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Health State Information Derived from Secondary Databases was Affected by Multiple Sources of Bias

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Abstract

Objective— Secondary databases are used in descriptive studies of patient subgroups; evaluation of associations between individual characteristics and diagnosis, prognosis, and/or service utilization rates; and studies of the quality of health care delivered. This article identifies sources of bias for health state characteristics stored in secondary databases that arise from patients' encounters with health systems, highlighting sources of bias that arise from organizational and environmental factors.

Study Design and Setting— Potential sources of bias, from patient access of services and diagnosis, through encoding and filing of patient information in secondary databases, are discussed. A patient presenting with acute myocardial infarction (AMI) is used as an illustrative example.

Results— The accuracy of health state characteristics derived from secondary databases is a function of both the quality and quantity of information collected prior to data entry and is dependent on complex interactions between patients, clinicians and the structures and systems surrounding them.

Conclusion— The use of health state information included in secondary databases requires that estimates of potential bias, from all sources, be included in the analysis and presentation of results. By making this common practice in the field, greater value can be achieved from secondary database analyses.

Keywords

Administrative Data; Databases; Medical Record System; Health Status; Methodology; Risk Adjustment

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1. Introduction

Administrative and clinical databases containing secondary data (subsequently referred to as “secondary databases”) are a valuable resource, yet their use is not without challenges. The use of secondary databases can be an economical alternative to primary data collection, with access to health state, demographic and health care utilization information for millions of patients. Secondary databases may have “hidden costs”, however, due to uncertainties arising from limitations in the researcher’s ability to detect information critical to their analyses reliably and validly. This uncertainty leads to imprecision and inaccuracy when describing patient subgroups or when investigating associations between outcome and patient-, intervention-, or organizational-level variables. Although results of secondary database analyses are routinely reported with estimates of precision, only recently has greater attention been focused on quantitative assessment and reporting of potential bias in effect estimates.[1–4]

The purpose of this article is to describe sources of bias encountered during generation and recording of data in an individual health care encounter, through processing and storage in a secondary database. The focus is on recorded signals - specific data entries or codes - that are stored first in a patient’s medical record and then combined to form secondary databases that reflect the health and health care of larger patient populations. The term “signal” is used to refer to any phenomenon, e.g. patient self-report, lab test result, prescription, or diagnosis code that carries health state information. Health state information is broadly defined as the full range of observed and unobserved physical, chemical, mental and social processes associated with a patient which represent the quantity and quality of an individual’s health or well-being.[5] Our discussion centers on the detection of health state characteristics – diagnoses and comorbidities – and uses the example of a patient presenting with symptoms of acute myocardial infarction. A novel perspective is provided, emphasizing the influences of organizational and environmental factors at the health systems level on the validity of secondary databases.

2. Conceptual Framework

The conceptual framework shown in Figure 1 builds on the work recently published by Schneeweiss and Avorn [1] to identify potential sources of bias in secondary database analyses, from patient access of services through a given health system through processing and storage of patient information in secondary databases. The model consists of a central set of blocks, representing factors that influence the quality of data collected during an individual health care encounter (Blocks 1 – 5 in Figure 1), and begins with an individual’s propensity to access health care services (Block 1 in Figure 1). Specific attention is given to sources of bias that arise from the health systems that surround an individual patient encounter (Blocks 3 and 4 in Figure 1). A concentric ring (Block 6 in Figure 1), representing the sequential steps and factors that influence the recording of patient data in a secondary database, is the final layer of the model.

Sources of bias encountered when encoding and electronically storing data within a secondary database (Block 6 in Figure 1) have historically received the most attention. However, the accuracy of data contained in secondary databases is not solely dependent on the data management systems and policies employed. The accuracy of the data is also a function of the quality and quantity of information collected prior to entry into the secondary database. Therefore, the interactions between patient and clinician, and the structure and systems surrounding an individual patient encounter, are important to consider. For example, the presence of recorded data in a secondary database for a given individual is fundamentally dependent on the individual having received services within a given health

care system. Those who do not obtain health care services within the given system, due to barriers to access or by preference, limit the external validity (generalizability) of any future analysis. This first source of bias derives from an individual's propensity to access health care services (Block 1 in Figure 1). Andersen's Behavioral Model of Health Services Use, employed extensively as a framework for health care utilization studies, can be used to understand better this first source of bias, as explained in greater detail below.[6,7]

Blocks 2, 3, 4 and 5 of Figure 1 represent additional factors that affect an individual patient encounter and influence the validity of health state information collected prior to summation and entry into an accumulating secondary database. Block 2 reflects a patient's propensity to report health state attributes and adhere to diagnostic and treatment recommendations. This component of the conceptual model relies on an extension of Andersen's Behavioral Model of Health Services Use and Cannell and colleagues' model of respondent behavior in interviews.[8] The clinician's propensity to detect, treat and report fluctuations in a given patient's health state are outlined in Block 3. The influence of the general characteristics of the visit (Block 4 in Figure 1) and community and system-based factors (Block 5 in Figure 1) are also included with empirical examples provided.

Each factor's influence on the validity of health state information collected within an individual patient encounter, and the interactions between factors, are discussed in greater detail in the following sections. We use a hypothetical case of acute myocardial infarction (AMI) in a 40 year old African American woman without prior history of cardiovascular disease who presents with non-specific symptoms, such as neck pain and nausea.

2.a The Health Service Encounter

To move forward with our example, we must first assume that our hypothetical patient seeks care. Many factors influence patients' propensity to access services. Based on Andersen's behavioral model of health services use, we can organize these factors into three constructs: predisposing characteristics, enabling factors and need.[6,7] In a recent study of women's knowledge of AMI symptoms, African American women and younger women were less likely than their Caucasian, older counterparts, to correctly identify symptoms with AMI.[9] Incomplete knowledge of potential AMI symptoms (a predisposing characteristic), misconceptions concerning risk (perceived need), or lack of social support in accessing treatment (an enabling factor) may result in delays or even failure to seek treatment.[10,11] Therefore, a 40 year old African American woman may be less likely to seek care under the circumstances described. This, in turn, may result in an under-representation of minority women and a bias within the secondary database towards older, non-minority individuals and their treatment and outcome experiences.

A cycle of information exchange begins with the patient's description of her reason for seeking health care (Block 2 of Figure 1). The validity of information provided by a patient within an individual encounter is subject to systematic sources of reporting and recall bias inherent in any interview process.[8,12] Her propensity to report specific health state attributes and/or adhere to recommended diagnostic evaluations may also be understood as an extension of the patient's propensity to initially access health care services (described above). For example, the patient may not perceive and may not have previous experience with cardiovascular disease to increase her awareness that these symptoms could represent AMI. Although she is seeking resolution or clarification from the physician for the symptoms she is currently experiencing, her lack of AMI risk awareness (perceived need) affects the language she uses in the interview and her persistence in ensuring her complaint is understood and addressed.

The information provided by the patient directs the clinician's initial perception of her health state. The clinician then extracts additional signals to establish his or her diagnosis, through physiological measurements, laboratory tests, imaging or additional clarifying questions posed to the patient. Accurate diagnosis of AMI among African Americans may introduce specific challenges. African Americans, for example, are more likely to present clinically with unstable angina and non-ST-segment elevation AMI, as compared to Caucasians.[13]

Beyond the validity of a given diagnostic test or technique, the data produced are dependent on a patient understanding and responding to a clinician's request for additional health state information [14] and the clinician's ability to communicate these requests to individuals with diverse levels of health literacy.[15–18] When a given patient group is at increased risk of missed diagnoses as a result of systematic deficiencies in physician-patient communication [13], bias is introduced into secondary databases that include their health services use. Interactions between patients and clinicians which affect the validity of data exchanged and recorded in an individual patient encounter are represented by Arrow A in Figure 1.

The validity of the information generated, processed and stored within an individual encounter is further dependent on additional characteristics of the health care provider or the processes used in their practice (Block 3 of Figure 1). These factors include the clinician's attitudes on screening for and valuation of likely outcomes associated with treatment for a given condition and a given patient [19–21], the clinician's breadth and currency of medical knowledge and ability to address specific issues relating to the patient's health state, and the large number of factors that compete for a clinician's time and attention.[22,23] For example, cardiologists, by their training, are predisposed to consider a cardiovascular etiology for patients presenting with non-specific symptoms, whereas a general practitioner may consider a broader range of initial diagnoses. Differences in training may therefore lead to differences in ascertainment of a true diagnosis of AMI. The clinician's practice structure and initiatives [24,25] may also affect the accuracy of data collected. Physicians with insufficient administrative support may systematically under or over-report certain diagnoses in their practice's documentation, leading to inaccuracies when the data is accumulated in secondary databases.

Encounter-level characteristics (Block 4 in Figure 1) may also directly affect the accuracy of health state information collected and recorded during an individual's receipt of health care services. For example, data generated during an emergency department visit for AMI may include information considered relevant to the presenting condition. A prior diagnosis of diabetes mellitus may be discovered and corroborated, but less relevant diagnoses, for conditions such as osteoporosis, may be (appropriately) ignored. If a researcher were evaluating the risk of a cardiac event associated with a therapeutic agent used by women with osteoporosis, it would be necessary to know whether a diagnosis of osteoporosis had been established for each individual in the study sample. A higher likelihood of misclassification may result if the data from the emergency department visit alone were used as the source of osteoporosis signals, as compared to an approach that included data from prior visits with a primary care physician or osteoporosis specialist. Further characteristics of the encounter, such as emergency department crowding and the availability of on-site advanced diagnostic resources, may also contribute to inaccuracies in health state determination and recording.[26,27]

Characteristics of the individual patient encounter also have the potential to interact with patient and physician characteristics to influence the validity of the health state information collected (Arrows B and C in Figure 1, respectively). For example, the venue of an individual encounter is dictated, in part, by a patient's enabling factors (i.e. insurance status,

place of residence) and predisposing characteristics (i.e. culture, social status). This is supported by a recent study by Barnato and colleagues, in which African Americans were more frequently found to present at hospitals that did not follow evidence-based AMI guidelines.[28] The propensity of the patient to report given health state characteristics is also influenced by the focus, venue and intensity of services provided during the health care encounter. Similarly, the clinician may recommend their patients seek care at specific venues for certain problems (e.g. the emergency department for those reporting severe and persisting sub-sternal chest pain; the physician's office for neck pain and nausea). The physician's approach to patient care is also influenced by characteristics of the encounter. In a study by Stenestrand and colleagues, the treatment patterns for patients with AMI were found to vary significantly among hospitals based on facility-level therapy traditions.[29] These encounter-level differences may influence the referral patterns of doctors with admitting privileges to more than one hospital, as well as the practice of physicians at a given hospital, including the extraction and documentation of health state information.

The validity of data collected within an individual patient encounter may also be influenced by characteristics of the larger environment in which health services are delivered (Block 5 in Figure 1), e.g. through the availability within a community or region of trained health care clinicians and the resources required to detect and treat fluctuations in an individual's health state; system-wide incentives, coding practices and reimbursement mechanisms; and the general evolution of medical knowledge. A recent example of diagnostic advances reflecting this latter trend involves detection of AMI with greater accuracy through the use of more sensitive cardiac biomarkers, such as serum troponin levels. If the use of newer diagnostic methods of this type is not widely adopted, the validity of cross sectional secondary database analyses may be affected. The evolution of diagnostic criteria may also impact longitudinal studies, with misclassification bias occurring among earlier cases.[30] Data on utilization of health care services from rural and resource-poor areas, which often have less access to specialists and advanced diagnostic equipment, may introduce bias in secondary databases from missed diagnoses of individuals from these regions. Conversely, in a recently published study, higher rates of colorectal cancer screening procedures among fee-for-service patients was found to be associated with higher levels of managed care activity.[31] System-wide incentives, such as hospital quality monitoring programs, may also influence the quantity and quality of data collected in a health service encounter. The relative validity of data available from hospitals participating in these programs may be greater, as compared to non-participating hospitals whose data is accumulated in the same secondary databases.

Further, community and system-level characteristics may interact with physician characteristics (Arrow D in Figure 1) to affect the accuracy of health state information collected. For example, community characteristics, such as a state's malpractice environment or the extent to which managed care health plans have penetrated a market [32] may result in different clinician practice behaviors, including increased service intensity (and availability of health state signals) [33], as well as improved accuracy of health state, diagnosis and treatment documentation.[34] The extent to which these interactions vary across large geographic areas also has the potential to introduce differences in the accuracy of signal extraction from region to region. An example of community and system-level characteristics and encounter-level characteristics interacting (Arrow E in Figure 1) to affect the quality and quantity of health state data collected within an individual encounter is illustrated by synthesizing the results of two empirical studies. In the first, hospitalists were shown to have improved communication with patients, resulting in direct effects on the course of care (and likely the quality and range of recorded health state signals available). [35] The link to community-level characteristics is found in the second study, where greater concentrations of hospitalists programs were found in regions with higher rates of managed care penetration.[36]

Patient attributes may also be modified by community and system-level characteristics (Arrow F in Figure 1) in ways that influence the validity of data collected within an individual patient encounter. Examples include the implementation of community-wide campaigns to educate members of the public on modifiable risk factors for highly prevalent chronic illnesses, such as cardiovascular disease, or the range of symptoms associated with AMI. Because these campaigns often raise public awareness about specific health issues, they have the potential to influence the propensity of patients to seek medical services and report specific health state characteristics.[13] Interactions of this type do not occur at random and are often related to the financial resources of a community. As a result, the likelihood that specific health state signals will be detected may vary considerably by community or region within a population.

2.b The Patient's Medical Record

The data generated within an individual health care encounter (subject to the influences and interactions represented by Blocks 1–5 and Arrows A-F in Figure 1) is typically stored within a patient's medical record or chart. The patient's medical chart is not explicitly mentioned in the proposed conceptual model as other types of records or forms may be used as vehicles for transferring information from an individual encounter to secondary databases (e.g. administrative forms that contain information eventually linked to a patient's health state information). Although our observations apply equally to any approach to information documentation and transfer, we will focus on the record clinicians use to document their impressions and recommendations for a patient in a health care encounter – the patient's medical chart.

In a patient's medical chart, laboratory test results and physiologic measurements are typically recorded in their entirety. In electronic records, diagnostic images may be directly imported to the patient's file. The content of the physician-patient exchange, however, is summarized and filtered by the clinician to include the details important for addressing the current health state of the patient, as well as their future health. The quantity and quality of the data recorded are based on the perceived needs of the clinician in caring for their patient, the time available, and the standards and systems implemented in their practice. In a study by Romm and Putnam [37], agreement between patient medical records and transcripts of health care encounters was highest for the presenting condition, and related factors, and was significantly lower for other aspects of a patient's health state which were viewed by the clinician as “less relevant” to the index condition. Similar results have been found in other studies comparing chart records and audio / videotapes of medical visits.[38,39]

Electronic medical records offer the potential to improve the reliability and validity of health state information recorded for patients and to ease the extraction of information for accumulation in secondary databases or for medical chart review studies. However, electronic medical records may not avoid all sources of bias associated with paper-based records. Systematic errors, for example, based on a clinician's typing or computer skills, may still occur. In a recently published study, a pain assessment tool was added to an electronic medical record system with the goal of reducing the rate of missed diagnoses. However, pain diagnoses did not increase with implementation of the new system, and in fact, decreased due to clinicians' perceived burden associated with its use.[40]

2.c The Secondary Database

Block 6 of the proposed conceptual model represents factors influencing the processing of health state information from a patient's medical chart (or other intermediary record) for storage within a secondary database. In general, two filters influence the accuracy of data contained within a secondary database.[41] The first filter arises from the database's

intended purpose and the resulting structure and policies developed by the database creators and ongoing administrators to govern how and what data is entered and stored. This first filter includes system-level efficiencies, such as quality control checks, data cleaning, and imputation of missing values. The second filter results from the policies and procedures for coding data into the database, as implemented by the interfacing health system or clinician. For administrative databases, these coding practices are aimed at maximizing the clinician's or organization's abilities to provide data that supports timely and optimal reimbursement. Systems may be put in place to ensure primary diagnoses, AMI in our example, are coded as accurately as possible. Secondary and tertiary diagnoses, which may not be linked to reimbursement, do not typically receive such careful attention.

The organization of data within a secondary database is driven by the need of database creators to reduce the resources required to extract data signals for administrative or clinical tracking of large groups of patients. For example, the recorded presentation of a given health state may be grouped together with similar, but not identical presentations, in relatively broad diagnostic classifications. The International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM) diagnostic codes have been commonly used in administrative databases. In 1992, the World Health Organization provided an update, the International Classification of Diseases, 10th Revision (ICD-10), which includes more diagnostic categories to provide additional detail and accuracy in coding. A diagnosis of AMI under ICD-9-CM may be considered to fall under the 410.x and 412.x codes, while under ICD-10, three coding categories, I21.x, I22.x and I25.2, may be used now.[42]

The validity of data in secondary databases can be optimized, in part, through the use of coding categories that are exhaustive (all possible scenarios are covered by the full set of categories) and mutually exclusive (there is no overlap between categories). In practice, this may not always be possible. The absence of consensus on the most appropriate coding categories or of clear clinical diagnostic criteria may introduce systematic error in recording at the level of the coder and clinician, respectively.[41] This risk is demonstrated by the recent work of Quan, Sundararajan and colleagues.[42,43] In this work, new algorithms have been proposed for the Charlson and Elixhauser comorbidity indices using the ICD-10 diagnostic codes to replace those based on ICD-9-CM.[44–48] Development of the ICD-10 algorithms involved a multi-step process, including review and consensus building among coders and clinicians. Through this process, enhanced ICD-9-CM algorithms also emerged to address inconsistencies in the clinical definitions previously employed and to better align future studies that would include both ICD-9-CM and ICD-10 coded data.[42]

Transitions to new or updated coding algorithms create significant risk of bias in secondary database analyses. Although these revisions are designed to improve the validity of future data, they create significant challenges for the researcher in making cross sectional comparisons among data sets, if different coding systems are used, or in longitudinal studies, when the coding algorithm for the secondary database has been changed at a given point in time. The transition periods, when a secondary database is switched from one coding algorithm to another, heighten risk for systematic errors as coders learn to implement the new system.

3. Discussion

In the past, studies examining the accuracy of secondary databases have been limited in their scope. Researchers have focused on a specific source and their ability to detect individual characteristics [49–54], assess the severity of a condition of interest [55,56], or differentiate between complications and comorbidities.[57–59] These have been primarily methodological studies, highlighting the challenges associated with the use of secondary

databases for epidemiological and health services research. In empirical research using secondary database analyses, it is standard practice to report estimates of random error through the use of confidence intervals. Systematic error, or bias, however, is usually dealt with only qualitatively in the limitation section of the report, with little attention given to the complexity described. This is changing, however, with recent calls for quantitative assessment and reporting of potential bias in effect estimates and suggestions made as to method and presentation.[1,2,4]

The conceptual framework presented in this article integrates theory and existing empirical evidence to illustrate points at which the validity of health state information contained within secondary databases may be influenced by multiple dynamic factors. These factors reflect the complexity of health care delivery and service utilization. Our discussion is not meant to disparage secondary database analyses. No source of health state information is perfect, nor ever will be. With these inherent limitations, however, we reduce the value of conclusions derived from secondary database analyses if we do not find efficient methods to use the information content available. At a minimum, we should explicitly and quantitatively acknowledge the uncertainty present, from all sources, in the form of both imprecision and inaccuracies.

As all models are simplifications, we are guilty of reducing the information content of our discussion by relying on conceptualizations to convey the complexity encountered in collection and processing of health state information. For example, we have largely ignored the impact of prior health care encounters and historical medical records on the quantity and quality of health state information collected in the present encounter. The issues discussed here challenge researchers to acknowledge the multiple sources of bias in assessing individuals' health state characteristics using secondary databases. A greater awareness of these biases may lead to further innovative strategies to reduce the limitations inherent in analyses of secondary databases and improve the accuracy and application of insights derived from this work.

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Figure 1.
Conceptual Framework to Identify Sources of Bias in Health State Characteristics Derived from Secondary Databases.