td>
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<td>Comparable treatment groups (absence of confounding by indication)</td>
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<td>Easily accessible by health services researchers</td>
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<td>Accurate coding</td>
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<td>No &quot;upcoding&quot; problem§</td>
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<td>Researcher control of the type and extent of information collection</td>
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<td></td>
<td>Actual practice research database†</td>
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<td>Example</td>
<td>Scandinavian Simvastatin Survival Study*</td>
<td>ARAMIS‖</td>
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*Conducted specifically for the research question under investigation.
†Compiled specifically for the research question under investigation.
‡Includes clinical and administrative information.
**For the primary research question.
§Upcoding: Coding of diagnosis or services to maximize the reimbursement.
∥Disregarding the original or setup cost.
Assuming that the data collection method was intrusive in nature.
Assuming that various aspects of health care services are recorded.
Considering difficulty in recruiting patients, or accessing already collected data.
Specialized Research Databases

As their names suggest, the primary purposes of research and administrative databases are different. Typically, we could assume that information provided by a research database would be more in-depth and valid than that provided by administrative database. Specialized research databases used for outcomes research include the American Rheumatism Association Medical Information System and the Duke Cardiovascular Data Bank. In general, research databases are preferred for more reliable results. However, researchers may find it more difficult to obtain access to research databases than to administrative claims databases. Moreover, most research databases are specific to a single disease category, which limits their applicability for research in other disease categories. These factors highlight the practical utility of administrative claims databases in outcomes research.

Administrative Database Advantages

Paul and Tilson and Edinberg and McCormick provide a primary listing of common databases available for use in pharmacoeconomic research. Popular databases include the U.S. Health Care Financing Administration’s Medicaid and Medicare databases, the National Ambulatory Medical Care Survey, the National Health Interview Survey, and the Health-care Cost and Utilization Project. These and other commercially available databases, such as those owned by managed care organizations (MCOs) and pharmacy benefits managers (PBMs), are relatively inexpensive and offer several advantages. Decision makers often want answers to questions about health care delivery in a relatively short time, too short for long-term prospective studies. Administrative patient databases are appropriate tools for this type of research. They offer ready access to the longitudinal data needed for retrospective studies on medical practice issues that would otherwise require lengthy prospective studies, especially in assessing the effectiveness of interventions in managing chronic diseases.

Using administrative databases also avoids recall bias, a threat when patients self-report. Studies relying on the memory of respondents to recall adverse events, visits to medical care providers, hospitalizations, and medication use run the risk of basing conclusions on unreliable data. Also, using administrative databases for research purposes is significantly less expensive than conducting prospective studies or clinical trials.

Using administrative databases is nonintrusive. Patients may not welcome data collection methods, such as mailed surveys or patient interviews, especially when they solicit personal information or information about stigmatized diseases. Claims databases may not make available all the information that researchers ideally wish to obtain, but the information is already gathered and, in the absence of other sources, can be a good source of patient care and outcomes data.

Conducting clinical trials involving rare diseases or events (e.g., NSAID-induced gastrointestinal hemorrhage) presents challenges. Enrolling patient populations large enough to conduct prospective studies is often difficult in such diseases. Many administrative databases are large enough to enable researchers to find sufficient numbers of patients with the rare condition under investigation.

POTENTIAL PROBLEMS

Such databases are primarily designed for administrative and financial purposes. Their primary shortcoming as a research tool lies in this lack of research orientation in their construction and in the data collection process. A number of other disadvantages arise in using administrative databases due to the fragmented nature of the U.S. health care delivery system, the lack of continuity of care, incentives to provide or not provide services, and incentives for miscoding diagnoses and procedures.

Reimbursement Mechanism

Administrative databases serve primarily to record the delivery of health services claims by providers in order to secure reimbursement from payors. Hence, the incentives provided by the payment system may drive the quality of the recording of diagnoses and the use of medical care resources. For example, data not required for administrative or financial purposes might not be recorded or might be recorded very poorly (e.g., inpatient prescription drug use). The extent of the importance of particular data to the reimbursement mechanism influences the detailed recording of that data.

Generalizability

One problem with several popular databases lies in the homogeneity of the patient population covered. For example, Medicare covers the elderly, Medicaid covers indigent and other special patient groups, and the Veterans Administration database covers predominantly an older and possibly poorer male population. Employer-based databases, on the other hand, may represent patient populations of a relatively higher socioeconomic class. These factors limit the generalizability of study results arrived at by using such databases.

The changing managed care patient population, as evidenced by the new Medicaid and Medicare managed care contracts, highlights the dynamic nature of the patient mix in different settings. Research using data predating these patient populations may limit the applicability of results to patient populations currently enrolled in managed care plans. While the use of databases with a more representative patient population is desirable, this in turn raises concerns about the applicability of results to specific patient populations. Readers need to be aware of specific study populations when extrapolating study results to other patient populations.

Patients’ health services utilization is believed to be a function of insurance coverage and the extent of their share of the financial burden of health care. Increasing user charges for prescription drugs, for instance, decreases drug utilization. MCOs provide varying levels of coverage to patients depending on
the nature of individual plans. Certain health coverage policies might have higher coinsurance or copayments in comparison to other coverage policies offered by the same health plan; thus, patients covered by the same insurer might show differing rates of utilization due to differences in policies and coverage. Combining these patient populations for the purpose of a utilization study would produce questionable results. Different levels of coverage should be accounted for in study designs or analyses involving administrative databases. Furthermore, many patients may change the level of their coverage during the same enrollment. This needs to be examined before including them in the study population.

Lack of Information Control

Because the information has already been gathered, the researchers have no control over the type of information available in an administrative database, a problem inherent in any study using secondary data sources. For example, almost no claims database currently has information on patient health status or quality of life. Also, as Mullins reported, direct information regarding illness severity can rarely be obtained. Certain proxy measures, such as specific drug use, can be used when illness severity information is absent; this technique, however, raises validity concerns. Researchers have to be aware of the type of information contained in the database and the type of research questions that the database can answer.

Nonrandomized Treatment Allocation Bias

Another problem with claims databases is nonrandomized treatment allocation to different patient groups, also known as confounding by indication. The allocation of treatment to different patient groups is systematic in the sense that more seriously ill patients might receive more efficacious and more expensive drug therapy than others. This factor might make the comparison of different treatment groups impossible. For example, only patients at high risk of GI hemorrhage due to NSAIDs might receive misoprostol, a cytoprotective agent. Comparing the health care resource utilization of patients on NSAIDs alone to patients on NSAIDs plus misoprostol could be inappropriate. Because the use of a cytoprotective agent indicates that this is a high-risk patient group, an economic comparison of the two patient groups will be inherently biased against misoprostol use. This also applies to treatment of asthma patients with aerosol beta agonists. A feasible but less-than-perfect solution in such cases is to monitor changes in the outcome variable in the pre- and post-treatment periods. Researchers and policy makers in managed care settings have to be aware of this problem when using retrospective data to compare different therapeutic alternatives in a naturalistic setting.

Off-Label Drug Use

In research using database analysis, drug use is often considered a marker to identify certain disease conditions. However, if a drug is used off-label or for unapproved indications, using that drug as a marker for certain disease conditions would produce erroneous results. Due to liability and reimbursement issues, the physician using a drug for an unapproved purpose may code the diagnosis differently, posing problems of validity.

High Patient Turnover

A high turnover of patients in health plans presents another problem in the analysis of claims databases. In studies requiring long-term follow-up of patients, a high dropout rate limits the number that can be included in the final analysis. Researchers should confirm the eligibility of all patients during the entirety of the study period; otherwise, they will be unable to conclusively determine if the absence of claims is attributable to lack of need for medical services or to lack of coverage, which could arise if the employer changes insurers or the patient changes jobs.

Fragmented Database

The fragmented nature of databases is a barrier to their use in outcomes research. For example, the pharmacy component of the health plan is often carved out to a PBM. Hence, the claims database of the health plan lacks information on the prescription drug utilization of enrollees. In these cases, the researcher will need a mechanism to link the databases of the PBM and the health plan, using unique patient identifiers.

Statistical Significance

Administrative databases may contain data on a large number of patients. For example, Medicaid databases contain records on millions of covered lives. This is one of the advantages of using these databases; however, handling such large databases (getting the data in the analyzable form and running statistical programs) is a major challenge. In addition, with large patient numbers the standard error reduces, making it easier to achieve statistical significance. Researchers and policy decision makers should strive for practical rather than statistical significance to support study hypotheses.

Problems With Coding

Incomplete coding of patient diagnoses is a threat to validity for studies using claims databases. In the absence of incentives, coding of patient diagnoses and comorbid conditions may be noncomprehensive. Inaccurate diagnostic coding has been widely reported. The primary cause of a patient visit is likely to be recorded, but other causes might be missed, posing a threat to the validity of study results. For example, in a study examining the impact of individual disease conditions on the use of health care services, missing data on comorbid conditions could present a serious problem. Uncertainty arises because it is difficult to determine from the database if a condition is truly absent or is absent from the record as a result of noncomprehensive coding.

Incomplete coding (under-reporting) of adverse effects of
drugs or other interventions is also a problem. This information may be vital in a comprehensive evaluation of a particular health care intervention. Health professionals and health information specialists must recognize the importance of consistency and completeness of data on health-related variables and delivery of health care services.

Upcoding of diagnosis presents another problem. Upcoding occurs when the recording of a diagnosis is influenced by the reimbursement mechanism. Health plans offering prospective reimbursement may inadvertently provide incentives for care givers to record diagnoses that receive the highest reimbursement, raising questions about the validity of the diagnoses recorded.

The coding system is modified periodically to improve consistency and precision. The 10th version of the International Classification of Diseases is already in use in certain countries. Changes in coding and recording require health care researchers to take precautions to ensure that they appropriately integrate data across different time periods. In addition, updating the old system with new coding may take some time, and thus the results of an analysis might be different if the same data are analyzed at two different times.

**Cost Versus Charge**

The type of cost information needed for economic evaluations varies depending on the perspective of the study. Reimbursement to the health plan for provision of health services, a cost to the payor, varies depending on the agreement between buyer and provider. Furthermore, most databases report charges made by the plan but not reimbursement to the plan. The use of charge data in outcomes research is not without problems, partly due to the difficulties in determining the actual cost of a unit of medical care service from the charge data.

Furthermore, different plans have different charge structures for similar services, attributable to geographical, technological, and business strategy differences. Indeed, the axiom “if you know one health plan, you know only one health plan” applies here. These attributes of the health plan data make it harder to obtain a direct generalizable estimate of the cost of an individual medical care unit. Use of individual organization accounting information may be a cumbersome means by which actual cost data can be obtained. This becomes a virtual impossibility when the data set consists of data from different providers (as is most often the case). Distinctions need to be made between charges and costs in studies using data from health plans. The perspective of the study also needs to be stated explicitly to comprehend the definition of costs and benefits.

**PRACTICAL CONSIDERATIONS**

The most important prerequisite for conducting research using administrative databases is easy access to a database. Government databases, such as certain state Medicaid and Medicare programs, are relatively accessible but have limitations in terms of population covered, type of services captured, and ability to link to other government databases. Academicians often do not have easy access to private databases, because of either their high costs or failure to arouse interest in the database lending agencies (e.g., HMOs). Researchers who can communicate explicitly the direct relevance and importance of the question being investigated to the database lending agency are likely to have greater success in obtaining access. A feasible solution to the difficulty of accessing commercial databases is to obtain funding from another party, such as the pharmaceutical industry or government agencies, to procure commercial databases for conducting research of mutual interest.

The nature of large data sets necessitates the availability of sophisticated computer systems and expertise in those systems. Most database vendors provide information on the hardware and software required to support specific data sets. Without such support, the research process may be delayed, a potentially costly problem when data sets are leased from commercial vendors for a limited time. In addition, the nature of database analysis requires researchers to have technical expertise in handling computer systems, designing research studies, and using statistical techniques and software. Availability of such expertise needs to be ensured before acquiring expensive data sets for research purposes.

Obtaining a commitment from the lending agency to provide continued assistance on the database is essential. After obtaining the database, certain issues relating to database structure or software or hardware needs may need clarification. Close ties with the database developers ensures help in anticipated and unanticipated logistics issues.

**CONCLUSION**

This article highlights the advantages of using claims databases in outcomes research and discusses several pitfalls. The shortcomings of large administrative databases cannot be ignored; however, these should not be allowed to undermine the importance of this research resource, which is increasing in popularity. For optimal use of this research tool, health services researchers need to be aware of issues related to analyses while planning or conducting research using administrative databases. Clinical practitioners, medical directors, pharmacy managers, and policy makers need to be cautious in interpreting results of studies based on administrative databases.

The use of administrative databases for research is popular in the research community for several reasons. Relatively inexperienced researchers should keep in mind that database analysis is not a source for answering all research questions. For example, most administrative databases do not allow for research relating to the health status of the patient population or provide information on relevant clinical variables.

Some of the limitations of administrative databases as research tools arise from the fact that they were not designed for research, but for processing claims and recording utilization of
medical services: utilization management, not quality-of-care improvement. Their immense potential as a research resource has yet to be fully realized by administrators and the database managers or information system specialists of individual health plans.\(^5^7\) With the basic framework in place, setting up an extensive network to record clinical, health status, and medical services utilization information to the desired detail and with satisfactory reliability and validity is possible. This information could eventually be used for research designed to guide health plans’ internal policy decisions. Research activities can be geared toward identifying therapies that would improve the health of the public and reduce health care utilization. Individual health plans need such data sources for their own benefit, considering the variability in coverage, enrolled patient population, and contracts with providers and suppliers across plans. More meaningful and valid research for individual health plans would be possible if recording went beyond capturing units of services utilized and included clinical and humanistic data.

The existence of a good internal database may also benefit health plans as more large employers and individual enrollees begin to base their choice of health plans on the quality indicators set up by accreditation agencies such as the National Committee on Quality Assurance and the Joint Commission on Accreditation of Healthcare Organizations. The information requirements for accreditation have been widening, as evident by Health Plan Employer Data and Information Set 3.0. Existing infrastructure and systems to document medical care processes and health outcomes in detail would enable health plans to make available timely data for scrutiny by outside reviewers. Furthermore, published guidelines now call for pharmaceutical companies to conduct pharmacoeconomic analyses specifically to meet the needs of individual health care plans.\(^5^7\) If data about a particular health plan are not adequate, pharmaceutical companies may be unable to conduct scientifically rigorous pharmacoeconomic studies to reflect individual managed care plan patient populations.

From the societal perspective, the health of the population is paramount to any other outcome variable. The utilization of health care services is a function of many variables other than health status,\(^5^6,5^8\) such as gender,\(^6^0\) race,\(^6^1\) income,\(^6^2\) age,\(^6^3\) education,\(^6^4\) behavioral factors (e.g., coping),\(^6^5\) and structural factors including access to care and type of insurance coverage.\(^6^6\) We must realize that utilization of health services is at best a proxy for health status; more valid and direct measures such as patient health-related quality of life can be made. By recording information on direct measures of health status in the future, we can further increase the utility of administrative databases.

The structure of health care administrative databases has improved, to a great extent, due to technological innovations.\(^6^7\) The use of administrative databases in outcome research initiatives has also increased in the last decade. Advances in computer systems and increasing awareness among researchers and administrators of the tremendous potential of this resource for outcomes assessment leads us to predict improvements in the structure and increased use of administrative databases in outcomes research initiatives. This direction is likely to facilitate more accountable health care decisions.

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