

Rotavirus Vaccine and the News Media, 1987-2001

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ROTAVIRUS IS THE MOST IMPORTANT cause of severe childhood diarrhea: globally about 1 in 200 children born each year die of rotavirus diarrhea, and approximately 1 in 100 children born in the United States each year are hospitalized.¹⁻⁶ Environmental measures, such as providing clean food, water, and sanitation, do not reduce rotavirus infection rates.⁴ Primary prevention is thought to be possible only through use of an effective vaccine.³⁻⁵

In August 1998, after more than a decade of clinical trials and research,⁷⁻¹⁵ a rotavirus vaccine (RotaShield) with an efficacy of about 80% against severe rotavirus diarrhea was licensed by the US Food and Drug Administration (FDA).¹⁵⁻¹⁸ In March 1999, the Advisory Committee on Immunization Practices (ACIP) recommended the vaccine for all US infants,⁵ as had the American Academy of Pediatrics (AAP) in December 1998.¹⁹ Adverse events were expected to be mild: in trials, 2% of vaccinees had experienced irritability, fever lower than 39°C, or decreased appetite.^{4,5,18,19}

However, with widespread use of the rotavirus vaccine, the Vaccine Adverse Event Reporting System (VAERS) of the FDA and the Centers for Disease Control and Prevention (CDC) received reports that some vaccinees had experienced intussusception, a potentially life-threatening intestinal blockage.^{20,21} In vaccine trials, intussusception had been noted in 5 per 10000 recipients, an association thought to be coincidental,⁵ but the VAERS data suggested the potential of a causal relationship.²¹ In July 1999, the manufacturer suspended

Context In August 1998, the US Food and Drug Administration licensed the first vaccine against rotavirus, the most important cause of severe childhood diarrhea. Fourteen months later, amid intense media activity, the vaccine was withdrawn after an association was found with intussusception.

Objectives To examine the character of news media stories about rotavirus vaccine before and after intussusception became an issue, to evaluate what prompted the stories, and to assess the extent to which they evoked public reaction.

Design and Setting We searched Lexis-Nexis and Video Monitoring Services of America databases for rotavirus vaccine stories from the first US clinical trials (January 1, 1987) until 17 months after withdrawal (March 31, 2001) and examined calls to the National Immunization Hotline during the period in which rotavirus vaccine information was captured (July 1–December 31, 1999).

Main Outcome Measures Mention of vaccine benefits and adverse events, classification of stories as positive, negative, or neutral toward the vaccine, story stimuli, and public response.

Results We included 280 newspaper (primary subject of analysis), 49 wire service, and 257 television stories. Prior to identification of the intussusception association (January 1, 1987–July 14, 1999), 21% of 188 newspaper stories mentioned vaccine adverse events and only 2 stories were negative toward the vaccine. Ninety-nine percent of stories mentioned vaccine benefits. During the period surrounding withdrawal (July 15–December 31, 1999), 93% of 90 stories mentioned adverse events and 77% were negative toward the vaccine. Eighty-four percent mentioned vaccine benefits. The rate of stories per month was 14-fold greater than the preceding period ($P < .001$); temporal and geographic patterns of media and hotline activity were similar. Thereafter (January 1, 2000–March 31, 2001), only 2 stories focused on rotavirus vaccine. Scientific research or public health actions prompted 80% of stories. Wire service and television stories showed similar patterns. The increase in rotavirus stories in July 1999 was followed by an increase in calls to the National Immunization Hotline regarding rotavirus but not other topics. The number of rotavirus calls that month was 57% higher than for any other childhood vaccine for any month since the hotline began in 1997. Rotavirus calls ceased almost completely after withdrawal of the vaccine in October 1999.

Conclusions In response to reports about an adverse event, news media stories about vaccines can change abruptly from positivity to negativity. Since most vaccine stories may be stimulated by research and public health actions, opportunities exist to provide the media with accurate information necessary to avoid the “early idealization–sudden condemnation” pattern seen with rotavirus vaccine.

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distribution²² and the CDC recommended postponing use of the rotavirus vaccine.²⁰ Large-scale case-control and population-based studies estimated that 1 to 2 per 10000 vaccinees were at risk for intussusception.^{23,24} In October 1999, the manufacturer withdrew the vaccine²² and ACIP withdrew its recommendation.²⁵

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Unique among pharmaceutical products, vaccines are routinely administered to the entire birth cohort so that even infrequent adverse events can create a public health burden. Since most vaccinated children are healthy, adverse events take on great importance for families and clinicians.^{26,27} Thus, vaccines must have exceptionally high safety profiles, and vaccination programs must enjoy a high level of public support to be successful.^{28,29}

Studies have suggested that news media reports are the primary source of most parents' information about health problems and vaccines.³⁰⁻³⁴ However, studies have also found that the media do not necessarily provide balanced information about health issues^{35,36} or vaccine risks,³⁷⁻³⁹ and that the media reports may affect vaccine coverage.³⁹⁻⁴⁴ Thus, public health authorities are legitimately concerned with media accounts of vaccine safety and the extent to which such accounts may affect public confidence in vaccination programs as a whole.⁴⁵

Because of intense news media activity surrounding the withdrawal of the rotavirus vaccine, we examined media accounts from the first US rotavirus vaccine trials through the aftermath of withdrawal in an effort to answer the following questions:

1. What was the character of news media reports about rotavirus vaccine before and after intussusception became an issue, in terms of positivity/negativity toward the vaccine, story prominence, and mention of vaccine benefits and adverse events?

2. What prompted the stories—scientific findings, public body recommendations, manufacturer actions, or other events?

3. To what extent did news media reports of the intussusception issue evoke public reaction?

METHODS

Media Data

Stories Included. We searched the Lexis-Nexis database for stories that (1) mentioned the rotavirus vaccine, (2) focused on the vaccine or disease, and (3)

appeared in newspapers or major wire services (as included in the *American Journalism Review* [available at: <http://ajr.newswlink.org>] listing),⁴⁶ between January 1, 1987, the year the FDA received an investigational new drug application for the vaccine, and March 31, 2001, 17 months after vaccine withdrawal. By *American Journalism Review* criteria, newspapers were categorized as major or other, and we subclassified 4 major newspapers as national: *New York Times*, *Washington Post*, *Wall Street Journal*, and *USA Today*. The Audit Bureau of Circulation⁴⁷ and individual newspapers provided circulation data. We searched the Video Monitoring Services of America (VMS) database from July 1, 1993 (first available date) to March 31, 2001, for television and radio stories, using identical inclusion criteria. The Mass Media Bureau, Federal Communications Commission, provided television station locations.⁴⁸ Since only 4 radio stories met study criteria and nonprint Internet stories were not captured by VMS or Lexis-Nexis, these stories were not included.

Data Collection. The 4 coders had at least 1 year of postgraduate public health education, had no previous involvement in rotavirus or media studies, and were trained in the pretested and piloted instrument. For print stories, the following data were abstracted: newspaper or wire service name, publication date, story placement, mention of vaccine benefits (clinical symptoms or public health burden), and adverse events. The story's stimulus (primary prompting event for the media report) was categorized as: publication/presentation of scientific research, action/announcement by public health authorities, action/announcement by the vaccine manufacturer, or other. Each coder evaluated each story as positive, neutral, or negative toward the vaccine, according to the coder's impression after reading the story. Television story data were collected with a similar instrument, but since VMS only provides a story summary, content was not evaluated in detail.

Intercoder Agreement. Agreement among the 4 coders was tested for 25 randomly selected stories using the κ statistic. For the variable involving subjective assessment, positivity/negativity of the story toward the vaccine, agreement was substantial⁴⁹: 0.76 overall (0.62, lowest κ scores comparing 2 coders, ie, lowest 2-coder). Similar agreement was found for vaccine benefits 0.81 (0.75), adverse events 0.97 (0.93), and other variables >0.80 (>0.71).

Thimerosal Stories. The week before the announcement of the potential association of the rotavirus vaccine and intussusception, the AAP and the US Public Health Service announced that the level of thimerosal (a mercury-containing preservative) in certain manufacturers' formulations of diphtheria and tetanus toxoids and acellular pertussis (DTaP), *Haemophilus influenzae* type b (Hib), hepatitis B, and influenza (but not rotavirus) vaccines placed infants at risk for an exposure to mercury that exceeded the allowable limit set by the Environmental Protection Agency.⁵⁰⁻⁵³ It was recommended that administration of the infant dose of hepatitis B vaccine be postponed, pending availability of thimerosal-free vaccines. As a comparison with rotavirus stories, we used the same media databases to examine the quantity and time course of stories focusing on thimerosal in vaccines during the 6-month period in which the number of stories for both issues permitted comparison (July 1–December 31, 1999). Because of the diversity of vaccines and formulations involved in the thimerosal issue, we did not attempt to evaluate story content.

National Immunization Hotline Data

To evaluate public response to news media activity around the intussusception and thimerosal issues, we examined calls to the National Immunization Hotline.⁵⁴ For 1 of 5 calls, hotline personnel administer an anonymous questionnaire, with answers entered into a database maintained for mana-

gerial tracking. For the 6-month period in which rotavirus vaccine call data were captured (July 1–December 31, 1999), we analyzed general public calls regarding child immunization issues with complete information for the call date and location, mention of vaccine, and adverse events. Temporal, geographic, demographic, and content patterns of rotavirus calls were compared with such patterns for non-rotavirus calls.

Analysis

Double-entered data were analyzed using SAS 8 (SAS Institute, Cary, NC). Newspaper stories were the primary subject of analysis, with separate analyses of wire service and television stories. Geographic patterns were analyzed by state (Washington, DC, aggregated to Maryland). To examine associations, we used risk ratios (RRs) with 95% confidence intervals (CIs), χ^2 , and Fisher exact tests. We considered $P < .05$ significant.

RESULTS

Of the 337 newspaper stories mentioning the rotavirus vaccine, 280 focused on rotavirus and were included in the analysis: 34 (12%) in national newspapers, 79 (28%) in other major newspapers, and 167 (60%) in other newspapers. The 57 stories not included mentioned rotavirus vaccine only in connection with other issues such as the spectrum of gastrointestinal diseases, vaccines in general, or the finances of pharmaceutical manufacturers. Of 74 wire service stories, 49 met study criteria, as did 257 of 516 television stories.

Time Course of Media Activity

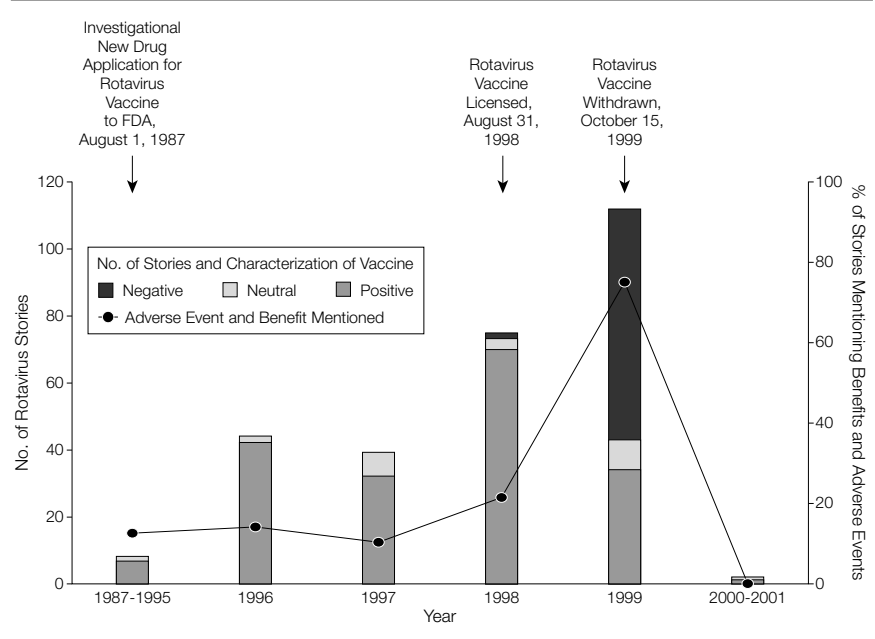
Prelicensure. During the 11-year period between the investigational new drug application and licensure (January 1, 1987–August 30, 1998), 103 stories were published and only 1 was negative toward the vaccine (FIGURE 1). Vaccine benefits were mentioned universally (100%) and adverse events rarely (13%), despite articles published during this period indicating that certain vaccine prototypes had high rates of adverse events (eg, up to 79% of vaccinees had fever $>38^\circ\text{C}$ in a Swedish trial).^{4,7,8} Fifty-seven percent of the stories were stimulated by scientific studies (TABLE 1).

Vaccine Use. During this 10-month period (August 31, 1998–July

14, 1999), 85 stories were published and only 1 was negative toward the vaccine (FIGURE 2). As in the prelicensure period, 99% of the stories mentioned vaccine benefits and only 31% mentioned adverse events. Seventy-two percent of stories were stimulated by public body deliberations and actions (Table 1) in which potential adverse events were extensively discussed.^{5,17,19}

Suspension and Withdrawal. On July 15, 1999, the CDC²⁰ reported 15 cases of intussusception following RotaShield vaccine at a time when the manufacturer estimated that 1.5 million doses had been administered (Figure 2 and FIGURE 3A). The manufac-

Figure 1. Rotavirus Newspaper Stories by Year



FDA indicates US Food and Drug Administration. Stories reported through March 2001.

Table 1. Primary Prompting Event for Newspaper Stories*

Source Stimulus	Prelicensure January 1, 1987, Through August 30, 1998 (n = 103)	Vaccine Use August 31, 1998, Through July 14, 1999 (n = 85)	Suspension and Withdrawal July 15, 1999, Through December 31, 1999 (n = 90)	Postwithdrawal January 1, 2000, Through March 31, 2001 (n = 2)	Total (n = 280)
Scientific research	59 (57)	1 (1)	11 (12)	0 (0)	71 (25)
Public bodies or health authorities	36 (35)	61 (72)	56 (62)	0 (0)	153 (55)
Manufacturer	0 (0)	0 (0)	14 (16)	0 (0)	14 (5)
Other	8 (8)	23 (27)	9 (10)	2 (100)	42 (15)

*Data are presented as number (percentage).

turer suspended vaccine distribution²² and the CDC recommended postponing vaccine use.²⁰ During the ensuing 5-month period (July 15–December 31, 1999), 90 stories were published, at a monthly rate that was 14 times higher than the preceding 12 years' monthly rate ($P < .001$). When each story is multiplied by the newspaper circulation in which it appeared, the level of potential exposure of the population to rotavirus stories during these 5 months was 44% higher than for the 10-month period of vaccine use and was almost identical to the total exposure for the 11 prelicensure years. In contrast to previous periods, 77% of these stories were negative toward the vaccine. Eighty percent of stories mentioned both benefits and adverse events, with 84% mentioning benefits and 93% mentioning adverse events. Sixty-two percent of stories were stimulated by public body actions (Table 1).

On July 8, 1999, the AAP and the US Public Health Service announced the

potential problem of mercury toxicity for infants who received a full series of thimerosal-containing vaccine formulations and recommended postponing the birth dose of hepatitis B.⁵⁰ Approximately half as many stories focused on thimerosal compared with rotavirus during that month (26 vs 46, respectively; Figure 3) and for the 6-month period (41 vs 90, respectively).

Postwithdrawal. During this 15-month period (January 1, 2000–March 31, 2001), we identified only 2 stories focusing on rotavirus, both published in the same newspaper: the first indicated that rotavirus vaccine was available, and the second issued a correction, indicating that the vaccine had been withdrawn (Figure 1). On February 22, 2001, the *New England Journal of Medicine* published a CDC study comparing 429 cases of intussusception with 1763 controls and established the association of the RotaShield vaccine and intussusception.²³ We

could not identify any newspaper or wire service story that mentioned this study. One local television station in Michigan telecast a 39-second story summarized by VMS as saying that the “rotavirus vaccine could cause gastroenteritis in babies.”

Similar temporal patterns were found for stories of all categories of newspapers and for wire service stories. Television stories differed only in a slightly higher frequency in 1998 with 119 vs 104 stories in 1999. In comparing print news media stories, 67% (33/49) of wire service vs 40% (111/280) of newspaper stories ($P < .001$) and 59% (20/34) of national vs 37% (92/247) of other newspaper stories ($P = .02$) mentioned both the benefits of and adverse reactions to the vaccine.

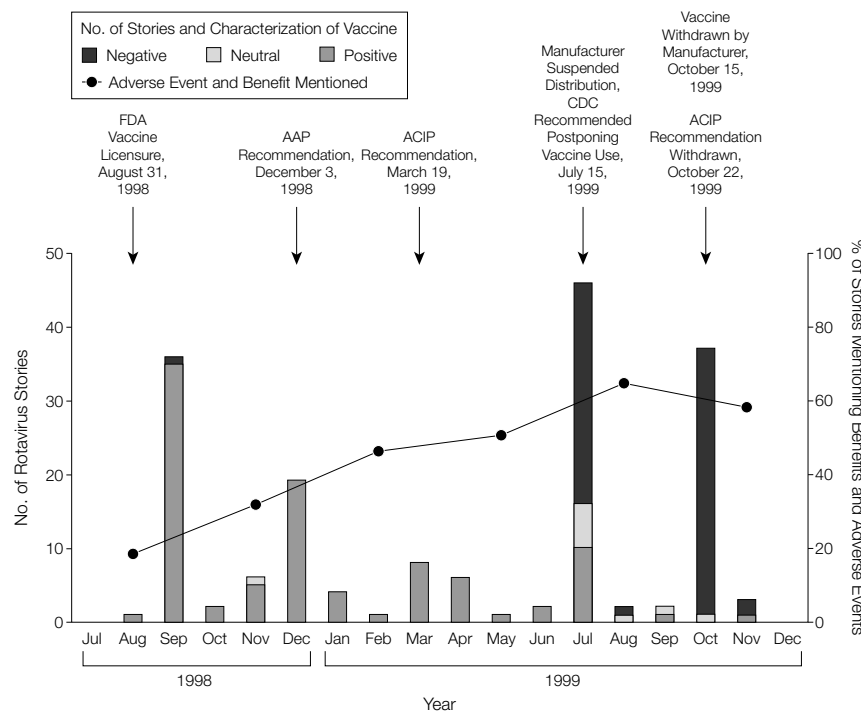
Stories Before and After Vaccine Suspension

Compared with presuspension stories, postsuspension stories were more likely to be in a major newspaper, to appear on a front page, and to mention the vaccine in the headline (TABLE 2). Few presuspension stories mentioned adverse events—despite adverse events having been itemized in the package insert,¹⁸ being mentioned in the manufacturer’s press releases in September 1998²² and May 1999,²³ and having been discussed by all public bodies in their deliberations and in their subsequently published recommendations.^{5,17,19} We could not identify any presuspension story that mentioned intussusception even though the potential association with the rotavirus vaccine had been presented at 2 public meetings of governmental advisory committees,^{55,56} examined in a published study,⁵⁷ and discussed in the package insert¹⁸ and in recommendations of the ACIP⁵ and AAP.¹⁹ After suspension, 92% of the stories mentioned intussusception. Similar before-and-after contrasts were found in wire service stories.

National Immunization Hotline Calls

Of approximately 10000 calls about child immunization issues, 2062 were

Figure 2. Rotavirus Newspaper Stories by Month



Stories mentioning both adverse events and benefits are graphed using a 3-point quarterly running average. FDA indicates US Food and Drug Administration; AAP, American Academy of Pediatrics; ACIP, Advisory Committee on Immunization Practices; and CDC, Centers for Disease Control and Prevention.

surveyed, and 1570 (76%) of these had complete data, with rotavirus calls accounting for 100 (6%).

Time Course. The increase in rotavirus stories in July 1999 was followed by an increase in rotavirus calls but not other calls (Figure 3). The number of rotavirus calls that month was 57% higher than for any other childhood vaccine for any month since the hotline began in 1997. Rotavirus calls ceased almost completely after withdrawal of the vaccine in October 1999. Media activity around thimerosal was not associated with any marked change in nonrotavirus calls, either in number or in proportion concerned with adverse events.

Caller Characteristics. Compared with other callers, a higher proportion of rotavirus callers were concerned about adverse events (92% vs 30%, $P < .001$), were white (90% vs 70%, $P < .001$), and were college graduates (55% vs 39%, $P < .001$).

Geographic Patterns. Rotavirus calls tended to originate in the same states in which rotavirus stories were published: 76% (19/25) of states with newspaper stories had calls vs 36% (9/25) of states without stories (RR, 2.11; 95% CI, 1.20-3.72; $P = .004$). Similarly, 81% (17/21) of calls came from viewing areas of television stations that ran stories vs 38% (11/29) of calls from areas in which the local television station did not run stories on the rotavirus vaccine (RR, 2.13; 95% CI, 1.28-3.55; $P = .003$). The geographic trend was even stronger when newspaper and television stories were combined with 73% (22/30) of calls coming from areas in which stories ran in either media vs 30% (6/20) of calls from areas that did not have any local coverage (RR, 2.44; 95% CI, 1.21-4.94; $P = .003$). Nonrotavirus calls were not associated with rotavirus stories.

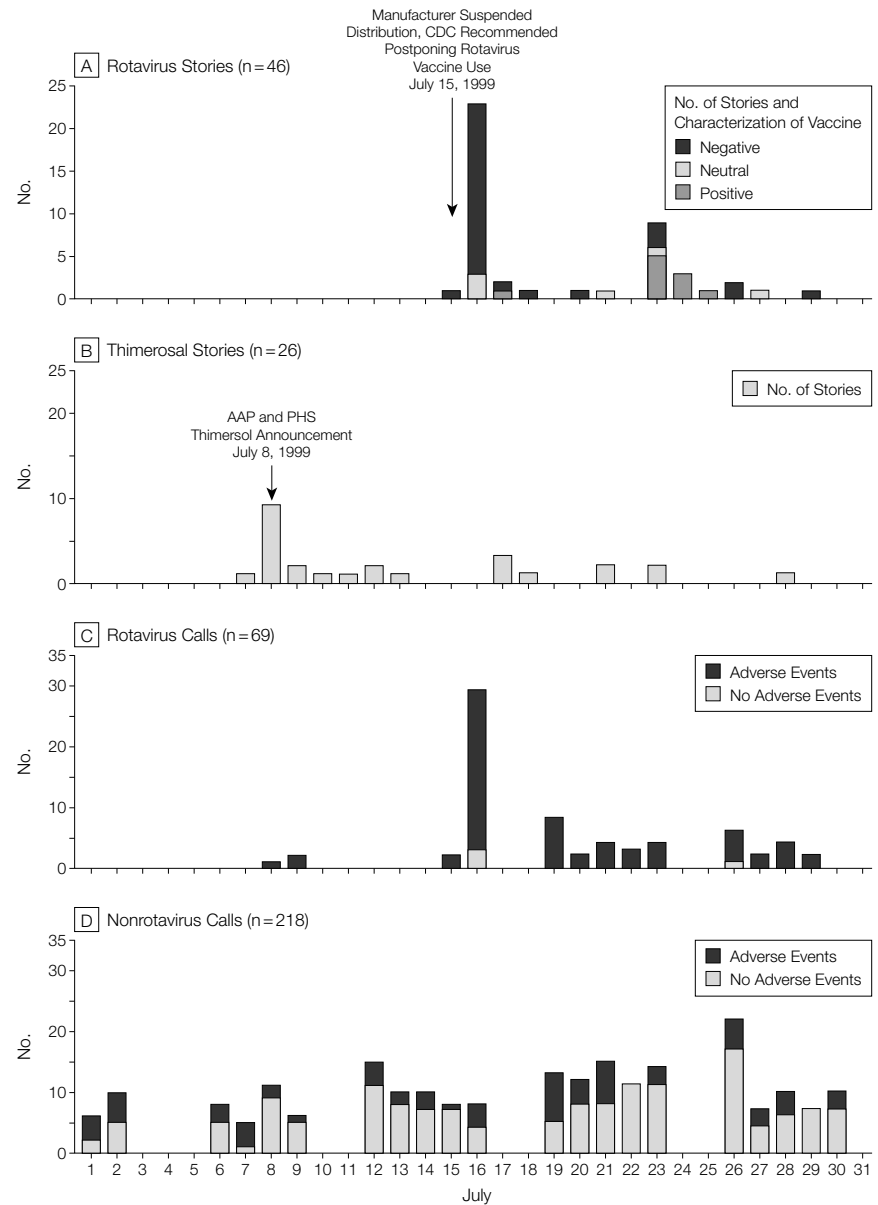
COMMENT

We found that over an initial 12-year period, rotavirus vaccine was portrayed positively by the news media and known adverse events were rarely mentioned. Then, on July 15, 1999, the

CDC published preliminary data concerning 15 cases of intussusception among those who received the rotavirus vaccine, and media portrayal of the vaccine changed abruptly to negativity. A high rate of newspaper, wire service, and television stories continued to appear until the vaccine was with-

drawn 3 months later. This upsurge of negative stories was followed temporally and geographically by an upsurge of immunization hotline calls concerning rotavirus vaccine adverse events. After vaccine withdrawal, the media reduced considerably the number of stories focusing on rotavirus de-

Figure 3. Rotavirus and Thimerosal Newspaper Stories and Calls to the National Immunization Hotline by Day, July 1999



The hotline was inactive on the following weekend and holiday dates: July 3 through 5, 10 and 11, 17 and 18, 24 and 25, and 31. CDC indicates Centers for Disease Control and Prevention; AAP, American Academy of Pediatrics; and PHS, US Public Health Service.

spite the health burden of the disease and the existence of other vaccines in clinical trials.

This “early idealization–sudden condemnation” sequence may occur frequently in the media for other issues, but it has not been documented for vaccines, to our knowledge. Other vaccines are associated with serious adverse events but have not been subject to equivalent media treatment. Febrile seizures occur in about 2 per 10000 DTaP and measles-mumps-rubella vaccinees,⁵⁸⁻⁶¹ thrombocytopenia occurs in 0.3 per 10000 measles-mumps-rubella vaccinees,^{61,62} and as many as 14 per 10000 DTaP vaccinees have been reported to suffer a shocklike state (hypotonic-hypo-responsive episode).^{59,63} These adverse events occur at approximately the same frequency as intussusception, but they are self-limited and are usually treated only with careful observation. Even if unrecognized, they would not be life-threatening in most cases.^{61,64} In contrast, untreated intussusception may progress to a life-threatening abdominal catastrophe.^{65,66}

Vaccine familiarity, as well as the character of the adverse event, may also

be important in media treatment. In contrast to the rotavirus vaccine, DTaP and measles-mumps-rubella vaccines have had a long history of providing clinical and public health benefits, their risks have been well characterized, and their use has been accepted by both health care professionals and the public. This familiarity factor may also help explain why the announcement that thimerosal in well-established vaccines might expose infants to excessive levels of mercury did not evoke the same media or public response as the rotavirus-intussusception announcement. This is true despite the fact that both announcements were nearly simultaneous, both involved postponing use of a vaccine, and far more infants had been exposed to thimerosal-containing vaccines than to the rotavirus vaccine.

Additionally, RotaShield was designed to protect against diarrhea, a condition that may have been viewed by the lay public, news reporters, and perhaps some health professionals as an annoyance rather than a public health problem in the United States, despite the large number of hospitalizations and potential sequelae.⁶⁷ After years of media reports rarely mentioning adverse

events, the discovery that RotaShield was associated with a life-threatening abdominal emergency was clearly treated as more important “news” by the media and the public than the damage and health care costs caused by the rotavirus disease.

Scientific or public health activities prompted 80% of media activity, thus opportunities may exist to avoid the “early idealization–sudden condemnation” pattern of reports like the rotavirus vaccine. Public health authorities might not need to fear loss of credibility if they proactively and objectively investigate the adverse events of vaccines. Despite negative media coverage of the rotavirus vaccine intussusception issue and publicity about the risks of toxicity from thimerosal in other vaccines, immunization rates in the United States remained at historically high levels in 1999 and 2000.^{68,69} In fact, widespread acceptance of vaccination may depend on public confidence that health authorities promptly, objectively, and transparently investigate potential adverse events associated with vaccines.

Our study has important limitations. We only examined print stories

Table 2. Characteristics of Newspaper Articles Before and After Announcement of Potential Association of Rotavirus Vaccine With Intussusception, July 15, 1999

Characteristics	No. (%)		Risk Ratio (95% CI)	P Value
	Prelicensure and Vaccine Use January 1, 1987, Through July 14, 1999 (n = 188)	Suspension and Withdrawal July 15, 1999, Through December 31, 1999 (n = 90)		
Major newspaper	67 (36)	46 (51)	1.4 (1.1-1.9)	.01
Front page	21 (11)	22 (24)	2.2 (1.3-3.8)	.004
Headline				
Vaccine mentioned	125 (66)	81 (90)	1.4 (1.2-1.5)	<.001
Benefits*	40 (32)	5 (6)	0.2 (0.1-0.5)	<.001
Adverse events*	0 (0)	24 (30)	Undefined	<.001
Text				
Vaccine mentioned†	188 (100)	90 (100)
Benefits	187 (99)	76 (84)	0.9 (0.8-0.9)	<.001
Adverse events	39 (21)	84 (93)	4.5 (3.4-6.0)	<.001
Adverse events and benefits‡	39 (21)	72 (80)	3.9 (2.9-5.2)	<.001
Vaccine portrayal				
Positive	173 (92)	12 (13)	0.1 (0.1-0.3)	<.001
Neutral	13 (7)	9 (10)	1.5 (0.6-3.3)	.37
Negative	2 (1)	69 (77)	72.1 (10.1-287.4)	<.001

*Benefits or adverse events in the headline is only for those stories that mentioned vaccine in their headline.

†Study inclusion criterion. Ellipses indicate not applicable.

‡Any adverse event and any benefits mentioned in the same story.

available in Lexis-Nexis, we could not examine the content of television stories in detail, and we did not include Internet stories from which many US adults obtain health information.^{70,71} A key study outcome, positivity/negativity, was subjective and, despite high intercoder agreement, bias may have been present. We did not examine the role of vaccine manufacturers, journals, or others in promoting media exposure of articles or public body actions although research has suggested that such promotional activities may be an important factor in determining whether media activity occurs around publication of a scientific article.^{72,73}

Despite these limitations, we believe our study suggests that news media activity around vaccines, far from being unpredictable, is primarily stimulated by scientific findings or public health decisions. The fact that scientists and health officials provide the basis for media stories does not guarantee that such stories are fair, accurate, or balanced. To prevent repetitions of the early¹¹ idealization–sudden condemnation sequence¹¹ seen with the rotavirus vaccine, scientists and health officials have an obligation to learn to work effectively with the media to ensure that the public is informed about both vaccine risks and benefits, particularly since the media may be the public's principal source of such information. Balanced portrayals of vaccines can help avert abrupt shifts in media and public reaction that can undermine the success of vaccination programs. As Feudtner and Marcuse⁴⁵ have stated, accurate portrayals of vaccines form the foundation of the dialogue that must take place between clinicians, health authorities, legislators, and the public to maintain public trust in immunization.

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