KEY WORDS

ACUTE OTITIS MEDIA SELF-REPORT MEDICAL RECORDS

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Self and Parental Report of Physician-identified Acute Otitis Media (AOM) in a Rural Sample

Autodéclarations et déclarations parentales d'otites moyennes aiguës identifiées par un médecin dans un échantillon de population rurale

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Abstract

Acute otitis media (AOM) is a leading cause of family medicine consultations. Rates of AOM are traditionally determined by review of medical charts, which can be costly and time consuming. This information can also be obtained directly from patients (or parents) by self-administered surveys or personal interview. To ensure the quality of self-reported AOM as a proxy for physician-recorded diagnosis, we assessed its accuracy compared to medical report documentation. Self (and maternal) reports of AOM at outpatient consultations at family practice clinics and hospital emergency departments were collected prospectively by interview from participants in the Hutterite Influenza Prevention Study. Similar data were also collected by fax requests for medical record information to the medical facilities. We calculated AOM reporting by each data source. Sensitivity, specificity, predictive values and likelihood ratios of self-reported AOM using medical record documentation as the gold standard were determined. Compared to the medical records, the proportion of AOM cases was underestimated by participants (22% versus 16%), but this difference was not significant (p = 07). Self-report of AOM was a very specific measure (93%), but had lower sensitivity (47%) than medical records. Positive predictive value was moderate at 64% but negative predictive value was good at 86%. The positive likelihood ratio was 6.7, while the negative likelihood ratio was 0.57. Self-report of AOM in our sample had high specificity and good negative predictive value. However, reliance on self-report without verification by medical record may result in a number of false negatives, which may affect enrolment eligibility or outcome analyses in medical research.

Abrégé

Les otites moyennes aiguës (OMA) sont la cause la plus fréquente de consultation des médecins de famille. Les taux d'OMA sont traditionnellement déterminés grâce à l'examen de dossiers médicaux, ce qui peut être coûteux et nécessiter beaucoup de temps. Or, cette information peut également être obtenue directement auprès des patients (ou de leurs parents) grâce à des sondages autoadministrés ou à des entrevues personnelles. Afin de déterminer à quel point les auto-déclarations d'OMA peuvent servir d'indicateur des diagnostics établis par les médecins, nous avons comparé la précision de ces autodéclarations à la documentation dans les dossiers médicaux. Des auto-déclarations (et déclarations par la mère) d'OMA lors de consultations comme patients externes dans une clinique familiale et des salles d'urgence en hôpital ont été recueillies de façon prospective grâce à des entrevues auprès de participants à l'étude sur la prévention de la grippe dans la communauté huttérienne. Des données semblables ont également été recueillies par le moyen de demandes d'information du dossier médical transmises par télécopieur aux établissements médicaux. Nous avons ensuite calculé le taux d'OMA pour chaque source de données. Nous avons déterminé les niveaux de sensibilité et de spécificité, les valeurs prédictives et les rapports de vraisemblance pour les OMA autodéclarées en utilisant la documentation des dossiers médicaux comme norme d'excellence. Comparativement aux dossiers médicaux, la proportion de cas d'OMA était sous-estimée par les participants (22 % contre 16 %), mais cette différence n'était pas significative (p = 07). L'autodéclaration d'OMA était une mesure très spécifique (93 %), mais avait une moins grande sensibilité (47 %) que la revue des dossiers médicaux. La valeur prédictive positive était modérée, soit de 64 %, mais la valeur prédictive négative était bonne, à 86 %. Le rapport de vraisemblance positive était de 6.7, alors que le rapport de vraisemblance négatif était de 0.57. L'autodéclaration des OMA dans notre échantillon avait un haut niveau de spécificité et une bonne valeur prédictive négative. Toutefois, l'utilisation de l'autodéclaration sans vérification du dossier médical pourrait mener à un certain nombre de faux négatifs, ce qui pourrait nuire à l'admissibilité des participants ou à l'analyse des résultats en recherche médicale.

cute otitis media (AOM) is a frequent complication of influenza virus infection and a leading cause of family physician visits (Charles, Pan, & Britt, 2004; Heikkinen & Chonmaitree, 2003; Heikkinen et al., 2004; Monto, Gravenstein, Elliott, Colopy, & Schweinle, 2000; Vergison et al., 2010). Medical records and parent report (for children) or self-report are common data sources for epidemiological studies of AOM. Medical chart review, commonly used for assessing medical events, can be costly, labour-intensive and time-consuming (Phillips et al., 2005). For province-wide or nation-wide studies where study participants access different medical services across large geographic areas, multiple personnel must obtain the data. However, the advantage of medical record review is that it removes the burden of data collection from research participants to the research team (Fukuoka, Dracup, Ohno, Kobayashi, & Hirayama, 2005).

When it is not possible to perform clinical tests or consultations, individuals' self-reports are used to measure disease status (Strauss, Rindskopf, Deren, & Falkin, 2001). Information is often obtained directly from research participants by self-administered surveys or personal interview (Okura, Urban, Mahoney, Jacobsen, & Rodeheffer, 2004). Self-report has disadvantages; it can be inaccurate because participants may not be aware of their diagnoses, may misunderstand their diagnoses, may not recall their diagnoses, or may simply not be willing to report (Goldman, Lin, Weinstein, & Lin, 2003). However, self-report can be relatively cost efficient and organizationally straightforward to implement, especially in large community samples (Englert et al., 2010; Newell, Girgis, Sanson-Fisher, & Savolainen, 1999).

Errors in self-reports of disease status can lead to errors in epidemiological estimates, such as prevalence and relative risks related to exposures that are being studied, flawed research conclusions and inadequate health care planning (Paganini-Hill & Chao, 1993). There are reports on the predictive value of parental reports of otitis media in infants under the age of 27 months using otoscopy, tympanometry, and audiometry as the "gold standard". These studies focused on parental recognition of otitis media before screening and evaluation, rather than validation of physician identification of otitis media cases (Anteunis, Engel, Hendriks, & Manni, 1999; J. Engel, Anteunis, Volovics, Hendriks, & Marres, 2000; J. A. Engel, Anteunis, Volovics, Hendriks, & Manni, 1999). The validity of retrospectively reported otitis media, or childhood history of otitis media, has also been addressed in the research literature (Alho, 1990; Anteunis, Engel, Hendriks, & Manni, 1999; Daly, Lindren, & Giebenk, 1994; J. Engel, Anteunis, Volovics, Hendriks, & Marres, 2000; J. A. Engel, Anteunis, Volovics, Hendriks, & Manni, 1999).

The Hutterite Influenza Prevention Study is a cluster randomized controlled trial (RCT) of vaccinating healthy children in Hutterite communities against influenza. Because viral upper respiratory infections commonly precede the onset of AOM (Heikkinen & Chonmaitree, 2003; Heikkinen et al., 2004; Monto et al., 2000), study RCT participants were monitored for physiciandiagnosed AOM as a potential sign or complication of influenza (Loeb et al., 2010). Using data from the RCT, we investigated how well self-(or parental) reports of AOM corresponded with physician identification in the medical records. To our knowledge, a prospective study evaluating self-reported (or parent-reported) physician diagnosis of AOM as a proxy for medical record data has not been reported in the literature.

METHODS

Study design and population

The present study is a cross-sectional analysis of data collected from the Hutterite Influenza Prevention Study. Hutterites are a communal religious group who live in self-governing, mostly thriving, technologically advanced, farming colonies and seek to actively detach themselves from the impact of the outside world. Participants from 49 Hutterite colonies participated in the trial; 22 in Alberta, 22 in Saskatchewan, and two colonies in Manitoba. Children, between the ages of 36 months and 15 years, were randomly assigned, according to colony and in a blinded manner, to receive either a standard dosing of inactivated trivalent influenza vaccine or hepatitis A vaccine. All colony members were then monitored during the influenza season for signs of respiratory-related illness. Details of the Hutterite randomized controlled trial (RCT) are described elsewhere (Loeb et al., 2010).

Self-report of AOM

Self-report data were collected by study diaries (completed by a family representative) and in-person interviews by trained research nurses from December 28, 2008 to June 23, 2009. During this period, RCT participants used family diaries to record influenzarelated signs and symptoms on a daily basis. The study diaries contained checklists of 11 signs and symptoms, (fever, cough, runny nose, sore throat, headache, sinus problems, muscle ache, fatigue, ear ache, chills and ear infection). Participants and mothers (of infants) were instructed that ear infection was a physician diagnosis and distinguished from the subjective symptom of earache; that is, ear infection should be reported on the day that it was diagnosed by a health care provider at a medical consultation. Each family was given similar thermometers to take oral temperatures whenever a family

member experienced any symptoms. Fever was defined as a temperature >38 degrees Celsius.

Research nurses visited the Hutterite colonies twice per week to check diary entries and interviewed individual participants (or mothers of babies and young children) regarding outpatient health care visits made for their symptoms, including medical visit date, physician name, health care facility, location (town or city, and address, if possible), and whether antibiotics were prescribed at the consultation. This surveillance approach ensured a limited time period between medical visits and verification of self-report data, e.g., one to three days on average; and up to seven days if a participant was away from the colony at the time of the nurse visit and data were obtained at the next visit.

Physician requests for medical record information

Written permission was obtained from study participants and parents to request influenza-related medical record information from health care providers visited during study surveillance. The Canadian Medical Directory (2009 edition) and online physician registries were used to obtain contact information of physicians for whom participants had provided incomplete addresses. For each reported medical visit, a one-page "Patient Information Request" form was faxed to the medical facility asking for individual patient record data regarding diagnosis (influenza, otitis media or other respiratory illness (Table 1). The procedure was approved by the institutional review boards at McMaster University, the University of Calgary, the University of Saskatchewan, and the University of Manitoba.

Faxed requests for information were sent to medical facilities. Reminders were faxed after one month if a response had not been received. A response indicating that there was "no visit" was followed up by (at least one) fax to an alternative medical facility, based on feedback from the original responder or geography. Participation by health care provider or medical institution was voluntary. Physicians were blind to patient's self-reported data. In cases where a copy of the patient record, rather than the completed form, was faxed back, one investigator (AB) transferred the medical record information to the study form. All faxes were sent between March and September 2009.

Statistical analyses

Descriptive statistics were used to examine the study sample demographics. Individual two-by-two contingency tables were calculated for AOM reporting by data source. We calculated the proportion of participants with AOM according to the medical record information and the self-reported data. For self-report, we looked at AOM (or physician-identified ear infection) reported on the family diary (and verified by nurse interview) on the day of the medical visit; that is, we looked at same-day reporting of AOM by both data sources.

Table 1

Request for Medical Record Information Form

The Hutterite Influenza Study is being conducted by researchers from McMaster University to better understand whether immunizing school-age children against influenza can protect high-risk members of their community.

Your patient, identified on the attached consent form, has agreed to participate in this study and has given us consent to contact you about his/her recent visit to you for treatment of respiratory infection symptoms.

1. What was actual date of the patient's visit?			
2. What were the patient's symptoms? Check all that apply.	Fever (≥38° C)	Muscle aches	
	Cough	Fatigue	
	Runny nose	Ear ache	
	Sore throat	Chills	
	Headaches	Other, specify:	
	Sinus problems		
3. What was the diagnosis?	Pneumonia		
	Otitis media		
	Other, specify:		

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For the primary analysis the medical report was considered the gold standard, since participants were specifically asked to report "physician-identified" or "physician-diagnosed" ear infection. Our medical record information came from different sources with different methods of documentation. We did not elicit information regarding the methods of determining or documenting AOM and we did not evaluate the quality, accuracy or comprehensiveness of the medical records. Therefore, the medical record was used as a proximate measure of the gold standard in the analyses.

Validity of self-report in comparison to medical record documentation was assessed by calculating the following estimates: sensitivity (correctly reported positive participant reports/all positive medical records); specificity (correctly reported negative participant reports/all negative medical records); positive predictive value (correctly reported positive participant reports/all positive self-reports); negative predictive value (correctly reported negative participant reports/all negative selfreports); likelihood ratio for a positive test (sensitivity/1 - specificity); and likelihood ratio for a negative test (1 sensitivity/specificity). Higher specificity and fewer false positive reports can lead to a higher likelihood ratio for a positive test and lower likelihood ratio for a negative test, both of which indicate better precision of reporting (Haynes, Sackett, Guyatt, & Tugwell, 2006).

Total agreement (number of concordant pairs/total sample) and kappa coefficient (and standard deviation) were computed. Kappa measures the strength of agreement beyond that expected solely by chance (observed agreement – chance agreement/1 – chance agreement), where 0 = chance agreement and 1 = perfect agreement (Cohen, 1960). To test for differences in mean number of reports per source, we used the paired Student's t-test.

Statistics were also calculated in four strata defined by sex, age group, level of risk for influenza complications, and number of sick days. The association between the stratification variables and agreement was further investigated using logistic regression analysis. The dependent variable was agreement, coded as 1 for agreement (if the participant and medical report both reported the presence of AOM or both reported the absence of AOM) or 0 for disagreement. All analyses were conducted using the Statistical Package of the Social Sciences (SPSS) version 16.0 for Windows (SPSS Inc., Chicago, IL). Significance levels were set at p < 0.05.

RESULTS

Characteristics of the participant sample

Of the 3,274 participants in the trial, 252 (8%)

reported at least one outpatient medical visit during the study influenza season. Six participants were unable to provide sufficient identifying information for the doctor or medical facility to be contacted. Therefore, requests for medical record information were faxed for 246 reported medical visits. The first medical visit reported by participants and confirmed by medical record information were included in the sample, resulting in 176 (70%) unique medical visits (Figure 1).

The mean age of the 176 participants was 24 years; 63 (36%) were under the age of seven years, and 46 (26%) were between the ages of 23 and 49 years. Over half of the sample (99, 56%) resided in Saskatchewan, 63 (36%) in Alberta and 12 (8%) in Manitoba. There were more females (110, 63%) than males and 63 (39%) were considered at high risk for influenza complications (Table 2). Medical visits were made between January and June 2009.

Characteristics of the medical facilities

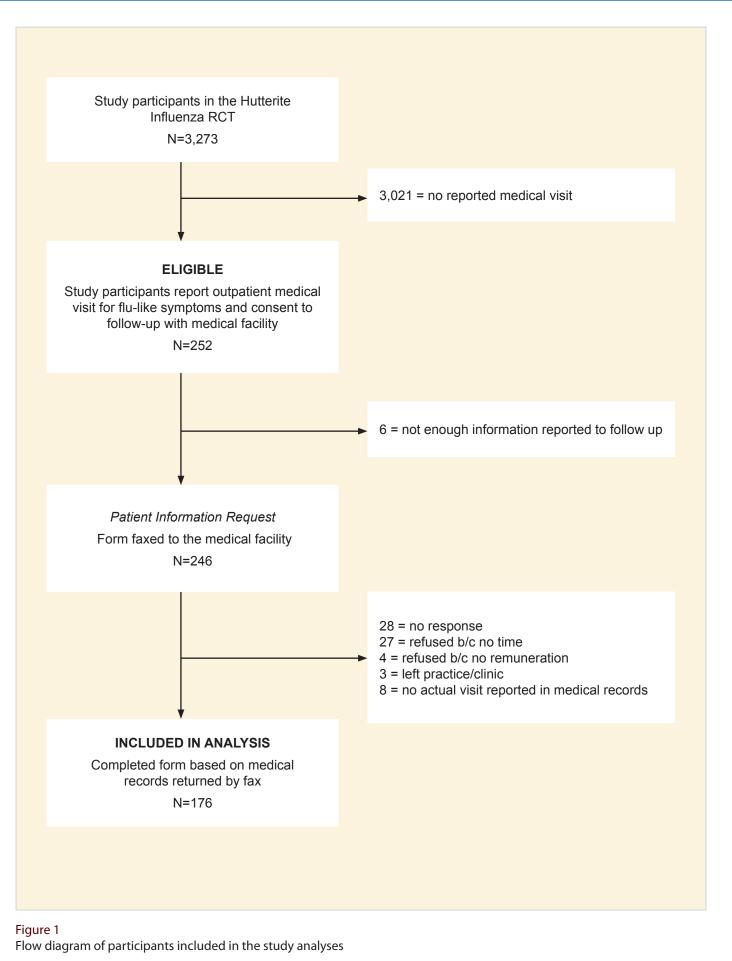
Three hundred and six initial faxes were sent to the physician offices or medical facilities; 131 fax reminders and 34 additional follow-up requests were also sent. A small number (n=11, 6%) from hospital emergency departments, opted to fax back a copy of the patient record for the specified visit; the information was then transferred to the study form by the first author (AB) (Table 2). Among the non-responders were two medical offices in Saskatchewan that declined participation in the study; 26 (10%) participants visited one of the two offices.

The 176 participants primarily visited family practice offices (80%), while almost a fifth of the sample (17%) accessed a hospital emergency department. Of the 176 medical visits, 167 (95%) were made to family doctors or general practitioners. Eighty nine individual health care providers were visited at 42 medical centres, 13 hospital emergency departments and two walk-in clinics. Almost half of the sample (48%) visited a medical facility in an urban centre, defined as an area that has more than 400 people per square kilometre and more than 1,000 people residing there (Statistics Canada 2002, 2005). Fifty-six percent sought medical care in their home province of Saskatchewan and only 8% lived and accessed medical care in Manitoba (Table 2). In total, participants visited 32 towns, cities or villages across the three provinces for medical care.

AOM reporting by data source

The proportion of physician-identified AOM (22%) was underestimated by participant self-report (16%) by 6%. This difference was not significant (95% CI -4.0 to 11.8, p = 0.068 (Table 3).

Of the 38 cases of AOM documented in the medical record, 28 (74%) were six years old or younger. Of the



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Table 2

Baseline demographic information of the 176 participants and characteristics of the participating medical facilities

Characteristic	No (%)
Participant	
Age groups, years	
Less than 7	63 (35.8)
7-15	27 (15.3)
16-22	13 (7.4)
23-49	46 (26.1)
50-64	15 (8.5)
65 and older	12 (6.8)
Mean age, years (SD) Province	23.7 (22.6)
Alberta	63 (35.8)
Saskatchewan	99 (56.3)
Manitoba	14 (8.0)
Female	110 (62.5)
High risk for influenza complications	68 (38.6)
Medical facilities	
Type of health care service	
Family practice/medical centre	140 (80.0)
Hospital emergency department	30 (17.0)
Walk-in clinic	6 (3.4)
Speciality of health care provider	
Family medicine/general practice	167 (94.9)
Emergency medicine	5 (2.8)
Pediatrician	2 (1.1)
Nurse practitioner	2 (1.1)
Urban area*	84 (47.7)
Fax response	
Completed form	165 (94)
Medical record	11 (6)

*Urban area = (population density = >400 people per sq. km) + (population = > 1,000 people) {859 Statistics Canada, 2003}

Table 3

Characteristics of reported acute otitis media (AOM) by data source

Patient characteristic	Presence of AOM		
	Medical record report n=38	Self- or maternal report n=28	
Age, years, n (%)			
< 2	16 (42.1)	7 (25.0)	
2-7	12 (31.6)	11 (39.3)	
Sex, male	25 (65.7)	16 (57.1)	
Prescription for antibiotics	34 (89.5)	27 (96.4)	
Amoxicillin	23 (67.6)	13 (48.1)	
Azithromycin	2 (5.9)	4 (14.8)	
Amoxicillin/clavunate	3 (8.8)	2 (7.4)	
Cefprozil	2 (5.9)	3 (11.1)	
Ciproflaxin	2 (5.9)	1 (3.7)	
Symptomatic	37 (97.4)	27 (96.4)	
Fever	27 (71.1)	6 (21.5)	
Earache	25 (65.8)	8 (28.6)	
Cough	23 (60.5)	17 (60.7)	
Runny nose	15 (39.5)	11 (39.3)	
Sore throat	13 (34.2)	6 (21.4)	
Self-reported sick days at medical visit			
1 - 3	15 (38.5)	12 (42.9)	
4 or more	20 (52.6)	14 (50.0)	

28 cases of AOM self-reported cases, 18 (64%) were six years old or younger (Table 3). Of the 63 (36%) children under the age of seven in the sample, 28 (44%) had a classification of AOM in the medical record; and 18 (28.6) self-reported AOM. All but one (37, 97%) of the documented AOM cases and the self-reported cases (27, 96%) were symptomatic at the time of the medical visit. The most frequently reported symptoms were fever, earache, cough and runny nose. Physicians reported that 90% (34 out of 38) of AOM cases were prescribed antibiotics. According to the research participants, all 28 cases were given a prescription and 27 (96%) provided the name of the antibiotic (Table 3).

Assessment of self-reported AOM

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Using medical record documentation as the gold standard, self-report of AOM was a very specific measure (93%), but had lower sensitivity (47%) (Table 4). The high specificity indicates the participant's very good

ability to accurately report not having AOM. However, the sensitivity means that participant self-report failed to identify more than half of AOM cases documented in the medical records. The probability of medical documentation of AOM in a participant, who reported AOM, or positive predictive value, was moderate with an estimate of 64%. That is, the medical records confirmed 64% of the self-report of AOM. The probability of not having AOM according to the medical records in a participant, who did not report the diagnosis, or negative predictive value, was good at 86%. The likelihood ratio of having AOM was 6.7 and the likelihood ratio of not having the AOM was 0.57, indicating moderate exactness with the medical record. The kappa estimate was 0.44, which according to Landis and Koch (1977) indicates moderate agreement. Prerequisites for high kappa are good agreement and a fairly even distribution between positive versus negative responses. That is, the kappa coefficient is sensitive to both prevalence and bias

(Feinstein & Cicchetti, 1990; Sim & Wright, 2005).

Indices for self-reported AOM were not affected by age, sex, number of sick days or influenza risk status. The results of logistic regression analyses showed that none of the variables examined were significantly associated with agreement.

DISCUSSION

We found good agreement (83%) between self-(and maternal) reported AOM and documentation in the medical record. Our estimates indicated that participants were quite good at identifying they did "not" have AOM, but poorer at identifying the actual diagnosis of AOM assuming medical record was the gold standard. Specificity of self-report remained high across all stratified variables (>89%). The overall sensitivity was modest (47%) and the positive predictive value was a moderate 64%. That is, 47% of participants with AOM documented in their medical records reported the diagnosis and 64% of participants with self-(or maternal) reported AOM had confirmation of diagnosis from medical record abstraction.

The low sensitivity and moderate positive predictive value may have resulted from limitations at each source. By having the physician or medical facility staff complete the "request for information" forms, we avoid errors associated with researcher reliability, legibility, and interpretability (Horowitz, 1986). Studies have shown that illegibility and conflicting data in a single medical note occur frequently. We also avoided researcher errors related to the ability to read the medical record and abstract subject information without bias (Nagurney et al., 2005). This method made it possible to obtain medical chart data from multiple medical practices and hospitals in various geographic areas across three provinces without being exceedingly labour-intensive and costly. However, medical records are not the perfect criterion standard for the presence of AOM. Several studies have found non-reporting and misreporting in medical records (Marrie, Durant, & Sealy, 1987; Bush, Miller, Golden, & Hale 1987). One study found underreporting in general practice records for chronic conditions and multiple health problems presented at one medical visit (Jordan, Jinks, & Croft, 2006). Busier physicians may record less in the medical record or delay recording, leading to recall bias (Ferrante et al., 2008). The process of abstracting information from the medical chart itself is also subject to imprecision (Pakhomov, Jacobsen, Chute, & Roger, 2008). We cannot assume that data were abstracted in a consistent manner across clinical sites. Furthermore, medical records accessed for this analysis were not written or kept for the purposes of this study (Fathelrahman, 2009) and, therefore, are subject to information bias.

Documentation may have been guided by institutional policy, physician training and physician preference, rather than research purposes (Kimberlin & Winterstein, 2008).

Clinicians were not asked to provide information about how the diagnosis was made. According to the American Academy of Pediatrics, otitis media is confirmed if all of the following three criteria are present: 1) recent or abrupt onset of symptoms, 2) the presence of middle ear effusion (defined by one of the following: bulging of the tympanic membrane, limited or absent mobility of the tympanic membrane, air fluid level behind the tympanic membrane, otorrhea), 3) evidence of middle ear inflammation (either distinct erythema of the tympanic membrane or distinct otalgia) (American Academy of Pediatrics, Subcommittee on Management of Acute Otitis Media, 2004). We cannot determine whether physicians followed these or other criteria to diagnose AOM. We also did not assess what procedure was used in determining AOM, such as visualization (otoscopic examination) or functional testing of the eardrum (tympanetry, acoustic reflex) (Vergison et al., 2010). The majority of clinicians in our sample were family doctors or general practitioners; diagnostic ability, training and certainty may differ within this group and from other health care professionals (Froom, 1990; Linsk & Cooke, 2004; Nozza, Bluestone, Kardatzke, & Bachman, 1994). Given these possible limitations, documentation in the medical record was used as a proximate measure of the gold standard. Therefore, reproducibility, rather than accuracy, of self-report, was examined.

Self-reported information can be also imprecise for various reasons, including underreporting, lack of motivation to report accurately, and poor compliance. It is possible self-report data may be systematically biased. For example, it may be that the Hutterites, because they have limited formal education and low health care literacy, were more likely to make errors in reporting the details of their medical visits. Another explanation is that clinicians provided insufficient information about AOM or communicated ineffectively so that patients or their parents misunderstood or quickly forgot the diagnosis (Westbrook, McIntosh, Rushworth, Berry, & Duggan, 1998). However, it is unknown exactly what physicians communicated to patients.

The two sources of data assessed in this study are forms of self-reports. Unlike survey methods that result in "unfiltered" self-reports, both medical record and participant data were filtered through the additional questioning of the physician or research nurse (Corser et al., 2008). The adequate capture of self-report data relied on both the participant's reporting and the research nurse's recording of the information. Likewise, the adequate capture of clinical data required the patient's reporting and the health care provider's documentation of the information (Babcock, Merz, Dubberke, & Fraser, 2008). However, the contexts and perspectives of self-reports are different (Kraemer et al., 2003). Differences in physician elicitation of health information can be compared to the RCT's focus on consistent and systematic collection of specific events.

In many studies, participants are asked if they have a medical problem, but not whether it has been identified by a health care professional (Okura et al., 2004). In this study, participants were asked about physician identification of AOM immediately following the medical visit. Unlike research using retrospective questionnaires, we attempted to monitor events as they occurred as close to "real time" as feasible. However, there is still the potential for recall bias between the actual visit and reporting for events for the study. Severity and recurrence of AOM may also have impacted reporting and agreement between sources, but this was not assessed.

AOM is a common infection for which antibiotics are prescribed, especially in children (Autret-Leca, Giraudeau, Ployet, & Jonville-Bera, 2002; Nyquist, Gonzales, Steiner, & Sande, 1998). Data regarding antibiotic prescriptions were collected from participants following medical visits. Almost all participants (96%) who reported AOM also reported getting an antibiotic prescription. Receipt of a prescription for antibiotics may have served as a prompt for AOM reporting.

To compare data sources, we limited the analyses to participants whose physician or hospital had provided medical record information, i.e., participants who had data from both sources. Thirty percent of the fax requests were not completed; responding physicians or medical facilities may differ from non-responders, resulting in self-selection bias. It is possible that agreement between sources would be different for these participants with missing medical record data.

Research on health services utilization by Hutterite colony members is lacking in the medical literature. This study contributes to the knowledge of this understudied group. Despite the inclusion of medical records abstracted from diverse medical facilities, generalizability may be limited by utilizing a homogeneous cohort; it is possible that agreement with the medical record may vary for other outpatient populations. However, we suspect that the underestimation of the incidence of AOM is likely to be generalizable to other non-Hutterite patient groups and with research methodologies that are less stringent than our surveillance methods; however such study designs may result in lower specificities or negative predictive values.

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Research studies commonly have access to only one source of data and may not compare reporting to other data sources. The two data sources in this study provided insights into the congruence between two methods. Our findings suggest that AOM reports from study participants may not be entirely accurate and may result in a number of false negatives without supplemental data collected from medical records. Reliance on self-report without comparison to medical records may lead to errors in determination of AOM rates and may affect enrollment eligibility or outcome analyses in research studies. The decision regarding which source of data to use will depend on the outcome of interest; whether findings are used for clinical decision making, population surveillance, outcome studies or other research purposes, availability of resources; and whether a false positive or false negative is of more concern (Ferrante et al., 2008).

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