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A systematic review of validated methods to capture several rare conditions using administrative or claims data

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ABSTRACT

Purpose: To identify and assess billing, procedural, or diagnosis code, or pharmacy claim-based algorithms used to identify the following health outcomes in administrative and claims databases: acute disseminated encephalomyelitis (ADEM), optic neuritis, tics, and Henoch Schönlein purpura (HSP).
Methods: We searched the MEDLINE database from 1991 to September 2012 using controlled vocabulary and key terms related to the conditions. We also searched the reference lists of included studies. Two investigators independently assessed the full text of studies against pre-determined inclusion criteria and extracted case validation data from those studies meeting inclusion criteria.
Results: Two eligible studies addressed ADEM, two addressed optic neuritis, and four studies addressed tics. Only one study addressed HSP. Among these, one study of ADEM reported a positive predictive value of 66%, however the identification algorithm contained a combination of International Classification of Diseases (ICD) codes and other identification methods and the performance of the ICD-9 codes alone was not reported. No other studies reported validation data.
Conclusions: The lack of data on the validity of algorithms to identify these conditions may hamper our ability to determine incidence patterns with respect to infection and vaccination exposures. Further epidemiologic research to define validated methods of identifying cases could improve surveillance using large linked healthcare databases.

Contents

Abbreviations: ACE, angiotensin converting enzyme; ADEM, acute disseminated encephalomyelitis; FDA, US Food and Drug Administration; HMO, health maintenance organization; HSP, Henoch Schönlein purpura; ICD, International Classification of Diseases; MS, multiple sclerosis; ON, optic neuritis; TCV, thimerosal containing vaccines.

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1. Introduction

Mini-Sentinel, a pilot project sponsored by the United States Food and Drug Administration (FDA), is one facet of the Sentinel Initiative, an FDA effort to develop a national electronic system that will complement existing methods of safety surveillance [1]. To support this goal, Mini-Sentinel uses administrative and claims data to examine relationships between medical product exposures and health outcomes. This serves to refine safety signals and facilitate active surveillance of adverse events potentially related to medical products.

A first step in developing the Sentinel system is to understand the validity of algorithms (i.e., combinations of billing, procedural, or diagnosis codes, or pharmacy claims) for identifying health outcomes of interest in administrative data. Mini-Sentinel collaborators selected health outcomes of interest using an expert elicitation process through which investigators developed a list of candidate outcomes based on input from global vaccine safety experts. A panel of five vaccine experts then prioritized the list via an iterative process using criteria including clinical severity, public health importance, incidence, and relevance [2].

The goal of this project was to identify algorithms used to detect four health outcomes of interest as derived via the expert elicitation process [2]. We sought studies identifying outcomes of interest in administrative data sources and describe the performance characteristics of algorithms as reported by the studies in which they were used. Our group analyzed several conditions of interest, and findings for other conditions are reported elsewhere in this supplement. Here, we summarize the findings for these four rare conditions, each with limited literature regarding algorithms for capturing cases: acute disseminated encephalomyelitis (ADEM), optic neuritis (ON), tic disorders, and Henoch-Schönlein purpura (HSP).

1.1. Health outcomes of interest

ADEM is a neurologic disorder with abrupt onset of multifocal neurologic deficits from likely autoimmune destruction of myelinated cells in the central nervous system, with clinical features potentially including encephalopathy, weakness, sensory loss, and seizures. This disorder is more common in children than adults, and there is often a history of preceding infection or immunization. Treatment is commonly with glucocorticoids and other immunosuppressants, and outcomes are often favorable [3].

ON is also considered an autoimmune demyelinating disorder, but the lesion is localized to one optic nerve, resulting in monocular visual acuity impairment or monocular vision loss, often with pain in the affected eye when eye movements are attempted [4]. Treatment is also with intravenous glucocorticoids, and outcomes are often favorable, though vision may not be restored. ON is often considered the first manifestation of multiple sclerosis (MS) although MS does not always follow a diagnosis of ON [5].

Tics are abrupt, repeated movements or utterances often partially suppressible by the patient. They can be quite subtle such as a forced blink or muscle tightness, or complex motor movements of a limb. The cause is often considered idiopathic, though tics are also seen as a feature of other disorders, including Tourette syndrome [6].

HSP is an autoimmune condition affecting young children, in which sudden onset of a raised purple rash occurs, most often in the lower extremities and buttocks. Abdominal pain, hematochezia, glomerulonephritis, and arthritis are also common features. Treatment is supportive, though renal disease may prompt immunosuppressive therapy [7].

2. Material and methods

Our methods are described fully in the accompanying paper by McPheeters et al. [8]. Briefly, we adapted the search strategy used in prior Sentinel approaches to searching [9]. We tested those approaches to determine the need to search grey literature, such as that located via Google Scholar. The tests did not yield any citations beyond the traditional search. Similarly, tests of other peer-reviewed databases such as EMBASE showed significant clinical overlap. Therefore, the final search strategy was executed in MEDLINE via the PubMed interface (Appendix A). We limited searches to the last 21 years (1991–September 2012) and required that included studies address one of the health outcomes of interest (ADEM, ON, tics, HSP); use an administrative database reporting data from the United States or Canada; and clearly define an algorithm to identify cases. We tracked whether studies reported validation of the algorithm (e.g., via chart review or independent diagnosis). We also searched the reference lists of included studies to locate additional citations. Two investigators independently assessed the full text of each study against our inclusion criteria with disagreements resolved via a third reviewer or discussion to reach consensus.

One investigator also extracted data regarding the study population, outcome studied, algorithms used, validation procedure, and validity statistics. A second reviewer independently verified the accuracy of the data extracted. We summarized results of studies qualitatively and report key characteristics below and in Table 1. Table 2 reports the disposition of studies identified for each topic.

3. Results

3.1. Acute disseminated encephalomyelitis

We identified two studies reporting data on ADEM. The first study, conducted by Leake et al. presented data from three inpatient facilities in San Diego County, California: the Children's Hospital and Health Center, the University of California San Diego Medical Center, and Kaiser Permanente San Diego Hospital [10]. The study included both retrospective identification of cases from 1991 through 1998 as well as prospective identification of cases from 1998 through 2000. Incident cases in subjects less than 20 years of age were ascertained via three mechanisms: (1) database search of ICD-9 codes 052.0 (Post varicella encephalitis), 055.0 (Post measles encephalitis), 136.9 (Unspecified infectious and parasitic diseases), 323.5 (Encephalitis, myelitis, and encephalomyelitis following immunization procedures), 323.6 (Postinfectious encephalitis, myelitis, and encephalomyelitis), 323.8 (Other causes of encephalitis, myelitis, and encephalomyelitis) and 323.9 (Unspecified cause of encephalitis, myelitis, and encephalomyelitis); (2) systematic review of radiology reports; and (3) prospective identification by study participants. Cases of ADEM were defined as subjects experiencing acute or subacute abnormal neurological symptoms with central nervous system demyelination not explained by another illness. Sixty-four ADEM cases were identified through this strategy, however, the number of cases specifically identified through use of the ICD-9 codes rather than the review of radiology reports or prospective identification was not reported.

Therefore, although 42 cases of ADEM were verified after medical record review, the positive predictive value of the ICD-9 codes alone was not available. However, the PPV of the entire case finding algorithm (using ICD-9 codes, radiology report review, and clinical reporting) was 66%.

The second study meeting our inclusion criteria also described incident cases of ADEM. This study by Langer-Gould, et al. identified cases of ADEM occurring in children less than 18 years of age