Comparing Shingles Incidence and Complication Rates From Medical Record Review and Administrative Database Estimates: How Close Are They?

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Accurate rates of herpes zoster incidence and complication have become of greater interest as studies have suggested an increasing temporal trend in incidence rates across all age groups and long-term follow-up studies of vaccine effectiveness are required by the Food and Drug Administration. This study compares the results obtained from the most commonly used method to obtain herpes zoster data (rates obtained from administrative data) with results obtained when administrative data are supplemented by medical record review. Administrative billing code data identified 1,959 cases of herpes zoster in Olmsted County, Minnesota, adults between January 1, 1996, and December 31, 2001. Of those 1,959 cases, 1,669 (85.2%) could be confirmed by medical record review, a decrease in incidence rate of 14.8%, resulting in a decrease of 0.61/1,000 person-years when adjusted to the US adult population. Complication rates were also significantly different between the 2 methods. It is not clear if the 15% decrease in incidence rates would be seen in every administrative data set or if the lack of confirmation of cases may be variable in both validity and reproducibility between data sets, making estimations in temporal trends and pre/post-vaccine rates difficult to compare across data resources.

administrative records; data collection; epidemiologic methods; herpes zoster; incidence rates

Abbreviations: HICDA, Hospital International Classification of Diseases Adapted; HZ, herpes zoster; ICD-9, International Classification of Diseases, Ninth Revision.

The approval of a vaccine to prevent herpes zoster (HZ) and postherpetic neuralgia in adults (1–3) has rekindled interest in the epidemiology of HZ (4–17). In particular, reliable and reproducible rates of zoster occurrence and complications will be needed to assess the national impact of HZ vaccination. Although simple administrative data counts may provide estimates of occurrence rates, few detailed data have been published to assess the relative accuracy of the administrative data versus medical records data in estimating occurrence rates or HZ complication rates (18–22).

Administrative data studies simply use a code of HZ or an HZ complication as a proxy for an HZ incidence case. Therefore, incidence rates become a straightforward tally of all administrative codes in the desired age range or by gender specification. Several types of administrative data have been used for such incidence estimates: single-insurer populations such as those covered by large health maintenance organizations (4), provincial populations (12), or country-wide populations (4, 5, 8, 10, 13, 22, 23). Such populations are usually large and are selected because they have data in a uniform electronic format that makes it efficient and relatively inexpensive to search for billing codes for HZ care. However, the breadth of the administrative data may vary by source (e.g., may not include emergency department, urgent care, or hospital-provided care), which underestimates the incidence rate (10). In addition, administrative data are often coded by nonphysicians who must interpret diagnoses, such as “rule out” or “identify” a diagnosis, to justify a viral culture or other test used to differentiate among a list of possible causes for rash or pain (24, 25). Estimating complication rates by using administrative data (usually billing codes) may produce widely variable estimates depending on whether and how physicians and coders choose to document and identify complications.
This study compares the HZ occurrence and complication rates obtained from administrative data sources and administrative data sources supplemented by medical record review. We explore potential reasons for differences and estimate the impact of each method on future assessments of HZ incidence and complication rates in the post-HZ vaccine era (19, 20, 23, 26, 27).

**MATERIALS AND METHODS**

This is a community population-based study comparing the estimated rates of occurrence of HZ and HZ-related complications as obtained from administrative data with estimates obtained from administrative data supplemented by medical record review. All adult residents of Olmsted County, Minnesota, aged 22 years or older who sought medical care for HZ between 1996 and 2001 were included. No attempt was made to identify community residents who may have had HZ but did not seek medical care. The methods have been presented in detail previously and are presented here only in brief except for the information required to understand the methods of administrative data retrieval and medical record review (14).

Olmsted County provides a unique population setting in which virtually all county residents’ medical care can be followed across all health-care systems within the county. The 2 main health-care systems, the Olmsted Medical Center and the Mayo Medical Center, provide care to people of all ages and with all types of insurance, as well as the uninsured. All patients have visit-specific records kept within their care facility and visit-specific diagnostic and procedural information warehoused within the Rochester Epidemiology Project database (28, 29). A person-specific identification number unique to the Rochester Epidemiology Project database is used to link each diagnostic or procedural code, including laboratory tests and surgical procedures, to the person as well as the site where the service was delivered (e.g., Olmsted Medical Center, Mayo Medical Center, or a specific hospital site). Over 94% of all Olmsted County residents have provided research authorization allowing inclusion of their medical records in population-based epidemiologic work (30, 31). Over 98% of all care provided to Olmsted County residents is provided within the county (32). Thus, the Rochester Epidemiology Project provides population-based medical data on the residents of Olmsted County, Minnesota.

**Identifying HZ subjects**

The Rochester Epidemiology Project database was searched for all patients who were residents of Olmsted County, Minnesota, and who had a diagnostic code related to HZ between 1996 and 2001. Specifically, we searched for patients with *Hospital International Classification of Diseases Adapted* (HICDA) (33) (Mayo Medical Center coding system) or *International Classification of Diseases, Ninth Revision* (ICD-9) (34), codes for HZ or HZ complications, such as postherpetic neuralgia and Ramsay Hunt syndrome (053.xx including 053.0, 053.10, 053.11, 053.12, 053.13, 053.19, 053.20, 053.21, 053.22, 053.29, 053.7, 053.71, 053.79, 053.8, and 053.9, as well as 351.0 when accompanied by 053.xx) (34). Initially, 2,176 potential incident cases of HZ were identified between 1996 and 2001 in Olmsted County residents 22 years of age or older. Of those, 48 were removed because they were not yet 22 years of age on the date of the incident diagnosis. An additional 137 individuals were not Olmsted County residents on the date of the HZ diagnosis, and 32 individuals did not provide permission for their medical records to be reviewed for research. This left 1,959 cases that were included in the comparison of administrative data and administrative data supplemented by medical record review of HZ incident and complication rates.

For each of the 1,959 potential subjects who were identified by administrative data and met the age and Olmsted County residence criteria, an in-depth review was completed of all of their medical records at all health-care sites where they received care within Olmsted County, Minnesota, between 1996 and 2001. The medical record notes were searched for 1) a physician’s diagnosis of HZ or an HZ complication (i.e., HZ affecting the eye) with documentation of a localized rash and pain or other dysesthesia or 2) a documented physician’s diagnosis of an acute localized rash or pain with a Tzanck smear, viral culture, or polymerase chain reaction test positive for herpes zoster virus. This required that, in addition to medical notes, laboratory data (cultures, polymerase chain reaction tests, and Tzanck smears) and tissue biopsies were reviewed. No case was considered a confirmed incidence case from medical record review unless at least 1 of these 2 criteria was met. Confirmation of an HZ complication required a physician’s diagnosis related specifically to that complication, such as an ophthalmologist’s diagnosis of HZ eye involvement. A diagnosis of secondary skin infection also required a positive skin culture (bacterial). The diagnosis of postherpetic neuralgia required a specific diagnosis of pain or postherpetic neuralgia in the same site as the original HZ rash at least 90 days after the acute HZ onset.

During medical record review, HZ cases identified by administrative data could only be confirmed or denied. No cases of HZ occurrence that were not coded in administrative data could be identified. However, during rate assessment of complications, all confirmed HZ cases had complete review of their medical records that allowed identification of complications with no documented administrative or billing codes. For example, a medical note might state that the patient continues to have pain at the HZ site and that a pain-related medication was prescribed, but no diagnostic code for HZ-associated pain or postherpetic neuralgia was entered. Medical record abstraction processes were assessed regularly for interrater reliability (35).

The cases identified by administrative codes used all codes for HZ and HZ complications that are currently available or were available between 1996 and 2001. Because we were assessing incidence, only the first occurrence in the time period was counted for each person. Very early in the medical record review process, it became clear that codes for postherpetic neuralgia were used as early as the day of HZ diagnosis and that use varied widely among physicians. We therefore chose to use other criteria to identify
postherpetic neuralgia, namely, continued notation of pain at the site of the HZ or continued prescribing of pain-related therapy for pain at the site of the HZ, with the last day of noted pain remaining 6 months or longer to be 30 days from the last recorded pain medication prescription or refill. This estimate was based on the assumption that most long-term pain medications are prescribed in amounts of a 30-day supply.

Data analysis

Crude incidence rates were calculated by using the number of incident cases from the administrative data and the confirmed cases from the medical record data as numerators. The denominators were the number of Olmsted County residents aged 22 years or older based on extrapolation for each year from 1996 to 2001 by using US census data (http://www.census.gov/). Incidence rates were stated as per person per year rates and were then compared by simple division, providing relative differences. Rates were also compared by subtraction of rates generalized to the US population to provide absolute differences. A 95% confidence interval for the percent increase in number of cases was computed by assuming a Poisson distribution for the number of additional subjects. Complication rates were handled similarly.

RESULTS

Administrative data review yielded a total of 1,959 people with a new ICD-9 code for HZ or an HZ complication during the study period of 1996–2001. Of those 1,959 adults aged 22 years or older at the time of the HZ code, 1,669 (1,669/1,959 = 85.2%) cases had medical record confirmation of the HZ diagnosis. The rate of medical record confirmation of administrative data cases was slightly higher in men (89%) than in women (83%) (P > 0.05) but did not vary by decade of age. The age and gender characteristics of the people identified from administrative data (n = 1,959) and by medical record confirmation (n = 1,669) are shown in Table 1.

Failure to confirm cases identified from administrative data by using medical record review fell under 3 major areas: misclassification, apparent coding errors, and the timing of coding based on episode of care rather than date of occurrence. The largest group of misclassifications for incidence estimates occurred when an HZ code was given for a diagnosis of history of HZ or family history of HZ in a person with no evidence of an acute HZ episode. The second most common issue was the use of an HZ code in a person with another type of viral infection (primarily herpes simplex infections confirmed by viral testing) (n = 84). Despite

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<th>No.</th>
<th>%</th>
<th>Males</th>
<th>No.</th>
<th>%</th>
<th>Females</th>
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<td></td>
<td>1,208</td>
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the medical record’s inclusion of test results confirming herpes simplex while failing to confirm herpes zoster, in none of these cases did a herpes simplex code appear within 3 months of the original HZ code, meaning that the administrative code was never corrected. For another 77 individuals, limitations of the current diagnostic coding systems (ICD-9 and HICDA, the coding system Mayo Clinic used at the time of this study) were responsible for the differences. In each of these cases, the diagnostic code for HZ was used for the visit, but the medical record noted that HZ was only part of a differential diagnosis or that HZ was under consideration (e.g., “rule out HZ” or “consider HZ vs. herpes simplex virus”). In each of these cases, HZ was later ruled out by culture, polymerase chain reaction, or an alternative diagnosis for the rash or pain confirmed at the next visit. For 50 people, a code for HZ was used when the medical notes stated that the person was being treated for postherpetic neuralgia, and no visits for acute HZ could be found within the previous 12 or following 3 months. In 13 cases, no diagnosis of HZ, any HZ-like rash, or any testing for HZ could be identified in the medical record notes or laboratory data. These were presumed to be coding errors (Figure 1). Five adults had acute chickenpox, but their illness was coded as HZ instead of as varicella. Four patients had the code of HZ recorded in a year different from the one in which the HZ occurred (presumed data entry errors). These 4 cases occurred in the first or last month of a calendar year with coding in the previous or next year, respectively.

Using administrative data alone resulted in an HZ occurrence rate that was 17.4% higher (95% confidence interval: 15.4, 19.5) than the rate obtained by administrative data and confirmed by medical record review. The absolute difference in incidence was 0.78/1,000 person-years. We were unable to use medical record review to confirm or reject 32 people who had a code of HZ. This included 13 Olmsted County residents who had HZ diagnosed outside of Olmsted County and who had insufficient medical record information to confirm the diagnosis, 3 individuals whose medical records were missing, and 16 individuals in the administrative data group who refused research authorization and, therefore, their medical records could not be reviewed (30, 32). These 32 people represent less than 2.0% of all cases. Assuming that all 32 would have been confirmed if medical record data were available, the calculated HZ incidence rate is still significantly higher when obtained from administrative data alone (15.2%, or 0.67/1,000 person-years) than when all cases are confirmed by medical record review. When the incidence rates age and sex adjusted to the US population were calculated from administrative data and compared with those from administrative data supplemented by medical record review, the difference in incidence rates was 0.61/1,000 person-years.

In our attempt to compare complication rates between administrative data and medical record review, the administrative data documented very few complications among people with HZ. Among the complications that were recorded, not all complications could be confirmed (Table 2). For example, of the 68 people whose medical records reported the presence of HZ affecting the eye, only 7 (7/68 = 10.3%) had an ICD-9 code indicating an ocular complication. Conversely, 28 people had administrative codes for herpes ophthalmicus that did not have any documented eye involvement by medical record review. Most of the differences between administrative and medical record documentations of HZ eye complications could be explained by 2 things: eye involvement stated in the medical notes that was not included.
impossible. making any administrative data assessment very difficult or cases, no codes for chronic pain were included that would extended periods, such as 6–12 months. In several of these documented pain at the acute HZ site that continued for HZ and failure to use the postherpetic neuralgia code for neuralgia code as early as the day of diagnosis of the acute complicates reporting of eye and pain complications (8, 14). In this study, postherpetic neuritis was included in the administrative data estimates related to miscoding herpes simplex as herpes zoster. However, nothing short of a new coding system will solve the problems of use of a definitive diagnostic code when what is desired is to code a differential diagnosis (34). Current coding systems make no provisions to designate a provisional or a “rule out” diagnosis rather than a confirmed diagnosis or an historical event. Therefore, the same ICD-9 HZ code (053.xx) may represent a past diagnosis, part of a list of differential diagnoses, or a confirmed diagnosis of HZ. When administrative data are used, these provisional diagnoses as well as historical diagnoses are given equal weight to that of the current diagnosis when incidence is assessed. This problem will continue as long as specific codes are required to support ordering tests, such as a viral culture or a polymerase chain reaction test, to confirm zoster or to affirm the need for a consultation or referral, such as an ophthalmology consultation for HZ occurring near the eye or to prove that a medical history has been included to allow billing for a longer or more intensive visit.

The ICD-9 system also has few codes for HZ-related complications, such as localized muscle weakness or cellulitis. Therefore, the failure to identify HZ cases with complications by using administrative data is likely to continue. In addition, the failure to use a standardized definition for both ophthalmic complications and postherpetic neuritis greatly complicates reporting of eye and pain complications (8, 14). In this study, postherpetic neuritis was included in the initial HZ diagnosis, as early as 3 days after the onset of the acute HZ rash. The lack of a standardized definition for postherpetic neuritis makes the administrative data from these practices useless for general epidemiology studies. In addition, herpes ophthalmicus is often diagnosed and coded for any involvement of the region around the eye (28, 29), making the codes of no value in determining when the eye

<table>
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<td>Olmsted County complication</td>
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<td>Eye</td>
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<tr>
<td>Neurologic</td>
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<tr>
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<tr>
<td>Skin</td>
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<td>US age- and sex-adjusted incidence rates</td>
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was actually involved without looking at the medical record notes.

Studies limited to calculations based on administrative data are less expensive and quicker to complete than studies that use medical record review to confirm the administrative codes. However, a difference in occurrence rates as high as 15%–18% may be too high to be acceptable for many purposes, such as economic or cost-benefit analyses (19, 26, 42–44). If coding systems remained unchanged, the differences might be less important when the same sites are used in before and after immunization calculations or when time trend analyses are computed. However, if the coding practices change as they have to meet new requirements for maximization of both inpatient and outpatient reimbursement, use of administrative data alone may result in unacceptable rates of noise that may hide epidemiologic trends.

A compromise has been sought when using administrative data by supporting the administrative data with a 1%–20% subsample (depending on the total number of identified subjects) in which medical record review or other confirmatory activity is completed (4, 8). When the only element of data required from medical record review is confirmation of the diagnosis, record review can be completed relatively rapidly and at modest cost. If we had used the first 200 medical records in this study (~10% sample) to estimate error rates or to determine a correction rate, we would have suggested a 15% downward adjustment that is comparable to the final rate of 14.5% but at a much lower study cost than occurred for reviewing all medical records. However, our data on complication rates using only 200 medical records provided very little useful data because many complications are too uncommon to be accurately represented in a sample this small.

Some cases of HZ are undoubtedly missed by administrative data with or without medical record review, such as the people who never seek medical care for their HZ, those who never get a diagnosis of HZ despite seeking medical care, those who were diagnosed outside the community (n = 13 identified over 6 years in our study), those who refused research access to their medical records (n = 16), and those whose medical records were lost (n = 3). Therefore, medical records missed 32 identified potential cases, while administrative data added 290 cases that were not HZ cases—a potential 1.9% underestimate by medical record review if all of the administrative data cases were confirmed cases compared with a 17.3% overestimate by administrative data. Some cases are missed by both administrative and medical record review data, such as those people who did not seek medical care, those who were diagnosed outside the county and never mention the diagnosis to their physician, and those who were miscoded as something other than HZ. These issues are common across all sites but may have different effect sizes at different sites, and it is not currently possible to calculate the magnitude of this type of misclassification bias.

Our study has limitations. All of the medical facilities in Olmsted County, Minnesota, were using only paper medical records at the time of this study. This may affect medical record documentation compared with that from the electronic medical records currently used. Additionally, medical record review studies rely on the judgment of the research nurses abstracting the medical records. In this study, the nurses were extensively trained, very experienced, and met the standards of repeated validity checks (14, 35). Similarly, administrative data collection depends on not only the data system but also the expertise of the people who retrieve data from that system. The specialists who initially retrieved the administrative data for this study work full-time with these data and have completed similar data retrievals for the hundreds of Rochester Epidemiology Project studies that occur yearly (32, 45). Therefore, the retrieval specialists are extremely familiar with the coding definitions and were able to take changes in the coding systems’ definitions into account. Quantifying internal consistency in coding is not feasible.

The Olmsted County data may be unique in other ways. First, all Olmsted County clinicians are aware of the research that regularly uses their medical records and, therefore, the clinicians may be unusually adept in minimizing lost records or documenting diseases and complications. However, publicly available reports of clinic-specific quality indicators abstracted from medical records do not suggest that documentation is unusually efficient within the county’s medical facilities (22). Second, we used a community population for this study as opposed to an insurance plan population. We were therefore able to include HZ diagnoses made in urgent care, emergency departments, and during hospitalizations for both insured and uninsured individuals, data that are often not available from most administrative data sets. Although this did not affect our comparisons, it may have resulted in higher overall incidence and complication rates than obtained by administrative data sets that include only office visits or “within plan care.”

In conclusion, HZ that results in one or more health-care contacts is common whether estimated by administrative data or medical record review. Knowing the magnitude of the difference in the estimates obtained from these 2 common epidemiologic study designs allows the investigator to determine what study design is required according to the study question and the strengths and limitations of each type of data capture. Administrative data use alone appears to overestimate HZ cases and cannot identify reliable rates of HZ complications.

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REFERENCES


