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Agreement between medical record and parent report for evaluation of childhood febrile seizures

Bradley K. Ackerson[a,*], Lina S. Sy[a], Janis F. Yao[a], T. Craig Cheetham[a], Ana M. Espinosa-Rydman[a], Tonia L. Jones[b], Steven J. Jacobsen[a]

[a] Department of Research and Evaluation, Kaiser Permanente Southern California, Pasadena CA 91101, USA
[b] H. Claude Hudson Comprehensive Health Center, Los Angeles, CA 90007, USA

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ABSTRACT

Background: The monitoring of vaccine safety is critical to maintaining the public acceptance of vaccines required to ensure their continued success. Methods used to assess adverse events following immunization (AEFI) must accurately reflect their occurrence. Assessment of AEFI is often done via medical record review (MR) or via patient report (PR). However, these sources of data have not previously been compared for the analysis of AEFI. The objective of this study was to evaluate the concordance between MR and PR for young children identified as having had a febrile seizure (FS), an important AEFI, in an integrated health care system. The variables chosen for analysis were those recommended by the Brighton Collaboration Seizure Working Group for the evaluation of generalized seizure as an AEFI [1].
Methods: Parent report from phone interviews and mailed questionnaires was compared to abstracted medical records of 110 children with FS between ages 3 and 60 months. Concordance between PR and MR for characteristics and predisposing factors of FS was assessed by percent total agreement and kappa statistic.
Results: Percent total agreement between PR and MR was between 43.6 and 100% for variables studied, with 62.5% of items having >70% agreement. However, kappa was poor to fair for all measures (−0.04 to 0.33). While some variables, such as history of seizures in a sibling or parent and several seizure characteristics, were reported more often by PR, other items, such as maximum fever and several concurrent conditions, were reported more often by MR.
Conclusion: These findings demonstrate the limitations of using MR or PR alone to assess febrile seizures in children. This analysis supports the practice of collecting data from both MR and PR to most accurately portray the spectrum of predisposing factors and seizure characteristics when evaluating FS in children whenever feasible.

1. Introduction

The maintenance of a safe and effective immunization program presents dynamic challenges. As the incidence of vaccine-preventable diseases decreases, more attention is focused on both real and perceived adverse effects of vaccination [2]. The ongoing monitoring of vaccine safety is critical to maintaining public confidence essential for the widespread acceptance and success of vaccines. Therefore, sound scientific vaccine safety research is of utmost importance and the accuracy of methods used to assess adverse events in vaccine safety research is crucial to improving post-licensure safety measures.

The acquisition of data is fundamental to vaccine safety research. Medical record review (MR) is frequently used as the data source for passively measuring adverse events in observational post-licensure safety studies. However, MR can be expensive, difficult to implement and inherently may not be complete. Sources of MR data errors include variable recording of sensitive topics; failure to include reports in the chart; delayed recording limiting provider recall; sparse documentation in time-pressured settings; and incomplete sharing of information by patients [3–5]. On the other hand, patient/parent reported data (PR), often used in clinical trial settings, also have potential sources of error including incomplete recall, social desirability bias and level of patient health knowledge. These errors can lead to biases in patient or observer

Abbreviations: Medical record, MR; Patient/parent reported data, PR; Febrile seizures, FS; Kaiser Permanente Southern California, KPSC; International Classification of Diseases Ninth Revision, ICD-9; Confidence interval, CI; Central nervous system, CNS; Adverse event following immunization, AEFI.

* Corresponding author at: Pediatrics and Pediatric Infectious Diseases, Kaiser Permanente Southern California, 100 S. Los Robles, 2nd Floor, Pasadena, CA 91101, USA. Tel.: +1 310 517 2827; fax: +1 310 517 4071.
E-mail address: Bradley.K.Ackerson@kp.org (B.K. Ackerson).

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reported events. Nonetheless, PR may provide an important source of events or event details not recorded in the medical record.

Febrile seizures (FS) are among the most anxiety-provoking adverse events following vaccinations. Although FS are normally benign events, the importance of FS to the public is reflected by the impact that the incidence of FS following vaccination has on vaccine recommendations [6]. In order to improve comparability of vaccine safety data, the Brighton Collaboration Seizure Working Group developed a case definition and guidelines outlining data they considered important to document when evaluating generalized seizures following vaccination. Recommendations for data collection included factors predisposing recipients to seizures and clinical features of the seizure. These data are used in the Brighton Collaboration guidelines for the evaluation of seizure as an AEFI to determine the level of diagnostic certainty of whether a seizure was present or not and whether fever was present immediately prior to the onset of possible seizure activity [1]. However, while several studies have evaluated concordance between MR and PR data sources, none have focused on the concordance of these data sources used to evaluate FS [7–12]. To fill this gap in knowledge, we conducted a study to evaluate the concordance between MR and PR data used in the Brighton Collaboration guidelines for young children who were diagnosed as having had a FS while members of an integrated health care system.

2. Materials and methods

2.1. Study setting

Kaiser Permanente Southern California (KPSC) is a large managed care organization with a membership of over 3.4 million with a racial/ethnic composition similar to that seen in the source population. Nearly all health care is provided to KPSC members at 14 medical centers and 197 satellite clinics. A minimal portion of emergent and specialty care is obtained from non-Kaiser Permanente providers through contractual arrangements or claims reimbursement. All health care encounters are tracked through electronic data systems, with detailed information on International Classification of Diseases, Ninth Revision (ICD-9) coded diagnoses applied and procedures performed during encounters. Importantly, reimbursement by KPSC for outside care requires that claims be submitted with documentation of the care that is entered into the administrative data systems. Thus, capture of care delivered to KPSC members by electronic administrative data is very comprehensive.

2.2. Study subjects

In this cross-sectional study, introductory letters were mailed to caregivers of 500 children aged from 3 months to 5 years of age who had a diagnosis of febrile seizure (FS) between January 1, 2002 and December 31, 2005 (Fig. 1). Febrile seizures were identified from computer records of hospital, emergency department and clinic visits based on the ICD-9 code for FS (780.31). Equal numbers of participants' parents were randomly selected to participate in either a phone interview or mailed written questionnaire on the medical history and clinical features of their child's FS with the goal of recruiting approximately 150 participants in each of the phone and mail cohorts. Parents of children randomized to the phone cohort who did not decline to participate after the introductory letters were sent were contacted for a phone interview. If parents of children randomized to the phone cohort could not be contacted by phone after up to 5 attempts and did not decline to participate in the study, a second letter inviting the caregivers to participate in the study was sent. Up to 5 additional attempts to contact phone cohort caregivers who did not respond to the second letter were again made. Parents of children randomized to the mail cohort received a questionnaire and the introductory letter. Those who did not decline to participate and did not respond within 2 weeks of the mailing of the first questionnaire received one additional mailed questionnaire. If no response to the second questionnaire was received, parents were contacted by phone to attempt to rescue their response. Participating parents were also asked for authorization to review their child's MR for FS-related medical visit(s) that occurred outside of KPSC. All materials were translated into Spanish for parents who were Spanish speaking.

2.3. Parent Questionnaire and medical record abstraction

The questionnaire mailed to participants' parents or utilized for phone interview was modeled after the Short Data Collection Form For Seizures [13]. Included were questions about clinical characteristics of the child's FS and factors predisposing children to FS identified by the Brighton Collaboration Seizure Working Group to be important to determining the level of diagnostic certainty that a seizure occurred. A MR abstraction tool was developed for use by trained abstractors to abstract data on predisposing factors and seizure characteristics recorded in the MR. Data abstracted from the MR was compared to data from questionnaires obtained by mail or telephone interview. One of our initial goals was to compare phone interview with mailed questionnaires as a source of PR data. However, this was precluded by the low rate of return of mailed questionnaires.

2.4. Statistical analysis

In order to compare MR and PR data for the same FS episode, we restricted our concordance analysis to those children who experienced only one seizure, who did not have missing chart data, and whose seizure dates from the MR and PR were within one year of each other. Demographic information was compared between all subjects included in the concordance analysis and those excluded from the analysis, and between participants and non-participants. For categorical data, the chi-square test was used to detect differences unless the expected cell size was less than 5, when the Fisher exact test was used. For continuous data, the Wilcoxon rank sum test was used to detect differences.

We estimated that we had a 99% power to detect a kappa statistic of 0.41 or greater using a sample size of at least 100 with an alpha of 0.05, two rating categories (yes versus no) and response frequencies of 0.4 and 0.6. Anticipating a non-response rate of 40%, we mailed 500 letters to parents of children aged 3–60 months who had a diagnosis of FS between January 1, 2002 and December 31, 2005 in the hopes of obtaining 300 parental responses and at least 100 participants after the application of exclusion criteria.

Concordance between the parent report questionnaire data (PR) and the medical record data (MR) was assessed by calculating percent total agreement (percent agreement on positives plus negatives) and kappa statistic. We applied the criteria of Tisnado et al. for evaluating percent total agreement: $\geq$0.9 indicates excellent agreement, $\geq$0.8 to <0.9 indicates good agreement, $\geq$0.7 to <0.8 indicates fair agreement and <0.7 indicates poor agreement [15]. Kappa coefficients <0.00 indicate poor agreement, 0.00–0.20 indicate slight agreement, 0.21–0.40 indicate fair agreement, 0.41–0.60 indicate moderate agreement, 0.61–0.80 indicate substantial agreement and 0.81–1.00 indicate almost perfect agreement [14].

The concordance and 95% confidence intervals were calculated at the item level (each question) as well as domain level (questions combined into categories). Item level analyses were based on the

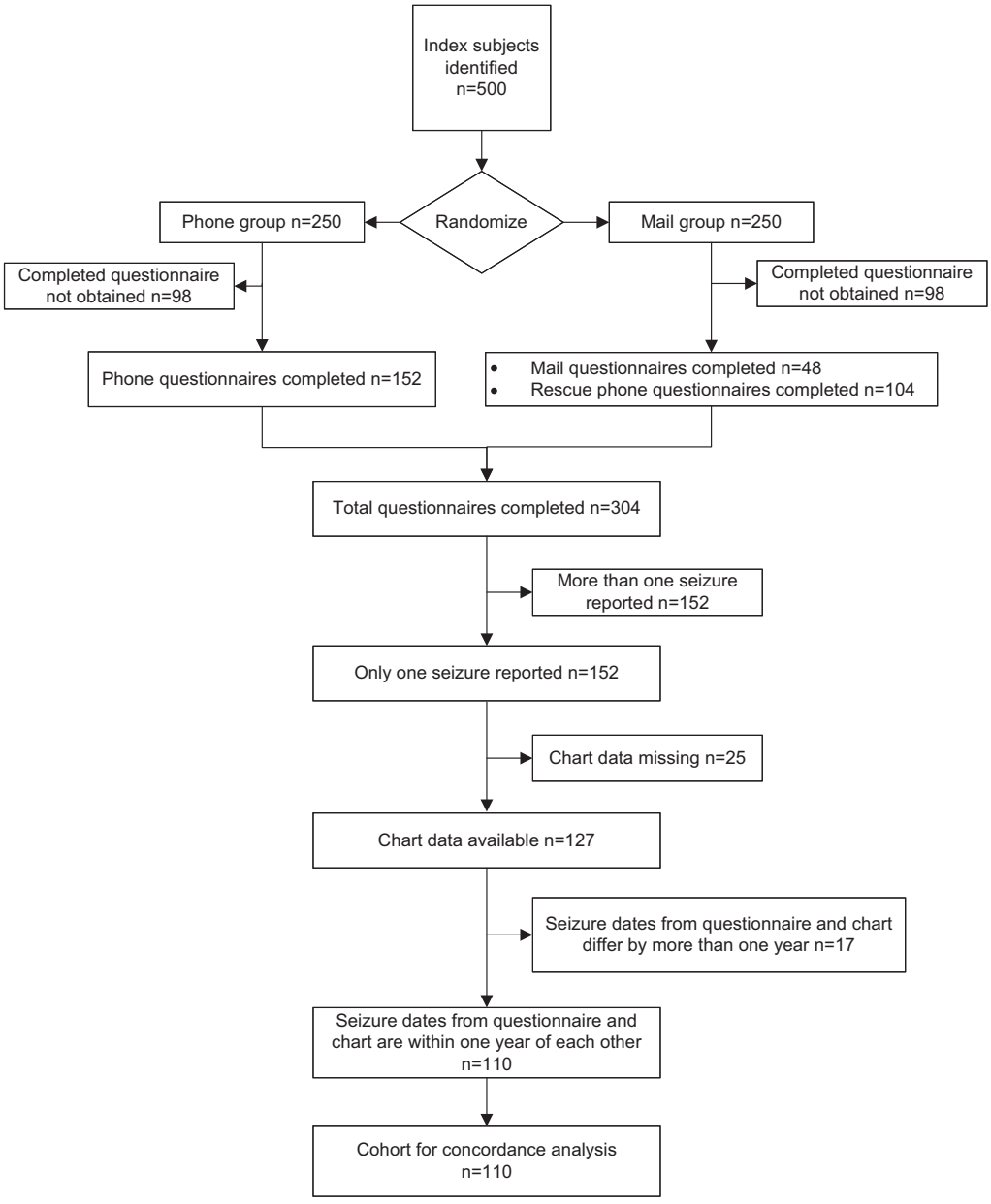

Fig. 1. Recruitment and analysis flow diagram.

binary answer to questions, classifying agreement and disagreement from the two data sources for individual items with each unique patient as the unit of analysis. For domain level analyses, questions were combined into two domains, predisposing factors and seizure characteristics as outlined in the Brighton Collaboration Short Data Collection Form for Seizure [13]. Within each domain, if the binary answer for any item was yes for a given patient, then that patient–domain dyad was yes. We calculated each patient's domain level dyad for MR and for PR. We then computed the kappa value based on the agreement and disagreement of the domain level dyads from the two data sources. To examine domain level agreement, we calculated the number of questions answered yes in a domain from PR and MR data and then calculated Lin's concordance correlation coefficient between the two data sources [16].

All tests were conducted using SAS software (SAS Enterprise Guide, v4.3, SAS Institute Incorporated, Cary, NC, 27513). The protocol for this study was approved by the KPSC Institutional Review Board.

3. Results

3.1. Response to mailed invitations, phone contact and mailed questionnaires

In 2007–2008, letters introducing this study were sent to the caregivers of 500 children aged 3 months to 5 years of age with a diagnosis of FS between January 1, 2002 and December 31, 2005. Among 250 caregivers randomized to the phone group, 152 completed phone interviews, 23 refused to participate, 28 could not be contacted, 4 had incomplete questionnaires, 1 was ineligible, and the remainder were not contacted since we had reached our target recruitment goal. Among 91 with outside records pertinent to their FS event, 37 authorized access to their child's outside medical record and 33 outside medical records were obtained.

Among 250 caregivers randomized to the mail group, 48 completed mailed questionnaires, 104 completed rescue phone interviews, 3 refused to participate, 24 were unable to be contacted,

4 had incomplete questionnaires, and the remainder did not reply to the mailed questionnaire. Among 101 with outside records pertinent to their FS event, 39 authorized access to their child's outside medical records and 32 outside medical records were obtained.

Of 304 completed questionnaires, 152 had a single FS event of which 127 had chart data available and 110 had a reported seizure date that was within one year of the date recorded in the MR (Fig. 1).

3.2. Participants

Among subjects with completed questionnaires, 59% were male, 62% were Hispanic and 38% were White (data not shown). Among subjects whose data were used in the concordance analysis, 56% were male, 58% were Hispanic, and 41% were White. The demographics of subjects included in and those excluded from the concordance analysis were not significantly different (Table 1). Similarly, the demographics of participants and non-participants were not significantly different (data not shown).

3.3. Concordance

Overall, we found fair to excellent concordance between MR and PR for many of the variables studied when measured by percent total agreement, with 62.5% of variables having greater than 70% total agreement [15]. In contrast, the kappa statistic was less than 0.33 for all measures (Table 2). While fever, maximum recorded fever and seizure duration were present in most MR and PR (51.8–82.7%), many variables (58.3%) were reported as absent by both sources more than 50% of the time.

3.4. Predisposing factors: past history and concurrent conditions

Most past history items were not reported in either MR or PR. One notable exception was a history of seizures in a sibling or a parent, reported more often in the PR than MR. Percent agreement was high for seizure disorder, head trauma, central nervous system (CNS) infection, hypoxic brain damage and metabolic disorder, and low for sibling or parent with seizures. Within concurrent conditions, fever and maximum fever recorded were reported as present in most cases by both MR and PR. Viral syndrome, otitis media, gastroenteritis and rash were reported as absent by both MR and PR in most cases. However, respiratory tract infection and gastroenteritis were reported more often by MR than by PR. Overall, percent total agreement was high at the domain level (89.1%) while percent agreement varied by item between 56.4% and 100%. Kappa was poor for all items, although the kappa statistic is expected to be low for rare events [17]. The concordance for the domain level of predisposing factors was found to be poor both when evaluated by kappa and by Lin's concordance correlation coefficient (0.08, 95% CI (−0.18, 0.35) and (0.16, 95% CI (−0.03, 0.34), respectively) [16].

3.5. Seizure characteristics

Seizure duration was reported by more than half of MR and PR (67/110 and 89/110, respectively). In addition, movement on both sides of the body, eye deviation and loss of consciousness was reported by the majority of PR (53.6, 67.3 and 55.5%, respectively).

The concordance for most seizure characteristics reported by MR and PR was poor. With the exception of percent total agreement of MR and PR for movement on one side of the body (90.9%), staring (78.2%), apnea (77.3%), and limpness (70.0%), percent total agreement was less than 66%. The kappa statistic was less than 0.25 for all seizure characteristics. The concordance for the domain level of seizure characteristics was found to be poor both when evaluated by kappa and by Lin's concordance correlation coefficient (0.07, 95% CI (−0.09, 0.23) and 0.13, 95% CI (0.02, 0.23), respectively) [16].

4. Discussion

This study provides important insight on the comparability of MR and PR data in evaluating childhood febrile seizures. Some analysis restrictions, including restricting to children who had one seizure in order to avoid parental confusion about multiple FS episodes, excluding children with missing chart data and including only children whose parents recalled the seizure date to within one year of the date reported in the medical record, would be expected to increase concordance between MR and PR. Nonetheless, we found that agreement between MR and PR was low for nearly all variables of childhood febrile seizures when analyzed by the kappa statistic, although the kappa statistic is expected to be low for rare events [17]. Furthermore, high concordance between MR and PR when measured by percent total agreement was seen almost exclusively for items of low prevalence. The only item with high prevalence and high concordance when measured by percent total agreement was history of fever, a prerequisite for inclusion in the study.

These findings underscore the limitations of using either MR or PR alone to assess either predisposing factors or characteristics of febrile seizures in children. While more reporting of some items by PR than by MR may reflect over reporting, previous studies have demonstrated under-reporting of some aspects of medical care in the MR, reflecting limitations of patient or caregiver recall, inconsistent reporting and delayed recording [18–20]. An example of likely true underreporting by MR compared to PR seen in this study was whether or not a sibling or parent has a history of seizures, a question not likely to be asked by most providers at the time of the evaluation of children with possible FS. In addition, increased reporting by PR compared to MR of several seizure characteristics, such as loss of consciousness, eye deviation, and tonic–clonic activity is more likely to reflect underreporting by MR than over reporting by PR. These are questions that might not have been asked or the answers not have been consistently recorded in the MR by providers, yet are memorable enough to have been recalled by some parents. On the other hand, patient or caregiver survey is limited by a variety of factors including patient recall, perception, health knowledge and observer bias [21]. The increased reporting of some items by MR compared to PR seen in this study, such as maximum fever, may reflect lack of documentation of some event details, such as temperature, by parents. In addition, increased reporting of some items, such as gastroenteritis or respiratory tract infection, by MR compared to PR may reflect variable parental recall of some concurrent conditions. In many cases analyzed in this study, the detailed information recommended by the Brighton Collaboration Seizure Working Group for the evaluation of seizures as an adverse event following immunizations was not documented in the MR [1]. In settings that utilize an electronic medical record, it is possible that incorporation of a check list of pertinent signs and symptoms for patients who have had a febrile seizure would facilitate obtaining of more accurate and complete recorded information in the medical record more proximal to the time of the event. Nonetheless, MR is likely to remain incomplete and this study demonstrates that while there may be some data overlap, the data sources appear to be complementary. Therefore, until Brighton Collaboration recommendations for documentation of data important in the evaluation of seizures in children are more widely implemented, the use of both MR and PR data may provide a more complete picture of febrile seizures than either MR or PR data alone.

Participation bias might limit the generalizability of our findings. While there were no significant demographic differences

Table 1
Demographic information obtained from questionnaires.

	Subjects included in the concordance analysis		Subjects excluded from the concordance analysis		*p*-Value[a]
	N	%	*N*	%	
Number of subjects	110		194		
Gender					
Male	61	55.5	119	61.3	0.32
Female	49	44.5	75	38.7	
Race/ethnicity					
White	45	40.9	70	36.1	0.56
Non-White	59	53.6	116	59.8	
Missing	6	5.5	8	4.1	
Hispanic	64	58.2	124	63.9	0.39
Non-Hispanic	45	40.9	66	34.0	
Missing	1	0.9	4	2.1	
Combined family income					
<$60,000	33	30.0	77	39.7	0.19
≥$60,000	60	54.5	86	44.3	
Missing	17	15.5	31	16.0	
Age at time of febrile seizure, in months, median (range)	18 (2–60)[b]		18 (2–65)[b,c]		0.21

[a] *p*-Values were obtained from chi-square, Fisher's exact test or Wilcoxon rank sum test.
[b] While recruitment was limited to those diagnosed with a febrile seizure in the medical record between 3 and 60 months of age, parent reported age at the time of febrile seizure ranged between 2 and 65 months.
[c] Analysis was done on 192 subjects for whom age was reported in the questionnaire.

between participants and non-participants in our study, it is possible the responses of participants differed from those non-participants would have provided. In addition, only approximately 30% of the mail group responded to mailed questionnaires, requiring that approximately 70% of the mail group questionnaires be completed by phone interview. The low caregiver response to mailed questionnaires precluded the possibility of comparing results between mail and phone groups and demonstrates the difficulty obtaining information from participants via mailed written questionnaire. Furthermore, given that parents of study subjects were interviewed between 2 and 6 years after the event, it is likely that the concordance between data acquired by using the MR or PR would be improved and recall of the event improved by acquisition of PR data more proximally to the event. The impact of incomplete medical records on MR data is another limitation of this study. However, this may be an even greater challenge in

Table 2
Measures of concordance for items by domain.

Domain item	Number of each cell				Measures of concordance			
	Both yes (A)	MR = Y, PR = N (B)	MR = N, PR = Y (C)	Both No (D)	% Total agreement (A + D)/total × 100	Kappa	95% CI of Kappa	
							Lower CL	Upper CL
Predisposing factors								
Past history								
Seizure disorder	0	1	4	105	95.45	−0.0148	−0.0383	0.0087
Head trauma	0	1	3	106	96.36	−0.0138	−0.0346	0.007
CNS infection	0	0	0	110	100.00	N/A		
Hypoxic brain damage	0	0	1	109	99.09	N/A		
Metabolic disorder	0	0	0	110	100.00	N/A		
Sibling or parent with seizures	8	4	44	54	56.36	0.0884	−0.0346	0.2114
Concurrent conditions								
Fever 24 h prior or 1 h after (Y/N)	91	9	8	2	84.55	0.1053	−0.1357	0.3462
Maximum fever recorded	65	22	7	16	73.64	0.3263	0.1414	0.5111
Respiratory tract infection	19	30	13	48	60.91	0.1808	0.0044	0.3573
Viral syndome	3	11	15	81	76.36	0.0517	−0.1503	0.2537
Otitis media	5	17	11	77	74.55	0.1139	−0.0936	0.3215
Gastroenteritis	1	20	2	87	80.00	0.0374	−0.1047	0.1795
Rash	0	4	1	105	95.45	−0.0148	−0.0383	0.0087
Domain level	97	6	6	1	89.09	0.08	−0.18	0.35
Seizure characteristics								
Seizure duration recorded	57	10	32	11	61.82	0.1173	−0.0536	0.2882
Movement on both sides of body	12	8	47	43	50.00	0.0442	−0.0921	0.1806
Movement on one side of body	0	3	7	100	90.91	−0.0397	−0.0728	−0.0066
Tonic, clonic or tonic	35	17	25	33	61.82	0.2401	0.0609	0.4193
Limpness	3	2	31	74	70.00	0.081	−0.0508	0.2128
Staring	1	4	20	85	78.18	0.0038	−0.1383	0.1459
Apnea	5	2	23	80	77.27	0.2047	0.0208	0.3887
Pale or blue color	7	2	36	65	65.45	0.1549	0.0194	0.2904
Drowsiness after seizure/post-ictal	15	10	38	47	56.36	0.1096	−0.0499	0.2692
Eyes deviation	27	7	47	29	50.91	0.1326	−0.003	0.2682
Loss of consciousness	6	7	55	42	43.64	−0.0406	−0.1533	0.0721
Domain level	68	6	31	5	66.36	0.07	−0.09	0.23

settings that are without centralized medical records. Similarly, potential limitations on MR data in this study that were due to the inability to obtain medical records from facilities outside the study setting are likely to be encountered in most study settings. It is also possible that our results obtained by analyzing MR and PR for all children with FS might impact the ability to generalize these results to FS following vaccine administration. However, the large sample size required for this study and the low frequency of FS following immunizations precluded the analysis of FS due to fever following vaccine administration only. Nonetheless, FS following vaccination are thought to be due to fever associated with vaccination not the vaccine itself, and have indistinguishable characteristics and identical prognosis to FS due to fever from other sources [22–25]. Serious sources of fever and seizures, such as meningitis and encephalitis, preclude the diagnosis of FS and hence, were not included in our analysis. Therefore, it is unlikely that PR or MR documentation would differ substantially for FS due to fever from other sources compared to FS due to fever following vaccine administration. Another potential limitation is the high prevalence of Hispanic participants in this study. While comparable to the Southern California population from which the sample was drawn, the proportion of Hispanic participants in this study is higher than that of the general United States population. Finally, this study was limited only to children diagnosed with febrile seizures reported by healthcare providers in the medical record. Hence, it is possible that additional parental reports of events not considered to be valid FS by providers are not included in this analysis.

5. Conclusions

Both MR and PR may be valuable in the acquisition of data identified by the Brighton Collaboration as important in the evaluation of generalized seizures as an adverse event following immunization (AEFI). In many cases, detailed information recommended by the Brighton Collaboration in the evaluation of generalized seizures as an AEFI was not documented in the MR or PR, but MR and PR information appeared to be complementary. Improved seizure event documentation recommended by the Brighton Collaboration would improve the evaluation of seizures in children using the MR alone.

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Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at http://dx.doi.org/10.1016/j.vaccine.2013.03.073.

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