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The Role of Media and the Internet on Vaccine Adverse Event Reporting: A Case Study of Human Papillomavirus Vaccination

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A B S T R A C T

Purpose: This study aimed to determine the temporal association of print media coverage and Internet search activity with adverse events reports associated with the human papillomavirus vaccine Gardasil (HPV4) and the meningitis vaccine Menactra (MNQ) among United States adolescents.
Methods: We used moderated linear regression to test the relationships between print media reports in top circulating newspapers, Internet search activity, and reports to the Vaccine Adverse Event Reporting System (VAERS) for HPV4 and MNQ during the first 2.5 years after Food and Drug Administration approval.
Results: Compared with MNQ, HPV4 had more coverage in the print media and Internet search activity, which corresponded with the frequency of VAERS reports. In February 2007, we observed a spike in print media for HPV4. Although media coverage waned, Internet search activity remained stable and predicted the rise in HPV4-associated VAERS reports.
Conclusions: We demonstrate that media coverage and Internet search activity, in particular, may promote increased adverse event reporting. Public health officials who have long recognized the importance of proactive engagement with news media must now consider strategies for meaningful participation in Internet discussions.

IMPLICATIONS AND CONTRIBUTION

The abundance of media coverage and public interest in human papillomavirus vaccination in the months after the Food and Drug Administration's approval of Gardasil was strongly related to the increase in human papillomavirus vaccine–associated adverse events reported to the Vaccine Adverse Event Reporting System.

In June 2006, the United States (U.S.) Food and Drug Administration (FDA) approved Gardasil (Merck & Co., Inc., Whitehouse Station, NJ), a quadrivalent recombinant vaccine that prevents certain strains of human papillomavirus (HPV) that can cause genital warts and are linked with the development of cancers, including cervical cancer [1]. Although Gardasil (HPV4) was lauded as a medical breakthrough, the social and political climate surrounding vaccination was tumultuous because of questionable lobbying practices and conflicts of interest, anecdotal reports of side effects, and public debate about parental rights and adolescent sexual practices.

The HPV vaccine differs from other childhood vaccinations in ways that the public found salient [2]. First, the FDA initially approved the vaccine for use only in females aged 9–26 years, so vaccine recommendations were gender specific, unlike other

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vaccines on the market. This targeting was purposeful in an effort to reduce the future burden of cervical cancer in women; however, it was also perceived as biased, because males are also able to be infected and transmit the virus. Second, legislation was introduced in several states to mandate HPV vaccine education and/or vaccination in middle school–aged girls [3], a period when the likelihood of HPV exposure is low (and thus, vaccination is most effective for prevention) and other adolescent vaccines are administered. The first such legislation was introduced by Texas Governor Rick Perry in February 2007. Governor Perry issued an executive order [4] that school girls over the age of 11 years be vaccinated against HPV—a mandate that received substantial national news coverage although it was quickly overturned by the Texas legislature after parental outcry and political descent on the issue of parental rights. Similar bills under consideration in most states were tabled, withdrawn, or vetoed soon thereafter. Third, the sexually transmitted nature of HPV garnered a great deal of media attention, differentiating it from diseases that can be transmitted by casual contact in the classroom (e.g., measles, mumps, whooping cough) [5]. Talking points about adolescent promiscuity and premarital sex were also present in the media [5] and distracted viewers from the primary messages about cervical cancer and prevention of sexually transmitted infections being presented by health professionals.

As the discourse unfolded, reports of HPV4-associated adverse events escalated on the Vaccine Adverse Events Reporting System (VAERS) maintained by the U.S. Centers for Disease Control and Prevention and the FDA. Slade et al [6] found that the VAERS reporting rate for HPV4 was triple the rate for all other vaccines combined from June 1, 2006 to December 31, 2008, citing a possible "Weber effect"—in which reporting of adverse events spikes after the licensure of a new product. In his work from the 1980s, Weber [7] described how the adverse event reporting rate can be influenced by factors such as exposure to a new treatment, new dosage forms, and exposure to journal articles or regulatory agency warnings. With the widespread availability of health-related information in the print news and online media, some have suggested that biased reporting can also result from "increased reporting after publicity about a particular known or alleged type of adverse event" [8].

Studies have long evaluated the effect of news media reports on knowledge [9] and risk perceptions [10]. Kelly et al [9] found that HPV-associated knowledge levels increased as media coverage increased, and found that knowledge remained high even as media coverage levels dwindled over time. This suggests that once gained, knowledge stays; conversely, perhaps information propagates on other sources (e.g., Internet). Ball et al [10] also mentioned the role of media outlets in molding the public's perceptions of vaccine risk. To our knowledge, however, we know of no studies that have quantified the association of print media with the frequency of adverse event reports to VAERS.

The current study aimed to determine the temporal association of print media and HPV4-associated VAERS reports among adolescents in the U.S. We also examined the mediating effect of Internet search activity. We conducted the same analyses for Menactra (Sanofi Pasteur, Inc., Swiftwater, PA) (MNQ), a meningococcal vaccine licensed for a similar age group just 18 months before HPV4, as a comparison case. We hypothesized that (1) the increased media coverage surrounding HPV4 in the initial period after FDA approval would be associated with an increased number of HPV-associated VAERS reports; and (2) the number of HPV-associated VAERS reports would remain steady despite waning print media coverage over time because of continued public interest in HPV vaccination, as evidenced by Internet search activity.

Methods

Data sources and procedures

Multiple data sources were included in our analysis, including the monthly total of adverse event reports from VAERS, the monthly total of print media reports from top-circulating U.S. newspapers, and the monthly frequency of Internet search activity as measured by Google Insights for Search beta. The public availability and de-identified nature of the data received from these sources did not necessitate institutional review.

The Vaccine Adverse Events Reporting System is a post-marketing, passive vaccine safety surveillance system established in the 1990s to collect and analyze data on reported adverse events after the administration of U.S.-licensed vaccines [11]. Anyone can report an adverse event, including health care providers, vaccine manufacturers, and the public. Medical events are encouraged to be reported, even if the reporter is unsure whether there is a causal link between the vaccination and the event, and selected reports will be followed up by VAERS staff. Over 85% of all the reports received are mild and include fever, injection site reactions, and irritability [12]. Publicly available data from 2005 to 2008 were retrieved from the VAERS Web site (http://vaers.hhs.gov/data/data/) in early 2009. We included VAERS reports from June 2006 to December 2008 for HPV4 and from January 2005 to July 2007 for MNQ. (The abbreviations HPV4 and MNQ are the respective terms used by VAERS for Gardasil and Menactra.) The dates we chose correspond to approximately 2.5 years after initial FDA approval of each vaccine. The VAERS data were only extracted for adolescents aged 11–18 years, because this range falls within the Advisory Committee on Immunization Practices' recommended age of vaccination for both vaccines (i.e., HPV4: 11–26 years; and MNQ: 11–18 years) [13,14]. Vaccine Adverse Events Reporting System reports that had both MNQ and HPV listed in the sample report were excluded (n = 1,160).

We searched LexisNexis, the largest database of public record news articles, for print media reports from top circulating U.S. newspapers (top 20) or top largest U.S. cities (top 10). Five newspapers unavailable through LexisNexis were not included. A total of 16 newspapers were analyzed (Table 1).

We limited our document search to the time periods June 2006 to December 2008 for print media reports related to HPV4 and January 2005 to July 2007 for those related to MNQ, so that they would also correspond to the 2.5 years after initial FDA approval of each vaccine. The following search terms were used to identify print media reports related to HVP4: "HPV" AND "vaccine OR vaccination OR immunization"; "Human papillomavirus" AND "vaccine OR vaccination OR immunization"; and "Gardasil." For those related to MNQ, we used the following search terms: "Menactra"; "Meningococcal" AND "vaccine OR vaccination OR immunization"; and "Meningitis" AND "vaccine OR vaccination OR immunization." We did not specifically search for the terms "HPV4" or "MNQ" because these are abbreviations used by VAERS, not the media or public. We excluded reports related solely to Merck or Sanofi Pasteur's financial status (e.g., profits) and duplicate reports from the monthly count. We did not exclude reports that fit the search criteria but were only