

2008: Vaccine Adverse Events Reporting System

1. BACKGROUND

The Vaccine Adverse Events Reporting System (VAERS) is a passive surveillance program that monitors vaccine safety in the United States. VAERS collects reports of adverse events occurring after vaccination from public and private providers, parents, patients, and vaccine manufacturers. Approximately 30,000 events are reported nationally each year, with 10-15% classified as serious and requiring follow-up investigations.

The primary purpose of VAERS is to signal negative effects of vaccines that were not detected during pre-market testing. Since VAERS reports are collected on any adverse event following vaccination, they may or may not be related to vaccine administration. Therefore, it can not be assumed that the events are caused by vaccine administration. However, VAERS data can help monitor or identify:

- Symptoms frequently associated with vaccination side effects
- New, unusual, or rare adverse events
- Large increases in adverse events occurring after vaccination
- Vaccine lots with a higher rate of adverse events than expected
- Potential risk factors for adverse events
- Potential vaccine safety issues.

Although VAERS data can serve as a useful indicator of vaccine safety issues, findings should be interpreted with caution. When interpreting this data, it is important to note that cases reported to VAERS contain both coincidental events and those truly caused by vaccines.

2008: Vaccine Adverse Events Reporting System

2. REPORTING PERIOD

This report summarizes adverse events reported to VAERS between January 1, 2000 and December 31, 2008, with an emphasis on **reports in Oregon during 2008**. Although VAERS cases were reported in 2008, vaccine administration and adverse events may have occurred in prior years.

2008: Vaccine Adverse Events Reporting System

3. LIMITATIONS

Although VAERS can serve as a useful indicator of vaccine safety issues, findings should be interpreted with caution. Some limitations include:

- Inability to show causality due to incomplete information and methodological limitations
- Simultaneous administration of multiple vaccine antigens
- Reporting bias, underreporting, untimely reports
- Lack of a denominator (total shots given)
- Inaccurate coding of symptoms
- Multiple reports on a single case.

2008: Vaccine Adverse Events Reporting System

4. RESULTS

In 2008, 28,075 VAERS cases were reported in the United States (*Table 1*). Of those, 413 were reported in Oregon. Although the total number of VAERS cases increase each year, the proportion of cases reported in Oregon has stayed somewhat constant (*Graph 1*). The largest proportion of reported cases usually occurs among children ages 0-6 years followed by adults, ages 19-49 years (*Table 2* and *Graph 2*). The majority of the recommended vaccine schedule involves children ages 0-6. Cases reported among 7-18 year olds in 2008 increased nearly eight percentage points making it the second largest group of reports. Most cases are reported among females (*Graph 3*).

Administration Source

The majority of cases both nationally and in Oregon are reported after vaccines administered by private providers. In 2008, almost half (49.2%) of cases in Oregon occurred after private provider vaccine administration compared to 16.7% by public providers (*Table 3* and *Graph 4*). In Oregon, public providers are required to submit VAERS reports to the Oregon Immunization Program. The Other/Unknown category includes cases following vaccines administered by military providers and unknown sources. Cases in which administration source was “unknown” are likely submitted by secondary sources (i.e., parents, providers who did not administer the original shot, etc.).

Symptoms

The most commonly reported symptom of an adverse event was injection site erythema, occurring in 4.8% of reports, followed by fever (4.2%) (*Table 4*). This is consistent with national symptom rankings. Since 2000, injection site erythema and fever have consistently been ranked as the most commonly reported adverse events. Most common symptoms pertain to local reactions.

Serious Events

Of the 413 reports in Oregon, 31 (7.5%) were classified as serious events (*Table 5* and *Graph 5*). Nationally, 8.7% of events were classified as severe. Severe events are those

2008: Vaccine Adverse Events Reporting System

where death, permanent disability, a life threatening illness/reaction, or hospitalization¹ was reported. Although the proportion of severe events in Oregon has fluctuated between 3.4% and 7.9% between 2000 and 2008, it has never exceeded that of the United States. This fluctuation may occur because of an increased awareness and use of VAERS reporting. Since VAERS is a passive surveillance system that accepts reports from anyone, there is variability from reporting bias and to some extent, selection bias. Additionally, reports are not validated unless they are classified as serious, which could lead to some serious events left misclassified as non-serious. Among the 31 severe cases, one death, eight permanent disabilities, eleven life threatening illnesses, and eighteen hospitalizations were reported (*Graph 6*). Cases can involve more than one severe event.

The majority of severe cases occur among 0-6 year old children (*Table 6*). As the number of vaccines received during these ages is greater than any other age group, it is reasonable to see the most severe events occurring in this age group. However, it is important to note that a variety of events classified as serious coincidentally occur during the first few years of life (i.e., Sudden Infant Death Syndrome) and have not been linked to vaccine administration.² Increases and decreases in severe events may also coincide with secular trends, interfering events, policies, and interventions. For example, a national decrease in infant deaths reported to VAERS since the early 1990s mirrored a national decrease in Sudden Infant Death Syndrome and successful outcomes of the “Back to Sleep” campaign.³

The largest number of severe cases was reported after receipt of influenza vaccine (13 severe reports after shots and two after nasal sprays). Of those 15 cases, five received multiple vaccines at the time. Out of all 31 severe events, 14 had received multiple vaccines.

¹ Hospitalization does not necessarily include emergency room visits.

² Fleming, Blair, Platt, et al. (2001). The UK accelerated immunisation programme and sudden unexpected death in infancy: Case-control study. *British Medical Journal*, 322, 822-825.

³ Silvers, Ellenberg, Wise, Varricchio, Mootrey, & Salive (2001). The epidemiology of fatalities reported to the Vaccine Adverse Event Reporting System 1990-1997. *Pharmacoepidemiology and Drug Safety*, 10, 279-285.

2008: Vaccine Adverse Events Reporting System

Adverse Events Following HPV Vaccination⁴

In 2008, 5,627 VAERS cases were reported following HPV vaccination in the United States. Among those cases, 0.9% were reported in Oregon. Most cases occurred in children 7-18 years old (66.0%). HPV vaccine administered by a private provider prior to adverse symptom onset was reported in 32.1% of Oregon cases compared to 26.4% following public provider administration. The most frequently reported symptoms during an adverse event following HPV vaccination were non-serious events. In 2008, pyrexia and headache were the most reported symptoms in Oregon cases. Nationally, dizziness and syncope were most reported. Among Oregon cases, 35.9% reported an emergency room or doctor visit compared to 42.4% nationally. One severe case was reported in 2008 which involved hospitalization.

Adverse Events Following Influenza Vaccination⁵

In 2008, 4,995 VAERS cases were reported following influenza vaccination in the United States. Among those cases, 1.9% were reported in Oregon. Many Oregon cases were among females (62.8%) and 19-49 year olds (27.7%). Flu vaccine administered by a private provider prior to adverse symptom onset was reported in 42.6% of Oregon cases compared to 13.8% following public provider administration. The most frequently reported symptoms during an adverse event following flu vaccination were non-serious events. In 2008, pain and nausea were the most reported symptoms in Oregon. Nationally, pyrexia and erythema were most reported. Among Oregon cases, 39.4% reported an emergency room or doctor visit compared to 34.7% nationally. Thirteen (13.8%) severe cases following flu vaccination were reported in Oregon compared to 457 (9.2%) nationally. Among the severe cases in Oregon, four (4.3%) reported disability, seven (7.5%) reported a life-threatening illness, and six (6.4%) reported hospitalization. None of the cases resulted in death.

Adverse Events Following Zoster Vaccination⁶

⁴ Includes cases where HPV vaccine was administered alone or in combination with other vaccines.

⁵ Includes cases where influenza vaccine was administered alone or in combination with other vaccines.

⁶ Includes cases where zoster vaccine was administered alone or in combination with other vaccines.

2008: Vaccine Adverse Events Reporting System

In 2008, 1,865 VAERS cases were reported following zoster vaccination in the United States. Among those cases, 1.2% were reported in Oregon. Many Oregon cases were among females (65.2%) and 65 years old and over (56.5%). Zoster vaccine administered by a private provider prior to adverse symptom onset was reported in 13.0% of Oregon cases compared to 4.4% following public provider administration. The most frequently reported symptoms during an adverse event following zoster vaccination were non-serious events. In 2008, Erythema and injection site pain were the most reported symptoms in Oregon. Nationally, herpes zoster and injection site erythema were most reported. Among Oregon cases, 39.1% reported an emergency room or doctor visit compared to 38.4% nationally. Only one (4.4%) reported case following zoster vaccination was reported as severe in Oregon compared to 115 (6.2%) nationally. The single severe case in Oregon involved hospitalization.

2008: Vaccine Adverse Events Reporting System

5. DISCUSSION

This overview summarizes adverse events reported to VAERS in 2008. In 2008, the most reports were submitted in Oregon since the beginning of VAERS. Several factors have contributed to this gradual increase. First, the growing number of vaccines introduced to the market and increasing immunization coverage means more shots are being administered. When there are more shots given, there is more opportunity to report an adverse event. Second, reporters have become increasingly aware of VAERS.

Overall, 2008 VAERS reports show no new vaccine safety concerns. The majority of cases occurred among young children. This is expected as most vaccines are received during this time. There was an increase in the proportion of reports among older children (ages 7-18 years), which may be attributed to the availability of new vaccines (i.e., Gardasil) and expanded school immunization requirements. Most Oregon reports cited vaccines administered by private providers, which is similar to the national pattern. Common symptoms were fever and local reactions such as injection site swelling, erythema, and pain. As most events were classified as non-severe, these events are expected. Very few events were classified as severe in 2008. Studies based on VAERS reports have demonstrated that vaccines are most likely safe and severe adverse events can occur, but are rare.⁷

These findings should be interpreted with caution because occurrence of an event is not necessarily related to vaccination. Temporal association between vaccination and symptom onset does not indicate causation. Symptoms could be misdiagnosed, coincidental, or attributed to an underlying condition or medication. Furthermore, because VAERS is a passive surveillance system, data may be limited in coverage and accuracy. VAERS relies on the public to voluntarily submit reports. However, variability in reporting standards, reporter bias, and under reporting may skew the data. Additional limitations are outlined in *Section 3*.

⁷ Centers for Disease Control and Prevention. *Surveillance Summaries*, January 24, 2003. MMWR 2003, 52(ss-1).

2008: Vaccine Adverse Events Reporting System

Despite the many limitations of VAERS, the public health contribution of this surveillance system is critical. VAERS continues to be the largest resource for evaluating adverse events occurring after vaccine administration. Detection of rare adverse events that may have gone undetected in pre-market vaccine testing has the potential of identification with this system. Therefore, timely analysis of VAERS data should be continued.

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2008: Vaccine Adverse Events Reporting System

5. TABLES

Table 1. VAERS cases.

Year	Oregon		United States	
	n	%	n	%
2000	197	1.4	14,205	100.0
2001	180	1.3	13,581	100.0
2002	190	1.3	14,202	100.0
2003	207	1.2	16,849	100.0
2004	221	1.4	15,464	100.0
2005	230	1.5	15,772	100.0
2006	213	1.2	17,433	100.0
2007	369	1.3	28,525	100.0
2008	413	1.5	28,075	100.0

Table 2. VAERS cases by age, Oregon.

Year	Age													
	0-6		7-18		19-49		50-64		65+		Unknown		Total	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%
2000	80	40.6	24	12.2	52	26.4	13	6.6	7	3.6	21	10.7	197	100.0
2001	92	51.1	15	8.3	31	17.2	15	8.3	19	10.6	8	4.4	180	100.0
2002	99	52.1	17	9.0	26	13.7	16	8.4	19	10.0	13	6.8	190	100.0
2003	109	52.7	14	6.8	45	21.7	21	10.1	8	3.9	10	4.8	207	100.0
2004	122	55.2	9	4.1	38	17.2	17	7.7	13	5.9	22	10.0	221	100.0
2005	111	48.3	27	11.7	40	17.4	16	7.0	24	10.4	12	5.2	230	100.0
2006	89	41.8	24	11.3	41	19.3	24	11.3	17	8.0	18	8.5	213	100.0
2007	108	29.3	48	13.0	71	19.2	39	10.6	49	13.3	54	14.6	369	100.0
2008	106	25.7	86	20.8	80	19.4	51	12.4	40	9.7	50	12.1	413	100.0

Table 3. VAERS cases by administration source.

Year	Oregon						United States					
	Public		Private		Other/Unknown		Public		Private		Other/Unknown	
	n	%	n	%	n	%	n	%	n	%	n	%
2000	47	23.9	72	36.6	78	39.6	2,990	21.1	5,598	39.4	5,617	39.5%
2001	68	37.8	72	40.0	40	22.2	3,241	23.9	6,447	47.5	3,893	28.7%
2002	58	30.5	100	52.6	132	69.5	3,233	22.8	6,683	47.1	4,286	30.2%
2003	68	32.9	95	45.9	44	21.3	4,090	24.3	7,161	42.5	5,598	33.2%
2004	56	25.3	105	47.6	60	27.2	2,735	17.7	6,770	43.8	5,959	38.5%
2005	50	21.7	110	47.8	70	30.4	2,413	15.3	6,191	39.3	7,168	45.5%
2006	40	18.8	95	44.6	78	36.6	2,334	13.4	6,339	36.4	8,760	50.3%
2007	84	22.8	162	43.9	123	33.3	4,009	14.1	10,654	37.4	13,862	48.6%
2008	69	16.7	203	49.2	141	34.1	4,097	14.6	10,319	36.8	13,659	48.7%

2008: Vaccine Adverse Events Reporting System

Table 4. Most frequently reported symptoms following vaccination, Oregon, 2008.

Symptom	n	%
Injection site erythema	82	4.8
Pyrexia	72	4.2
Erythema	60	3.5
Injection site swelling	52	3.1
Injection site pain	45	2.6
Nausea	43	2.5
Pain	38	2.2
Pain in extremity	34	2.0
Headache	33	1.9
Oedema peripheral	33	1.9

Table 5. Severe VAERS cases.

Year	Oregon			United States		
	n	% of OR total	Total OR events	n	% of US total	Total US events
2000	15	7.6	197	1,228	8.6	14,205
2001	16	7.2	180	1,450	10.7	13,581
2002	15	7.9	190	1,414	10.0	14,202
2003	7	3.4	207	1,614	9.6	16,849
2004	11	5.0	221	1,267	8.2	15,464
2005	15	6.5	230	1,298	8.2	15,772
2006	9	4.2	213	1,462	8.4	17,433
2007	14	3.8	369	2,296	8.1	28,525
2008	31	7.5	413	2,452	8.7	28,075

Table 6. Severe cases by age, Oregon.

	Age													
	0-6		7-18		19-49		50-64		65+		Unknown		Total	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%
2000	9	4.6	2	1.0	3	1.5	0	0.0	0	0.0	1	0.5	197	100.0
2001	7	3.9	1	0.6	1	0.6	3	1.7	0	0.0	1	0.6	180	100.0
2002	4	2.1	0	0.0	1	0.5	2	1.1	7	3.7	1	0.5	190	100.0
2003	5	2.4	1	0.5	0	0.0	0	0.0	0	0.0	1	0.5	207	100.0
2004	8	3.6	0	0.0	1	0.5	0	0.0	2	0.9	0	0.0	221	100.0
2005	11	4.8	1	0.4	1	0.4	0	0.0	2	0.9	0	0.0	230	100.0
2006	4	1.9	0	0.0	3	1.4	1	0.5	1	0.5	0	0.0	213	100.0
2007	6	1.6	1	0.3	1	0.3	1	0.3	4	1.1	1	0.3	369	100.0
2008	8	1.9	4	1.0	3	0.7	4	1.0	3	0.7	9	2.2	413	100.0

2008: Vaccine Adverse Events Reporting System

Table 7. Total VAERS cases reporting death.

Year	Oregon			United States		
	n	% of OR total	Total OR cases	n	% of US total	Total US cases
2000	4	2.0	197	144	1.0	14,205
2001	1	0.6	180	176	1.3	13,581
2002	1	0.5	190	138	1.0	14,202
2003	0	0.0	207	197	1.2	16,849
2004	3	1.4	221	162	1.1	15,464
2005	1	0.4	230	130	0.8	15,772
2006	2	0.9	213	119	0.7	17,433
2007	0	0.0	369	162	0.6	28,525
2008	1	0.2	413	182	0.7	28,075

Table 8. Total VAERS cases reporting permanent disability.

Year	Oregon			United States		
	n	% of OR total	Total OR cases	n	% of US total	Total US cases
2000	5	2.5	197	303	2.1	14,205
2001	4	2.2	180	383	2.8	13,581
2002	6	3.2	190	408	2.9	14,202
2003	2	1.0	207	296	1.8	16,849
2004	2	0.9	221	274	1.8	15,464
2005	2	0.9	230	264	1.7	15,772
2006	1	0.5	213	298	1.7	17,433
2007	1	0.3	369	506	1.8	28,525
2008	8	1.9	413	541	1.9	28,075

Table 9. Total VAERS cases reporting a life threatening illness.

Year	Oregon			United States		Total US cases
	n	% of OR total	Total OR cases	n	% of US total	
2000	2	1.0	197	211	1.5	14,205
2001	2	1.1	180	222	1.6	13,581
2002	6	3.2	190	235	1.7	14,202
2003	2	1.0	207	277	1.6	16,849
2004	1	0.5	221	237	1.5	15,464
2005	5	2.2	230	230	1.5	15,772
2006	5	2.4	213	272	1.6	17,433
2007	3	0.8	369	474	1.7	28,525
2008	11	2.7	413	493	1.8	28,075

2008: Vaccine Adverse Events Reporting System

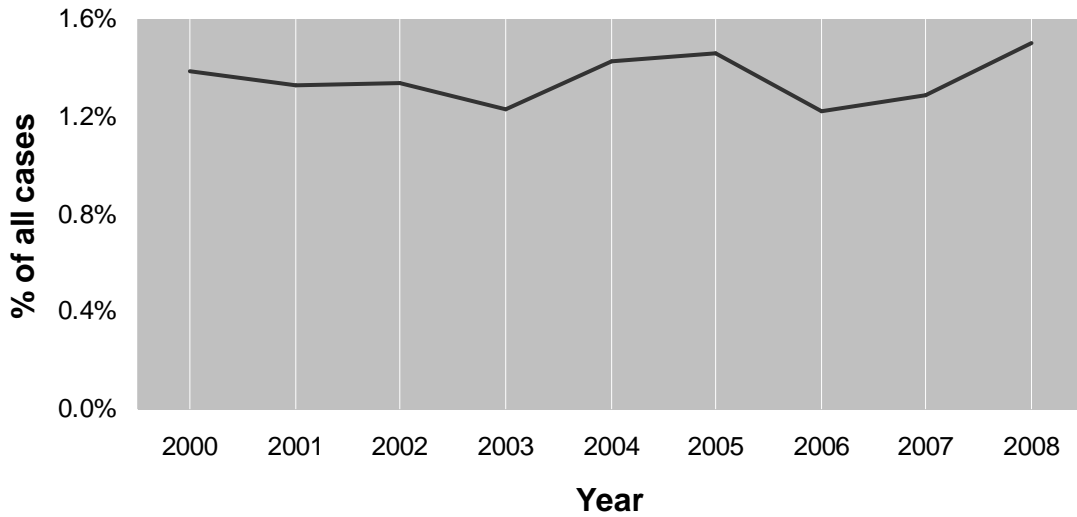
Table 10. Total VAERS cases reporting hospitalization.

Year	Oregon			United States		
	n	% of OR total	Total OR cases	n	% of US total	Total US cases
2000	7	3.6	197	812	5.8	14,205
2001	7	3.9	180	932	6.9	13,581
2002	9	4.7	190	912	6.4	14,202
2003	4	1.9	207	1,162	6.9	16,849
2004	6	2.7	221	859	5.6	15,464
2005	8	3.5	230	929	5.9	15,772
2006	4	1.9	213	1,049	6.0	17,433
2007	12	3.3	369	1,673	5.9	28,525
2008	18	4.4	413	1,791	6.4	28,075

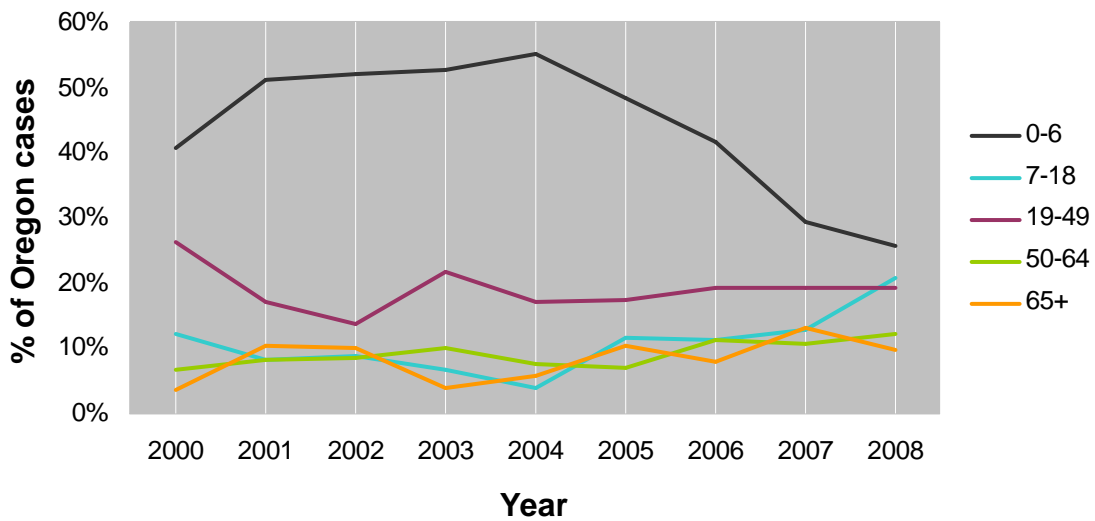
2008: Vaccine Adverse Events Reporting System

6. GRAPHS

Graph 1. Percent of VAERS cases reported in Oregon

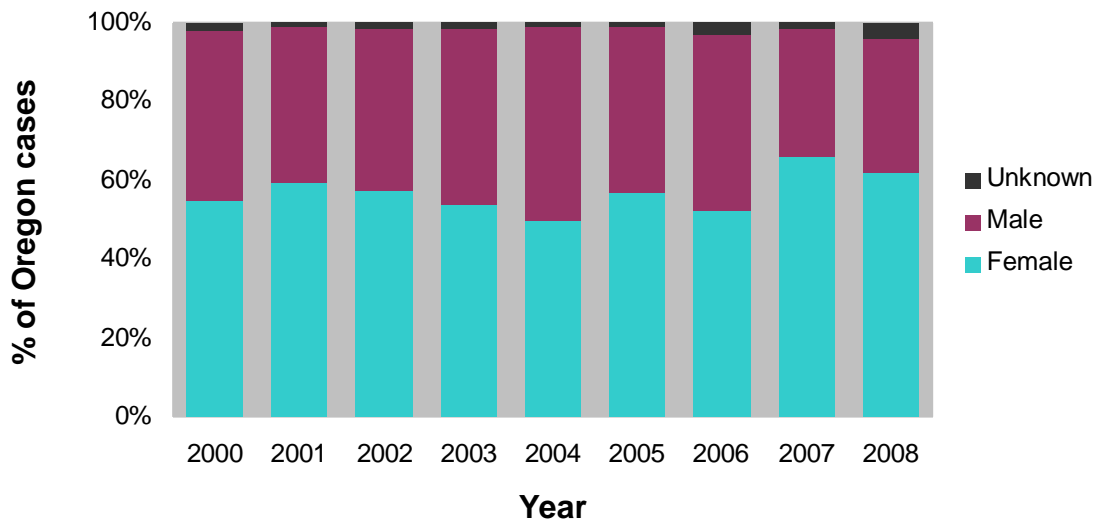


Graph 2. VAERS cases by age, Oregon

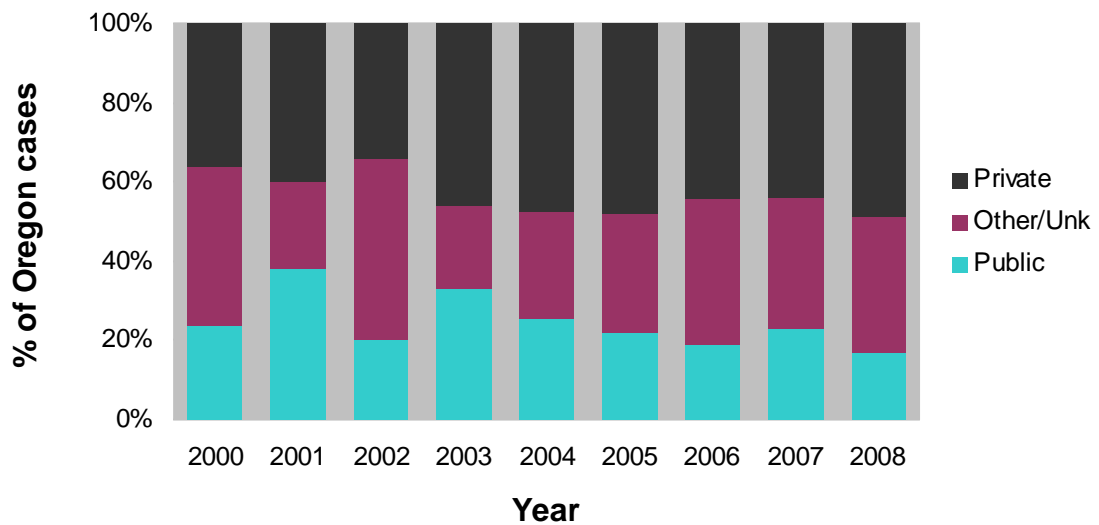


2008: Vaccine Adverse Events Reporting System

Graph 3. VAERS cases by gender, Oregon

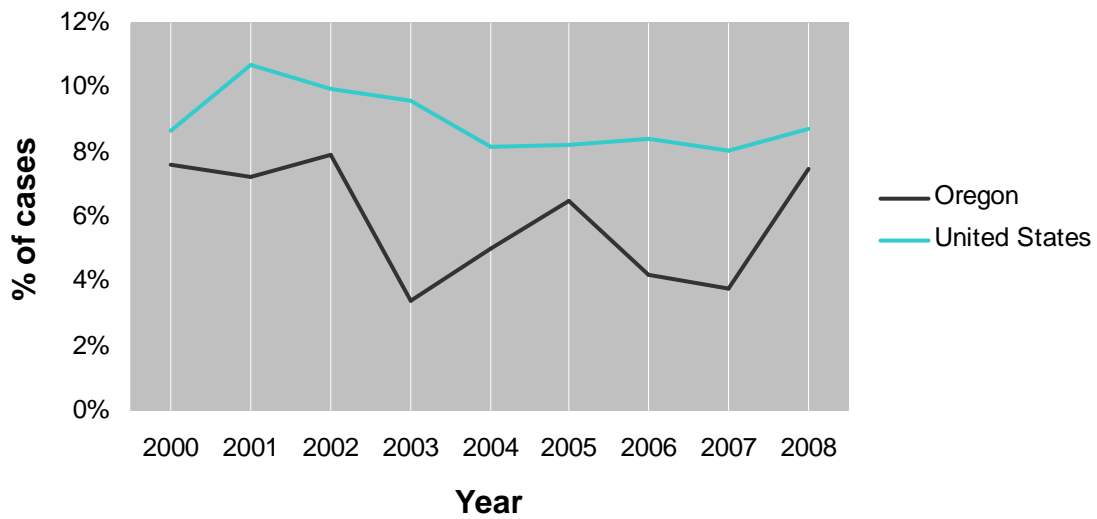


Graph 4. VAERS cases by source, Oregon



2008: Vaccine Adverse Events Reporting System

Graph 5. Proportion of cases classified as serious



Graph 6. Percent of cases by type of severity, Oregon

