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Physicians' confidence in vaccine safety studies

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Abstract

Objectives—To ascertain, through two separate surveys among nationally representative networks of pediatricians (Peds) and family physicians (FM): 1) physicians' reported level of confidence in pre- and post-licensure vaccine safety studies; and 2) changes in reported level of confidence from 2007 to 2010/11.

Methods—Two surveys were conducted in August to October 2007 and in November 2010 to January 2011. The survey response rates were 81% (FM, 79%, Peds, 84%, p=0.07) for the 2007 survey (691/848) and 66% (FM, 61%, Peds, 70%, p=0.003) for the 2010/11 survey (532/811).

Results—One in three family physicians compared to one in ten pediatricians in both surveys reported little or no confidence in *pre-licensure* vaccine safety studies (p<0.001). Compared to pre-licensure studies, higher percentages of both specialties reported a great deal of confidence in post-licensure vaccine safety studies in both years, and more physicians from both specialties reported a great deal of confidence in 2010/11 than in 2007.

Conclusion—While most family physicians and pediatricians report confidence in post-licensure vaccine safety studies, one third of family physicians report little or no confidence in pre-licensure studies. More research is needed to better understand the reasons behind some physicians' lack of confidence in vaccine safety studies.

Keywords

Vaccination; Preventive medicine; Pediatrics; Family practice; Attitude of health personnel

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Conflict of interest statement

None of the authors has any financial conflicts of interest.

The findings and conclusions in this report are those of the authors and do not necessarily represent the views of the Centers for Disease Control and Prevention.

Introduction

The United States has an elaborate system for assessing vaccine safety (Salmon et al., 2011). Vaccines undergo extensive testing prior to approval to assess immunogenicity, efficacy, and safety. Rare adverse events, however, are difficult to detect pre-licensure (Jacobson et al., 2001). Because of this, the Centers for Disease Control and Prevention and others have developed systems for post-licensure vaccine safety monitoring, including the Vaccine Adverse Event Reporting System (Varricchio et al., 2004) and the Vaccine Safety Datalink (Baggs et al., 2011; Chen et al., 2000). Since 2005, there have been nine new vaccines introduced into the child and adolescent immunization schedule including two rotavirus vaccines, two meningococcal conjugate vaccines, two human papillomavirus vaccines, two tetanus–diphtheria–acellular pertussis vaccines, and a 13-valent pneumococcal conjugate vaccine. There have also been several new combination vaccines introduced.

As the perception of vaccine hesitancy among parents appears to be on the rise (Kempe et al., 2011), there is growing concern among vaccine advocates regarding effective ways to communicate accurate vaccine safety information to the public (Kennedy et al., 2011). A child's physician, however, has consistently been shown to be the most trusted source of information about vaccines among parents (Benin et al., 2006; Freed et al., 2010; Gellin et al., 2000). The level of confidence that physicians themselves have in vaccine safety studies is therefore important to gauge, but is currently unknown. The objectives of this study were to ascertain, through two separate surveys among nationally representative networks of pediatricians and family physicians: 1) physicians' reported level of confidence in pre- and post-licensure vaccine safety studies; and 2) changes in reported level of confidence from 2007 to 2010/11.

Methods

Two national surveys were conducted August to October 2007 and November 2010 to January 2011 using two distinct physician survey networks designed to be representative of the American Academy of Family Physicians (AAFP) and American Academy of Pediatrics (AAP) memberships. These networks are similar to physicians randomly sampled from the American Medical Association master file with respect to demographics and vaccine-related attitudes (Crane et al., 2008). The human subjects review board at the University of Colorado Denver approved this study.

The questions assessed physicians' confidence in pre- and post-licensure vaccine safety studies using 4-point Likert scales and were embedded in larger surveys regarding rotavirus vaccine. Physicians were asked "How much confidence do you have in pre-licensure studies (prior to FDA approval) in determining vaccine safety?" and "How much confidence do you have in the post-licensure surveillance (VAERS and other safety mechanisms) to monitor vaccine safety?" The surveys were pretested by physician advisory boards and pilot tested in national samples of primary care physicians (Varricchio et al., 2004). They were administered via mail or Internet (Vovici, Dulles, VA) using a tailored approach (Dillman et al., 2009).

Tests for association with the primary outcome of reporting little or no confidence in pre-licensure vaccine safety studies were performed on both survey populations of family physicians using chi-square analyses. Factors significant at $p<0.25$ in bivariate analyses were tested in multivariable models, and only factors that were significant at $p<0.05$ were retained in the final model. Similar analyses were not performed for pediatricians, because their rate of responding 'little or no confidence' was so low.

The survey response rates were 81% (FM, 79%, Peds, 84%, p=0.07) for the 2007 survey (691/848) and 66% (FM, 61%, Peds, 70%, p=0.003) for the 2010/11 survey (532/811). Survey populations are shown in Tables 2–4, online supplementary material.

Results

While most respondents overall reported a great deal or moderate confidence in pre-licensure vaccine safety studies in both 2007 and 2010/11, approximately one-third of family physicians reported little or no confidence in both years (Table 1). Compared to pre-licensure studies, higher percentages of both specialties reported a great deal of confidence in post-licensure vaccine safety studies in both years, and more physicians reported a great deal of confidence in 2010/11 than in 2007. For all comparisons, pediatricians were more likely than family physicians to report a great deal or moderate confidence and less likely to report little or no confidence ($p<0.001$). In both bivariate and multivariable analyses among family physicians (Tables 5–6, online supplemental material), only practice location was associated with reporting little or no confidence in pre-licensure vaccine safety studies in the 2007 survey, with respondents practicing in a non-inner-city/suburban environment more likely to report 'little or no confidence' than those practicing in urban/inner city or rural settings (p=0.03). In 2010, the only associated factor was a practice setting of community/hospital-based/managed care organization vs. private practice (p=0.03).

Discussion

Our study using national networks of primary care physicians found that confidence in post-licensure vaccine safety studies increased from 2007 to 2010/11, but that confidence in pre-licensure studies remained unchanged. Our data suggest that pediatricians have more confidence in vaccine safety studies compared to family physicians.

Many physicians report a great deal of confidence in post-licensure vaccine safety studies, and this appears to be increasing. There are several potential reasons for this high level of confidence. Though adverse events are rare, post-licensure studies have successfully identified potential vaccine-associated events (Klein et al., 2010; France et al., 2008; O'Leary et al., 2012), the most notable of which was the withdrawal of the rhesus-based rotavirus vaccine (RotaShield, Wyeth-Lederle) 11 months after licensure after detection of a slightly increased risk of intussusception after the first dose (McPhillips et al., 2001; Murphy et al., 2001). It is also possible that awareness of post-licensure safety monitoring following the introduction of the newer rotavirus vaccines influenced physicians' reported level of confidence in post-licensure studies, particularly since these questions were asked in the context of larger rotavirus vaccine surveys.

It is unclear why one-third of family physicians report little or no confidence in pre-licensure vaccine safety studies. While pre-licensure studies did not detect the slightly increased risk of intussusception after RotaShield, since that time pre-licensure studies have had remarkable concordance with post-licensure studies in the US. Family physicians' lower confidence in pre-licensure vaccine safety studies may be one factor that helps explain why family physicians in general adopt new childhood vaccines more slowly than pediatricians (Davis et al., 2003; Kempe et al., 2009).

This study has important strengths and limitations. To our knowledge, it is the only study in the last 10 years to directly assess physicians' confidence in vaccine safety studies, and the only one to make a longitudinal comparison. The surveyed physicians are generally representative of members of the AAP and the AAFP (Crane et al., 2008), and although there was a notable difference in response rates from 2007 to 2010/11, the response rates were high. However, respondents may have differed from non-respondents. In addition, the response rates were lower for family physicians than for pediatricians which may limit the validity of the comparison between specialties. Also, although the questions in the survey were asked generically about safety studies in general, they were asked in the context of a larger rotavirus survey which may have influenced physicians' responses.

As pediatricians and family physicians deliver most vaccines to children in the US, their confidence in the safety of new vaccines is crucial to the ongoing success of our national immunization program and delays in adoption of new vaccines could have important consequences. While most physicians report confidence in post-licensure vaccine safety studies, if many physicians are not confident in pre-licensure studies, it is hard to expect the general public to have confidence in a new vaccine. Discerning which physicians lack confidence in vaccine safety studies and why will help policy makers target educational campaigns. Physician confidence in vaccine safety studies should continue to be monitored, and reasons for lack of confidence should be explored.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at http://dx.doi.org/10.1016/j.ypmed.2013.01.001.

References

Baggs J, Gee J, Lewis E, et al. The vaccine safety datalink: a model for monitoring immunization safety. Pediatrics. 2011; 127(Suppl. 1):S45–S53. [PubMed: 21502240]

Benin AL, Wisler-Scher DJ, Colson E, Shapiro ED, Holmboe ES. Qualitative analysis of mothers' decision-making about vaccines for infants: the importance of trust. Pediatrics. 2006; 117:1532–1541. [PubMed: 16651306]

Chen RT, Destefano F, Davis RL, et al. The vaccine safety datalink: immunization research in health maintenance organizations in the USA. Bull World Health Organ. 2000; 78:186–194. [PubMed: 10743283]

Crane LA, Daley MF, Barrow J, et al. Sentinel physician networks as a technique for rapid immunization policy surveys. Eval Health Prof. 2008; 31:43–64. [PubMed: 18184632]

Davis MM, Ndiaye SM, Freed GL, Clark SJ. One-year uptake of pneumococcal conjugate vaccine: a national survey of family physicians and pediatricians. J Am Board Fam Pract. 2003; 16:363–371. [PubMed: 14645326]

Dillman, DA.; Smyth, J.; Christian, LM. Internet, Mail and Mixed-Mode Surveys: the Tailored Desgin Method. 3rd. John Wiley Co.; New York: 2009.

France EK, Glanz J, Xu S, et al. Risk of immune thrombocytopenic purpura after measles–mumps–rubella immunization in children. Pediatrics. 2008; 121:e687–e692. [PubMed: 18310189]

Freed GL, Clark SJ, Butchart AT, Singer DC, Davis MM. Parental vaccine safety concerns in 2009. Pediatrics. 2010; 125:654–659. [PubMed: 20194286]

Gellin BG, Maibach EW, Marcuse EK. Do parents understand immunizations? A national telephone survey. Pediatrics. 2000; 106:1097–1102. [PubMed: 11061781]

Jacobson RM, Adegbenro A, Pankratz VS, Poland GA. Adverse events and vaccination—the lack of power and predictability of infrequent events in pre-licensure study. Vaccine. 2001; 19:2428–2433. [PubMed: 11257373]

Kempe A, Patel MM, Daley MF, et al. Adoption of rotavirus vaccination by pediatricians and family medicine physicians in the United States. Pediatrics. 2009; 124

Kempe A, Daley MF, McCauley MM, et al. Prevalence of parental concerns about childhood vaccines: the experience of primary care physicians. Am J Prev Med. 2011; 40:548–555. [PubMed: 21496754]

Kennedy A, Lavail K, Nowak G, Basket M, Landry S. Confidence about vaccines in the United States: understanding parents' perceptions. Health Aff (Millwood). 2011; 30:1151–1159. [PubMed: 21653969]

Klein NP, Fireman B, Yih WK, et al. Measles–mumps–rubella–varicella combination vaccine and the risk of febrile seizures. Pediatrics. 2010; 126:e1–e8. [PubMed: 20587679]

McPhillips HA, Davis RL, Marcuse EK, Taylor JA. The rotavirus vaccine's withdrawal and physicians' trust in vaccine safety mechanisms. Arch Pediatr Adolesc Med. 2001; 155:1051–1056. [PubMed: 11529808]

Murphy TV, Gargiullo PM, Massoudi MS, et al. Intussusception among infants given an oral rotavirus vaccine. N Engl J Med. 2001; 344:564–572. [PubMed: 11207352]

O'Leary ST, Glanz JM, McClure DL, et al. The risk of immune thrombocytopenic purpura after vaccination in children and adolescents. Pediatrics. 2012; 129:248–255. [PubMed: 22232308]

Salmon DA, Pavia A, Gellin B. Editors' introduction: vaccine safety throughout the product life cycle. Pediatrics. 2011; 127(Suppl. 1):S1–S4. [PubMed: 21502245]

Varricchio F, Iskander J, Destefano F, et al. Understanding vaccine safety information from the Vaccine Adverse Event Reporting System. Pediatr Infect Dis J. 2004; 23:287–294. [PubMed: 15071280]

Table 1

Physicians' reported level of confidence in pre- and post-licensure vaccine safety studies among pediatricians and family physicians administering childhood vaccines in their practice.

Pre-licensure confidence	2007	2011	p-value[d]
Pediatricians, n (%)[a]			
A great deal of confidence	120 (34)[c]	116 (41)	0.38
Moderate confidence	202 (58)	138 (49)	
A little confidence/No confidence at all	29 (8)	30 (11)	
Family physicians, n (%)[b]			
A great deal of confidence	23 (9)	24 (13)	0.22
Moderate confidence	142 (56)	107 (57)	
A little confidence/no confidence at all	87 (35)	58 (31)	
Post-licensure confidence			
Pediatricians, n (%)			
A great deal of confidence	160 (45)	168 (59)	0.002
Moderate confidence	171 (49)	101 (36)	
A little confidence/no confidence at all	22 (6)	15 (5)	
Family physicians, n (%)			
A great deal of confidence	49 (20)	57 (30)	0.007
Moderate confidence	165 (66)	113 (60)	
A little confidence/no confidence at all	37 (15)	19 (10)	

Portions of the 2007 data for family physicians were previously used as part of a multivariable analysis of factors associated with routinely offering rotavirus vaccine to eligible infants (Kempe A, Patel MM, Daley MF, Crane LA, Beaty B, Stokley S et al. Adoption of Rotavirus Vaccination by Pediatricians and Family Medicine Physicians in the United States. Pediatrics 2009; 124(5)).

Data from the US national physicians' survey administered 08/2007–10/2007 and 11/2010–01/2011.

[a] For pediatricians, n=360 for 2007 survey and n=274 for 2011 survey.

[b] For family physicians, n=263 for 2007 survey and n=189 for 2011 survey; family physicians who reported not seeing infants under 6 months were excluded.

[c] Some numbers may not sum to group totals due to missing answers and some percentages may not add to 100 due to rounding.

[d] Comparison is Mantel–Haenszel χ^2 test, 2007 vs. 2011.