



Published in final edited form as:

Med Care. 2012 July ; 50(0): S30–S35. doi:10.1097/MLR.0b013e318259c011.

Diabetes and Asthma Case Identification, Validation, and Representativeness When Using Electronic Health Data to Construct Registries for Comparative Effectiveness and Epidemiologic Research

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Abstract

Advances in health information technology and widespread use of electronic health data offer new opportunities for development of large scale multisite disease-specific patient registries. Such registries use existing data, can be constructed at relatively low cost, include large numbers of patients, and once created can be used to address many issues with a short time between posing a question and obtaining an answer. Potential applications include comparative effectiveness research, public health surveillance, mapping and improving quality of clinical care, and others. This paper describes selected conceptual and practical challenges related to development of multisite diabetes and asthma registries, including development of case definitions, validation of case identification methods, variation in electronic health data sources; representativeness of registry populations, including the impact of attrition. Specific challenges are illustrated with data from actual registries.

Keywords

Registries; Comparative Effectiveness Research; Surveillance; Diabetes; Asthma

Introduction

Patient registries are defined as “an organized system that uses observational study methods to collect uniform data (clinical and other) to evaluate specified outcomes for a population

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The authors declare no conflict of interest.

defined by a particular disease, condition, or exposure, and that serves a predetermined scientific, clinical, or policy purposes.”[1] Large administrative datasets and regional and national patient registries have been used for decades to support clinical research, public health surveillance, quality improvement, and accountability activities in the United States and other countries.[2–9] Advances in health information technology (HIT) and widespread implementation of electronic health data (EHD), including increased access to clinical data, offer new opportunities to establish large disease-specific registries, cohorts, and databases, especially for managed care systems, large integrated health systems, large medical groups with sophisticated EHD systems, and large public and private insurers.[10–13]

Because such registries use existing data, they can be constructed at relatively low cost, include large numbers of patients, and once constructed, be used to address many issues with a short time between posing a question and obtaining an answer. Potential applications include: (a) comparative effectiveness research (CER) that assesses the relative effectiveness of various treatments and systems of care in defined patient populations; (b) filling knowledge gaps that are ethically and/or logistically not feasible for randomized controlled studies, or that require large samples like studies among specific subpopulations or studies of rare conditions; (c) public health surveillance of diseases, risk factors, patterns of care, undesirable side effects of care, and quality of care; and (d) for identifying patient and care factors associated with important clinical outcomes or with resource use. [14–18]

Essential tasks in developing and applying results from any health registry or research study include identifying cases and understanding the population from which the cases are derived. In this article, we focus on EHD case identification and validation, the influence of different EHD data sources, and population representativeness, including issues of attrition. Our discussion is drawn from ongoing experiences in developing two large multi-site disease-specific registries: (a) The SUPREME Diabetes DataLink (DataLink) includes 12 sites with 1.2 million persons with diabetes, and (b) the Population-based Effectiveness in Asthma and Lung Diseases (PEAL) Network, which has identified patients with lung diseases, including almost 1.4 million patients with asthma at four HMO Research Network (HMORN) sites plus Tennessee’s TennCare (Medicaid) population. The DataLink and PEAL Network are two initiatives that build on the data resources of the HMORN, a consortium of 16 private integrated health care systems across the United States and in Israel comprising of over 11 million enrollees.[13] Both projects receive funding from the Agency for Healthcare Research and Quality (AHRQ) with an emphasis on constructing multi-site EHD-linked registries for CER. Issues of governance, confidentiality, protection of human subjects, and technical issues like data architecture, integration, consolidation, cleaning, storage, and management are clearly key considerations in the creation and use of registries for CER but they are beyond the scope of this discussion. [1, 19–21]

Cases Definitions for Diabetes and Asthma

Establishing valid case definitions to identify those with diabetes or asthma is a fundamental task in registry construction. However, the task is complicated by the fact that there is often no feasible gold standard for assessing validity of case definitions derived from EHD. Numerous epidemiological studies have tried to assess and improve on case definitions for

diabetes and asthma with self-report or medical record review as criterion measures.[22–30] Diabetes validation studies have found relatively good sensitivity (76%–97%), specificity (95–100%), and predictive positive values (PPV) up to 94% using various EHD algorithms compared to the medical record.[24, 25] Accuracy of pediatric asthma (sensitivity: 44–92%; specificity: 80–94%) and adult asthma (sensitivity: 68–95%; specificity: 59–90%) are more variable, complicated by variation in severity and the remission and relapse of asthma in patients. [23, 31] Verification of asthma at a single point in time based on biological measures is difficult because those with asthma may have normal pulmonary function off medications at many points in time and spirometry or other validated pulmonary function testing is often not done. [32] Although diagnostic standards for diabetes are clearly linked to glucose and A1c thresholds, diabetes patients receiving active lifestyle or pharmacological treatment may have normal glucose and A1c levels when tested. Unlike university-based research registries that often only include patients with advanced disease states who meet rigorous criteria for diagnosis of a specific condition, EHD-based case definitions often rely heavily upon diagnosis codes, routinely done laboratory tests, and pharmacy data.

Lack of a rigorous biometric gold standard for classification of diabetes or asthma status using routinely collected clinical data makes it difficult or impossible to precisely determine the sensitivity, specificity, and PPV of proposed case identification methods. However, we can approach this conceptually and then practically. Ideally we want to maximize both sensitivity and specificity, with the latter leading to improved PPV by reducing false positives. Unfortunately, there is typically a trade-off between sensitivity and specificity and we have to decide which is more important in chronic disease case identification. Furthermore, PPV is driven by the prevalence of a condition, the lower the prevalence, such as with diabetes and asthma, the lower the PPV even with sensitivity and specificity above 90%. [33] Registries designed to support clinical management, patient outreach, or practical randomized interventions require high certainty that identified cases truly have the condition of interest and, therefore, would be designed to maximize PPV. This can be done by using a restrictive case definition but often at the expense of lowering sensitivity (the likelihood that all those with the condition of interest will actually be identified). For example, requiring three or more diabetes diagnosis codes would usually assure relatively high PPV but likely miss many cases. In contrast, requiring only one diabetes diagnostic code for diabetes will increase sensitivity but will very likely include many false positives and yield lower PPV. [25] While registries to guide clinical interventions want to maximize PPV, registries to support public health surveillance, population-level monitoring of care quality, accountability, and health services research, or to support CER studies may often be better designed to maximize sensitivity from the outset with refinement as needed. In many cases, such as public health surveillance, it is important to capture the vast majority of cases consistently over time, despite including more false positives.

The approach taken by both the Diabetes DataLink and the PEAL Network was to initially maximize sensitivity by using broad case definitions to capture all persons with any indication of diabetes or asthma. Such an approach allows flexibility in tailoring case definitions to particular studies by subsequently applying more stringent criteria. For example, if the high sensitivity registry includes all those with one or more diabetes

diagnosis codes, PPV could be increased by identifying a patient subset based on two or more codes. Note that if a registry attempts to maximize PPV initially, for example, by requiring two or more diagnosis codes, it is not possible to extract from this registry all those with only one or more diabetes codes.

Therefore, the DataLink initially captured patients with any indication of diabetes based on diagnosis codes, diabetes-specific pharmaceutical use, or elevated glucose or glycated hemoglobin (A1c) values. This was further refined to identify prevalent diabetes cases as patients who met at least one of the following criteria within a 18-month period: 1+ diabetes-specific medication, 1+ inpatient diabetes diagnosis, 2+ face-to-face outpatient diabetes diagnoses on separate days, *or* 2+ elevated blood glucose values performed on separate days or one elevated oral glucose tolerance test. This method is based on prior studies and is compatible with the then-current diabetes definition used by the National Committee on Quality Assurance (i.e., HEDIS).[3, 24, 25] The current DataLink case definition is unable to distinguish type 1 and type 2 diabetes. However, it does capture persons with undiagnosed diabetes who meet blood glucose laboratory criteria but have no diagnosis or treatment. As expected, patients who may have clinical diabetes but do not have a diagnosis, take no glucose-lowering pharmacotherapy, and have no laboratory glucose or A1c tests would be missed.

The PEAL Network has identified an initial set of patients with lung diseases, including asthma, based on ICD-9 codes. At the start of each study, more specific case definitions will be employed. For example, a few studies with TennCare data identify pediatric asthma cases using an established modified HEDIS algorithm incorporating diagnostic coding and asthma-specific medication use. [23] Criteria include: (a) at least one inpatient, outpatient, or emergency department (ED) claim listing asthma (ICD-9 493.xx) in any discharge diagnosis fields during an 18-month period, a time frame intended to capture at least one well-visit for minimally symptomatic children presenting once a year for routine preventive care to their physician.[23, 34, 35], or (b) 2+ prescriptions for any short-acting beta-agonist or 1+ prescriptions for any other asthma medication (inhaled anti-inflammatory, long-acting beta agonist, leukotriene modifying drug) during an 18-month period will be considered to have asthma. To further increase specificity of the definition, asthma diagnosis is limited to children of school age because 'transient early wheezing' instead of asthma is often diagnosed at younger ages.

Both the diabetes and asthma definitions represent base case definitions which may be further refined or restricted based on the desired balance between sensitivity, specificity, and PPV. Most CER studies start with an inclusive base case definition and then apply additional inclusion and exclusion criteria. For example, a CER study comparing two treatments head-to-head in real world settings, may exclude from analysis those with any contraindication to either one of the comparators. If metformin and sulfonylurea are to be compared, those for whom either of the treatments is contraindicated (sulfa allergy, renal dysfunction, congestive heart failure, others) would be excluded prior to analysis to enable a fair comparison of the two treatments on clinical outcomes such as cardiovascular events or mortality.

To address concerns about validity, there are several ways to build confidence in EHD-based case definitions. One approach used within both the Diabetes DataLink and the PEAL Network is to extend the time frame used to identify or confirm cases. In developing a diabetes case definition, the DataLink relies on previous EHD work that found 18-month to 2-year time frames were reasonable to allow for at least two diabetes outpatient visits or two elevated blood glucose labs, the latter being current diagnostic practice.[6, 24, 25] A similar rationale is applied in the TennCare with an 18-month window for case identification. [34, 35] However, it may be worthwhile for investigators to vary these time periods and assess impact on case capture rates, recognizing that shorter time periods often identify fewer cases but they are more likely to be ‘true’ cases, but may also be more severe cases.

Another use of time is to periodically re-apply the case definition to a patient population every few months or else to use a rolling identification process. This may increase sensitivity by capturing those with mild asthma that only relapses periodically, or picking up initially euglycemic diet-controlled diabetes patients as they drift into higher A1c ranges or require pharmacotherapy over a longer period of time. [23, 27] In the Datalink, a rolling case identification process is applied over a multi-year period, resulting in a dynamic cumulative prevalence cohort as more and more years of EHD become available. This increases case capture relative to the traditional static approach that may where a defined calendar time period is used to identify cases which results in a unique cohort followed over time without adding new cases. The time frame and process used for establishing the cohort are important because they can yield different results. For example, in one DataLink health system, the prevalence from identifying cases within only a 2-year period (2008–9) is 7.4%. If the rolling cumulative approach is used from 2000 through 2009, the prevalence is 8.2%. With the rolling approach static cohorts or serial cross-sectional samples of persons with diabetes can still be created.

Another important strategy to improve capture of ‘true’ cases is to adopt more restrictive case definitions. For example, instead of requiring at least two outpatient visits with a diabetes diagnosis in two years, one might require three such visits during that same time frame. Applying more stringent case criteria increases PPV, while using less stringent criteria maximizes sensitivity, as discussed earlier.

Weiner et al suggest a third strategy—using a Bayesian inference engine to assign confidence probabilities to case identification. [36] A conceptually similar but computationally simpler approach is to determine how many of a set of diabetes or asthma case definition criteria or data sources are met within specified time intervals. The more met, the greater the confidence that a “true” case has been identified. For example, in the DataLink the primary data sources for case identification are diagnosis codes, pharmacy use, and laboratory values. In one DataLink system, over a 2-year period (2008–9) 18.1% of cases were identified based on meeting criteria from only one source, 36.2% were captured by independently meeting criteria from two sources, while 45.6% independently met criteria from all three data sources. This might suggest more case confidence for those meeting multiple qualifying criteria compared to only one qualifying criteria. Alternatively, a higher confidence probability could be placed on the 65.1% of cases qualifying through lab values.

Such methods can be used to tailor the performance characteristics of a registry to the purpose for which it is used, and thus increases confidence in specific case definition criteria, which may vary across registry applications. These strategies have been used in developing the DataLink and PEAL networks, but there is much that remains to be done to better understand and quantify the impact of case definition strategies on relative sensitivity, specificity and PPV. Furthermore, applying a range of case identification strategies from broad to more restrictive may help assess the robustness of study results.

Variation in Registry Members related to Sources of Data

Data sources available to those who are constructing a registry may influence the number and the characteristics of registry members, and have far-reaching consequences when registries are used for certain purposes.[37] When registries based on different sources of data are used to compare quality of care or assess patterns of care across care systems, bias may be introduced into those comparisons. Claims-based diagnoses (i.e., outpatient and inpatient) are the most commonly available EHD, followed by pharmacy claims and lab data. In the TennCare population, 49% of child asthma cases were identified by asthma specific medication claims only, 12% by claims-based diagnoses codes only, and the remainder (39%) by both data sources. Table 1 examines the capture of prevalent diabetes cases at one Datalink Health System. During a 2-year period (2008–9), 91.4% of cases were identified based on two or more outpatient claim-based diagnosis codes. The sequential addition of cases based on different data sources yielded 0.8% from one or more inpatient claims diagnosis codes, 4.8% from one or more diabetes-specific medication claim, and 3.0% from at least two elevated blood glucose labs. This suggests that available electronic outpatient and pharmacy claims information identify virtually all diagnosed diabetes cases, with few new cases added through inpatient claims. Table 1 also suggests that cases identified solely through one source may have different characteristics. Those captured only through inpatient diagnoses tend to be younger women with low HbA1c levels suggesting pregnancy-related identification, even with the deliberate exclusion of pregnancy-related diabetes diagnoses codes. Pharmacy only cases also tend to be younger but in poorer health (some may be on diabetes medications for polycystic ovarian syndrome) while it is likely that those identified only by laboratory data are those with undiagnosed and untreated diabetes – a group of special interest in some studies – as their HbA1c levels are lower. Interestingly, the percent meeting diabetes recommended LDL-c and blood pressure level thresholds are lower as might be expected since they are not being managed to these levels.

Variation in diagnosis coding or in data entry practices can result in missing information and impact case identification, thus biasing comparisons across clinics, medical groups, or care systems. Currently, there is considerable variation in diagnostic coding practices within and across care systems. [38] Some experts believe that broader use of EMRs will likely improve standardization and comparability of coding practices because primary care provider coding patterns can be easily compared and outliers identified and corrected.[38] However, issues of omission and commission may persist. Diagnosis and medications may not be captured in structured formats but only in text notes. The increased use of natural language processing technologies may improve this by identifying key information (i.e., diagnoses and medications) from notes and translating it into a structured format. [39]

Another concern is technology or databases not effectively interfacing with EMRs such as with point-of-care desktop analyzers not being integrated into EMRs or lab databases. Dual or supplemental insurance coverage may also vary across demographic subgroups, care systems, or time, and may result in incomplete outpatient, inpatient, or pharmacy claims data. EMR-derived data may also be incomplete if a subject receives care from different systems. External factors such as changes in diabetes or asthma diagnostic criteria and care recommendations, reimbursement practices, or the increasing attention to accountability measures may all influence data accuracy and completeness in unanticipated ways and may vary locally, nationally, and over time. There is currently no systematic approach to monitoring such variation or its impact on EHD quality. The creation of large nationally representative registries provides the opportunity to examine these issues and variation in greater depth.

External Validity or Population Representativeness

The enrolled populations of health systems in the DataLink and PEAL Network are defined by insurance coverage, geographical scope, and, for diabetes, receiving care from medical groups that use EMRs. Although both registries include robust samples of those with Medicaid, Medicare, and commercial health insurance, subjects with no health insurance may be under-represented. In recent years the uninsured 0–64 years of age were 6% in Minnesota and 21% in Tennessee.[40] However, for CER studies, the important question is whether populations receiving health care services are adequately represented. A CER study comparing two different diabetes education strategies in a clinic serving predominantly higher income patients is likely to have different results than the same study done at a federally qualified community health center. Large registries such as DataLink and PEAL provide excellent opportunities for a wide range of CER studies. They have substantial age, race, ethnic, and socioeconomic diversity, and the members of these registries receive care from many providers and health systems in the region. Furthermore, if case identification is based on EMR data many uninsured patients may also be included.

Population representativeness is also affected by the inevitable attrition with time in any registry or traditional study cohort. Potential consequences, such as loss of study power, bias, or generalizability, may occur but are also influenced by specific study designs and aims. Fewtrell and colleagues have suggested minimum reporting requirements to address attrition.[41] These include providing clarity on the flow of participants at each stage of the cohort, the ability of the final sample size to detect the hypothesized outcome effect, the potential for bias, generalizability, and appropriate sensitivity analyses. [41]

In the Diabetes DataLink and PEAL Network the main source of attrition is disenrollment due to changes in insurance coverage. This may be moderated in integrated health systems or Accountable Care Organizations, and even with changes in coverage individuals may remain in the same provider system, particularly older patients with chronic conditions. Therefore, their EHD may often remain available. Once again using a single DataLink system as an example, among the 2004 prevalent diabetes cohort, there was 47.2% attrition by 2010. Of this, an absolute 9.7% died and an absolute 37.5% disenrolled. In a 2006 incident cohort, those lost due to disenrollment tended to be younger (18–44 years of age)

and have worse HbA1c and LDL-c control at baseline. Various analytic strategies can be used to compensate for bias introduced by attrition, but a full discussion of these is beyond the scope of this paper. [41, 42]

Summary and Conclusions

Registries based on administrative data available in Medicaid and Medicare are useful for tracking prevalence, health care utilization, and costs in some of our most vulnerable populations. However, many registries now combine administrative data with more detailed clinical data including vital signs, laboratory tests, and even the verbal data from office notes. The potential applications of such registries for CER, surveillance of patterns of care, and other purposes are much greater than what has been previously available in the U.S. There are many strategies available to establish the accuracy of case definitions when clinical and administrative data are available. A guiding principle in chronic disease registry design is to initially be as inclusive as possible of cases, and then subsequently apply more restrictive case definitions for specific research purposes. Despite recent advances, challenges still remain in accurately identifying cases of diabetes or asthma, constructing dynamic population cohorts, assessing data quality, and understanding how biases related to attrition and other factors may influence cohort characteristics and, ultimately, study results.

Acknowledgments

Funding was provided by a contract from AcademyHealth. Additional funding was provided by AHRQ 1R01HS19859 (SURveillance, PREvention, and ManagEment of Diabetes Mellitus (SUPREME-DM)), AHRQ 1R01HS19669 (The Population-Based Effectiveness in Asthma and Lung Disease) and HMORN UCSF Center for Diabetes Translational Research P30 DK092924.

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TABLE 1
 Sequential Identification and Select Characteristics of Prevalent Diabetes Cases Based on Qualifying Criteria From January 1, 2008 Through December 31, 2009 at 1 Participating DataLink Site

		Case Definitions ^W						
		A	B	C	D	E	F	G
Population Characteristics*	Prevalence	Inpatient Diagnosis Codes Only		Outpatient and Inpatient Diagnosis Code		Additional Pharmacy Claims Only		All Claims + Laboratory Values (All Criteria)
		Outpatient Diagnosis Codes	Codes Only	Codes Only	Diagnosis Codes+Pharmacy Claims	Laboratory Only	Laboratory Only	
N (%)		12,916 (7.0)	111 (0.1)	13,027 (7.1)	140 (0.1)	13,167 (7.1)	422 (0.2)	13,589 (7.4)
Female (y) (%)		49.1	59.5	49.1	54.3	49.2	50.2	49.2
0-17		1.1	0.9	1.1	2.1	1.1	0.5	1.0
18-44		11.9	26.1	12.1	31.4	12.3	8.5	12.1
45-64		48.5	39.6	48.4	33.6	48.3	44.1	48.1
65-74		18.7	9.9	18.6	7.9	18.5	22.5	18.7
75+		19.8	23.4	19.8	25.0	19.9	24.4	20.0
Body mass index								
Mean (kg/m2)		32.58	33.63	32.59	31.48	32.57	30.53	32.50
Z 30 kg/m2 (%)		40.5	36.0	40.5	47.1	40.5	54.7	41.0
Current smoker (%)		11.2	11.4	11.2	27.6	11.3	15.2	11.5
HbA1c								
Mean		7.18	6.34	7.18	7.40	7.18	6.35	7.16
< 8 (%)		80.8	90.9	80.9	75.9	80.8	98.0	81.3
LDL-c (mg/dL)								
Mean		85.91	85.27	85.91	102.03	86.01	97.58	86.35
< 100 (%)		73.5	70.6	73.5	50.8	73.3	55.8	72.8
Systolic blood pressure (mm Hg)								
Mean		124.40	122.22	124.38	124.98	124.39	125.51	124.43
< 130 (%)		71.1	72.0	71.1	65.8	71.0	59.2	70.6
Diastolic blood pressure (mm Hg)								
Mean		70.78	70.99	70.78	72.17	70.79	72.11	70.84

Case Definitions ^W		A	B	C	D	E	F	G
Population Characteristics*	Outpatient Diagnosis Codes	81.4	Inpatient Diagnosis Codes Only	71.0	Outpatient and Inpatient Diagnosis Code	81.3	Additional Pharmacy Claims Only	75.0
< 80 (%)		81.4		71.0		81.3	Diagnosis Codes+Pharmacy Claims	70.9
							Laboratory Only	80.9
								All Claims +Laboratory Values (All Criteria)

* Most recent values by December 31, 2009.

^W Qualifying case identification criteria: between January 1, 2008 and December 31, 2009, (a) at least 2 outpatient claims with diabetes diagnosis claims (ICD-9-CM codes 250.xx, 357.2, 366.41, 362.01–362.07) on separate days; (b) at least 1 inpatient claim with diabetes diagnosis (same ICD-9-CM codes); (c) at least 1 pharmacy claim for an antihyperglycemic medication except for metformin, thiazolidinedione, or exenatide; or (d) at least 2 elevated tests of HbA1c, fasting plasma glucose, random plasma glucose, or some combination of these and measured on separate days.