



Modular Program Report

The following report(s) provides findings from an FDA-initiated query using its Mini-Sentinel pilot. While Mini-Sentinel queries may be undertaken to assess potential medical product safety risks, they may also be initiated for various other reasons. Some examples include determining a rate or count of an identified health outcome of interest, examining medical product use, exploring the feasibility of future, more detailed analyses within Mini-Sentinel, and seeking to better understand the capabilities of the Mini-Sentinel pilot.

Data obtained through Mini-Sentinel are intended to complement other types of evidence such as preclinical studies, clinical trials, postmarket studies, and adverse event reports, all of which are used by FDA to inform regulatory decisions regarding medical product safety. The information contained in this report is provided as part of FDA's commitment to place knowledge acquired from the Mini-Sentinel pilot in the public domain as soon as possible. Any public health actions taken by FDA regarding products involved in Mini-Sentinel queries will continue to be communicated through existing channels.

FDA wants to emphasize that the fact that FDA has initiated a query involving a medical product and is reporting findings related to that query does not mean that FDA is suggesting health care practitioners should change their prescribing practices for the medical product or that patients taking the medical product should stop using it. Patients who have questions about the use of an identified medical product should contact their health care practitioners.

The following report contains a description of the request, request specifications, and results from the modular program run(s).

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Overview	
<u>Request Description</u>	<p>FDA requested execution of Modular Program #3 (MP3), version 2, to investigate influenza vaccinations (TIV - trivalent inactivated influenza vaccine and LAIV - live, attenuated influenza vaccine) and diagnosis of seizures (ICD-9 780.3 and subcodes). The query was run against the Mini-Sentinel Distributed Database (MSDD) for the time period of September 2004 through March 2012. This request was distributed to five Data Partners on November 6, 2012.</p> <p>Results provide counts of newly vaccinated members (new users), total vaccinations, new episodes, events, days at risk, eligible members, and member-days among members with both medical and drug coverage. A member was considered newly vaccinated if he/she had no influenza vaccination in the previous 14 days. Because the multiple (MULT) incidence type was chosen, a user could have more than one incident vaccination episode during the query period. To find seizure events 1 and 20 days after influenza vaccination, exposure extension periods of 1 day (scenario one) and 20 days (scenario two) were used. Only TIV (not high dose, not intradermal) influenza vaccine was analyzed. To be considered, a seizure event must have occurred in the specified post-vaccination period and be the only seizure diagnosis in the previous 183 days in all care settings. Seizure events were considered in the inpatient and emergency department care settings only and no principal diagnosis flag was required. The blackout period was set to 0 days for scenario one so events the day of vaccination would be included. The blackout period was set to 14 days for scenario two so events the day of vaccination and 13 days post-vaccination would be excluded. This report contains 6 scenarios, which can be segregated into 2 groups based on unique sets of parameters used for these different age groups. Please see the specifications for details into the exact parameters used in this request.</p> <p>This report presents incidence data for influenza vaccination and diagnosis of seizures only. Data for incident influenza vaccinations followed by a diagnosis of Guillain-Barre is presented in a separate report.</p>
<u>Request ID</u>	MSY4_MPR03_V1 - Report 1 of 2

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Notes: Please contact the Mini-Sentinel Operations Center (MSOC_Requests@harvardpilgrim.org) for questions and to provide comments/suggestions for future enhancements to this document

Modular Program Specifications for MSY4_MPR03

Modular Program #3 (MP3) was used to investigate influenza vaccination and diagnosis of seizures (ICD-9 780.3 and subcodes). The time window for the request is September 2004 through March 2012. Because only procedure codes were used for influenza vaccination, the days supplied were automatically set to 1 day. Episode gap, minimum episode duration, and minimum days supplied parameters were set to 0 days. In total, 6 different scenarios were examined in this report with differing age groups, event incidence criteria, and principal diagnosis criteria. See below for a description of each of these scenarios.

Scenario	Drug/Exposure									Event/Outcome								
	Incident exposure	Incident w/ respect to:	Incidence Type*	Washout Period (days)	Episode Gap (days)	Exposure Extension Period (days)	Minimum Episode Duration (days)	Minimum Days Supplied (days)	Event/ Outcome	Incident Only Event/ Outcomes	Incidence Type**	Washout Period (days)	Care Setting	Principal Dx	Blackout Period	Incident Only Care Setting	Incident Only Principal Dx	
Ages 6 Months - < 2 Years, 2 Years - < 5 Years																		
1	TIV(not high dose, not intradermal)	TIV(not high dose, not intradermal)	MULT	14	0	1	0	0	Seizures	Seizures	MULT	183	IP ED	NO	0	ALL	NO	
2	TIV(not high dose, not intradermal)	TIV(not high dose, not intradermal)	MULT	14	0	20	0	0	Seizures	Seizures	MULT	183	IP ED	NO	14	ALL	NO	
Ages 2 Years - < 5 Years																		
3	TIV(not high dose, not intradermal)	TIV(not high dose, not intradermal)	MULT	14	0	3	0	0	Seizures	Seizures	MULT	183	IP ED	NO	1	ALL	NO	
4	TIV(not high dose, not intradermal)	TIV(not high dose, not intradermal)	MULT	14	0	20	0	0	Seizures	Seizures	MULT	183	IP ED	NO	15	ALL	NO	
5	LAIV	LAIV	MULT	14	0	3	0	0	Seizures	Seizures	MULT	183	IP ED	NO	1	ALL	NO	
6	LAIV	LAIV	MULT	14	0	20	0	0	Seizures	Seizures	MULT	183	IP ED	NO	15	ALL	NO	

NDC codes checked against First Data Bank's "National Drug Data File (NDDF®) Plus"

ICD-9-CM diagnosis and procedure codes checked against "Ingenix 2012 ICD-9-CM Data File" provided by OptumInsight

HCPCS codes checked against "Optum 2012 HCPCS Level II Data File" provided by OptumInsight

CPT codes checked against "Optum 2012 Current Procedure Codes & Relative Values Data File" provided by OptumInsight

*MULT Incidence type for the exposure will consider all episodes for each user during the query period that satisfies the Washout Period criteria (14 days).

**MULT Incidence type for the event will consider all episodes in the query period with an event that meets the Washout Period criteria (183 days)

Glossary of Terms in Modular Program 3*

- Blackout Period** - Number of days at the beginning of a treatment episode that events are to be ignored. If an event occurs during the blackout period, the episode is excluded.
- Care Setting** - Type of medical encounter or facility where the exposure, event, or condition code was recorded. Possible care settings include: Inpatient Hospital Stay (IP), Non-Acute Institutional Stay (IS), Emergency Department (ED), Ambulatory Visit (AV), and Other Ambulatory Visit (OA).
- Days at Risk** - Number of days supplied plus any episode gaps and exposure extension periods.
- Eligible Members** - Number of members eligible for an incident treatment episode (defined by the drug/exposure and event washout periods) with drug and medical coverage during the query period.
- Enrollment Gap** - Number of days allowed between two consecutive enrollment periods without breaking a “continuously enrolled” sequence.
- Episode Gap** - Number of days allowed between two (or more) consecutive exposures (dispensings/procedures) to be considered the same treatment episode.
- Exposure Extension Period** - Number of days post treatment period in which the outcomes/events are counted for a treatment episode.
- Lookback Period (pre-existing condition)** - Number of days wherein a member is required to have evidence of pre-existing condition (diagnosis/procedure/drug dispensing).
- Incidence Type (drug/exposure)**- *Minimum incidence type* will consider the first treatment episode in the query period as long as it is the first treatment episode in the user's entire available history. *Single* and *Multiple incidence types* will use the washout period to establish incidence, however *Single* will only consider the first treatment episode whereas *Multiple* will consider all qualifying incident treatment episodes.
- Incidence Type (event/outcome)**- *Minimum incidence type* considers the first event in a valid episode as long as it is the first event in the user's entire available history. *Multiple incidence type* uses the washout period to establish incidence and considers all qualifying incident treatment episodes. The program will only consider one event per episode, but the *Multiple incidence type* will consider more than one event per user if a user has more than one incident episode.
- Member-Days** - Sum of all days of enrollment with medical and drug coverage** in the query period preceded by an exposure washout period.
- Minimum Days Supplied** - Specifies a minimum number of days in length of the days supplied for the episode to be considered.
- Minimum Episode Duration** - Specifies a minimum number of days in length of the episode for it to be considered.
- New Episodes** - New treatment episodes; length of episode is determined by days supplied in one dispensing (or consecutive dispensings bridged by the episode gap).
- New Users** - Number of members with incident exposure during the query period. Member must have no evidence of exposure (s) of interest (defined by incidence criteria) in the prior washout period. A user may only be counted once in a query period.
- Principal Diagnosis** - Diagnosis or condition established to be chiefly responsible for admission of the patient to the hospital. YES will only consider diagnoses flagged as Principal.
- Query Period** - Period in which the modular program looks for exposures and outcomes of interest.
- Total Days Supplied** - Number of days supplied for all dispensings in qualifying treatment episodes.
- Washout Period (drug/exposure)**** - Number of days a user is required to have no evidence of prior exposure (drug dispensing/procedure) and continuous drug and medical coverage prior to an incident treatment episode.
- Washout Period (event/outcome)**** - Number of days a user is required to have no evidence of a prior event (procedure/diagnosis) and continuous drug and medical coverage prior to an incident treatment episode.

*all terms may not be used in this report

**incident treatment episodes must be incident to both the exposure and the event

Table 1. Summary of Incident Influenza Vaccination and Seizures in the MSDD between September 1, 2004 and March 31, 2012

	New Users	Total Vaccinations	New Episodes	Days at Risk	New Seizure Events	Eligible Members	Member-Days	New Users/ 1K Eligible Members	Episodes/ User	New Events/ 1M Vaccinations
Ages 6 Months - < 5 Years										
<i>TIV (not high dose, not intradermal)</i>										
0-1 Day Post-Vaccination	2,076,943	3,797,428	3,746,826	7,491,226	173	5,944,939	2,931,973,360	349	2	46
14-20 Days Post-Vaccination**	2,045,272	3,732,531	3,682,823	25,655,514	527	5,944,939	2,931,973,360	344	2	141
Ages 2 Years - < 5 Years										
<i>TIV (not high dose, not intradermal)</i>										
1-3 Days Post-Vaccination*	1,144,789	1,628,327	1,599,853	4,793,960	52	4,696,079	2,029,078,771	244	1	32
15-20 Days Post-Vaccination†	1,128,139	1,603,767	1,575,770	9,421,156	124	4,696,079	2,029,078,771	240	1	77
<i>LAIV</i>										
1-3 Days Post-Vaccination*	433,924	560,244	560,175	1,678,654	26	4,699,540	2,044,249,871	92	1	46
15-20 Days Post-Vaccination†	427,779	552,135	552,067	3,300,711	34	4,699,540	2,044,249,871	91	1	62

* Does not include seizures on day of vaccination

** Does not include seizures 0-13 days post-vaccination

† Does not include seizures 0-14 days post-vaccination

Table 2. Summary of Incident Influenza Vaccination and Seizures in the MSDD between September 1, 2004 and March 31, 2012 by Age Group

	New Users	Total Vaccinations	New Episodes	Days at Risk	New Seizure Events	Eligible Members	Member-Days	New Users/ 1K Eligible Members	Episodes/ User	New Events/ 1M Vaccinations
Ages 6 Months - < 5 Years										
<i>TIV (not high dose, not intradermal)</i>										
0-1 Day Post-Vaccination	2,076,943	3,797,428	3,746,826	7,491,226	173	5,944,939	2,931,973,360	349	2	46
6 Months - < 2 Years	1,273,727	2,167,636	2,145,528	4,289,583	138	2,044,666	416,557,749	623	2	64
23 Months - < 5 Years	1,145,816	1,629,792	1,601,298	3,201,643	35	4,696,621	2,029,432,518	244	1	21
14-20 Days Post-Vaccination**	2,045,272	3,732,531	3,682,823	25,655,514	527	5,944,939	2,931,973,360	344	2	141
6 Months - < 2 Years	1,252,887	2,126,930	2,105,256	14,656,629	389	2,044,666	416,557,749	613	2	183
23 Months - < 5 Years	1,129,318	1,605,601	1,577,567	10,998,885	138	4,696,621	2,029,432,518	240	1	86
Ages 2 Years - < 5 Years										
<i>TIV (not high dose, not intradermal)</i>										
1-3 Day Post-Vaccination*	1,144,789	1,628,327	1,599,853	4,793,960	52	4,696,079	2,029,078,771	244	1	32
15-20 Days Post-Vaccination†	1,128,139	1,603,767	1,575,770	9,421,156	124	4,696,079	2,029,078,771	240	1	77
<i>LAIV</i>										
1-3 Day Post-Vaccination*	433,924	560,244	560,175	1,678,654	26	4,699,540	2,044,249,871	92	1	46
15-20 Days Post-Vaccination†	427,779	552,135	552,067	3,300,711	34	4,699,540	2,044,249,871	91	1	62

* Does not include seizures on day of vaccination

** Does not include seizures 0-13 days post-vaccination

† Does not include seizures 0-14 days post-vaccination

Table 3a. Summary of Incident Influenza Vaccination and Seizures in the MSDD between September 1, 2004 and March 31, 2012 by Sex, Ages 6 Months - < 5 Years

	New Users	Total Vaccinations	New Episodes	Days at Risk	New Seizure Events	Eligible Members	Member-Days	New Users/ 1K Eligible Members	Episodes/ User	New Events/ 1M Vaccinations
TIV (not high dose, not intradermal)										
<i>0-1 Day Post-Vaccination</i>	2,076,943	3,797,428	3,746,826	7,491,226	173	5,944,939	2,931,973,360	349.36	1.80	45.56
Female	1,004,061	1,833,750	1,809,525	3,617,897	65	2,891,032	1,426,340,714	347.30	1.80	35.45
Male	1,068,302	1,955,709	1,929,384	3,857,499	108	3,035,217	1,495,438,719	351.97	1.81	55.22
Unknown	4,580	7,969	7,917	15,830	0	18,690	10,193,927	245.05	1.73	0.00
<i>14-20 Days Post-Vaccination*</i>	2,045,272	3,732,531	3,682,823	25,655,514	527	5,944,939	2,931,973,360	344.04	1.80	141.19
Female	988,669	1,802,359	1,778,557	12,389,702	255	2,891,032	1,426,340,714	341.98	1.80	141.48
Male	1,052,090	1,922,332	1,896,476	13,211,454	271	3,035,217	1,495,438,719	346.63	1.80	140.97
Unknown	4,513	7,840	7,790	54,358	1	18,690	10,193,927	241.47	1.73	127.55

* Does not include seizures 0-13 days post-vaccination

Table 3b. Summary of Incident Influenza Vaccination and Seizures in the MSDD between September 1, 2004 and March 31, 2012 by Sex, Ages 2 Years - < 5 Years

	New Users	Total Vaccinations	New Episodes	Days at Risk	New Seizure Events	Eligible Members	Member-Days	New Users/ 1K Eligible Members	Episodes/ User	New Events/ 1M Vaccinations
TIV (not high dose, not intradermal)										
<i>1-3 Day Post-Vaccination*</i>	1,144,789	1,628,327	1,599,853	4,793,960	52	4,696,079	2,029,078,771	243.78	1.40	31.93
Female	548,699	777,824	764,282	2,290,124	22	2,284,460	987,653,862	240.19	1.39	28.28
Male	593,058	846,131	831,234	2,490,843	30	2,395,024	1,033,849,723	247.62	1.40	35.46
Unknown	3,032	4,372	4,337	12,993	0	16,595	7,575,186	182.71	1.43	0.00
<i>15-20 Days Post-Vaccination †</i>	1,128,139	1,603,767	1,575,770	9,421,156	124	4,696,079	2,029,078,771	240.23	1.40	77.32
Female	540,662	766,086	752,763	4,500,567	57	2,284,460	987,653,862	236.67	1.39	74.40
Male	584,488	833,381	818,740	4,895,054	67	2,395,024	1,033,849,723	244.04	1.40	80.40
Unknown	2,989	4,300	4,267	25,535	0	16,595	7,575,186	180.11	1.43	0.00
LAIV										
<i>1-3 Day Post-Vaccination*</i>	433,924	560,244	560,175	1,678,654	26	4,699,540	2,044,249,871	92.33	1.29	46.41
Female	220,420	285,566	285,533	855,611	15	2,286,126	994,652,451	96.42	1.30	52.53
Male	212,349	273,151	273,115	818,466	11	2,396,815	1,041,981,201	88.60	1.29	40.27
Unknown	1,155	1,527	1,527	4,577	0	16,599	7,616,219	69.58	1.32	0.00
<i>15-20 Days Post-Vaccination †</i>	427,779	552,135	552,067	3,300,711	34	4,699,540	2,044,249,871	91.03	1.29	61.58
Female	217,330	281,457	281,424	1,682,583	11	2,286,126	994,652,451	95.06	1.29	39.08
Male	209,304	269,164	269,129	1,609,060	23	2,396,815	1,041,981,201	87.33	1.29	85.45
Unknown	1,145	1,514	1,514	9,068	0	16,599	7,616,219	68.98	1.32	0.00

* Does not include seizures on day of vaccination

† Does not include seizures 0-14 days post-vaccination

Table 4a. Summary of Incident Influenza Vaccination and Seizures in the MSDD between September 1, 2004 and March 31, 2012 by Year, Ages 6 Months - < 5 Years

	New Users	Total Vaccinations	New Episodes	Days at Risk	New Seizure Events	Eligible Members	Member-Days	New Users/ 1K Eligible Members	Episodes/ User	New Events/ 1M Vaccinations
TIV (not high dose, not intradermal)										
<i>0-1 Day Post-Vaccination</i>	2,076,943	3,797,428	3,746,826	7,491,226	173	5,944,939	2,931,973,360	349.36	1.80	45.56
2004	126,511	156,858	154,869	309,675	4	744,978	74,983,979	169.82	1.22	25.50
2005	167,414	203,127	201,184	402,284	3	996,203	232,485,355	168.05	1.20	14.77
2006	203,023	238,317	235,894	471,685	8	1,054,616	244,551,994	192.51	1.16	33.57
2007	236,394	287,808	285,038	569,913	20	1,146,855	256,600,693	206.12	1.21	69.49
2008	633,385	774,225	762,718	1,524,969	26	2,412,440	439,086,355	262.55	1.20	33.58
2009	645,053	817,494	804,275	1,608,107	31	2,530,991	594,121,187	254.86	1.25	37.92
2010	572,610	743,916	734,565	1,468,735	37	2,350,628	558,123,373	243.60	1.28	49.74
2011	438,519	556,796	549,571	1,098,439	43	2,155,221	506,819,817	203.47	1.25	77.23
2012	16,912	18,887	18,712	37,419	1	308,296	25,200,607	54.86	1.11	52.95
<i>14-20 Days Post-Vaccination*</i>	2,045,272	3,732,531	3,682,823	25,655,514	527	5,944,939	2,931,973,360	344.04	1.80	141.19
2004	125,182	155,132	153,164	1,069,135	22	744,978	74,983,979	168.03	1.22	141.81
2005	165,626	200,772	198,857	1,387,842	28	996,203	232,485,355	166.26	1.20	139.46
2006	200,927	235,580	233,179	1,627,516	36	1,054,616	244,551,994	190.52	1.16	152.81
2007	233,976	284,623	281,880	1,967,093	51	1,146,855	256,600,693	204.02	1.20	179.18
2008	625,639	763,677	752,339	5,246,536	106	2,412,440	439,086,355	259.34	1.20	138.80
2009	636,958	806,288	793,279	5,532,169	100	2,530,991	594,121,187	251.66	1.25	124.03
2010	565,244	733,289	724,079	5,047,441	109	2,350,628	558,123,373	240.47	1.28	148.65
2011	424,312	534,455	527,505	3,648,338	72	2,155,221	506,819,817	196.88	1.24	134.72
2012	16,761	18,715	18,541	129,444	3	308,296	25,200,607	54.37	1.11	160.30

* Does not include seizures 0-13 days post-vaccination

Table 4b. Summary of Incident Influenza Vaccination and Seizures in the MSDD between September 1, 2004 and March 31, 2012 by Year, Ages 2 Years - < 5 Years

	New Users	Total Vaccinations	New Episodes	Days at Risk	New Seizure Events	Eligible Members	Member-Days	New Users/ 1K Eligible Members	Episodes/ User	New Events/ 1M Vaccinations
TIV (not high dose, not intradermal)										
<i>1-3 Day Post-Vaccination*</i>	<i>1,144,789</i>	<i>1,628,327</i>	<i>1,599,853</i>	<i>4,793,960</i>	<i>52</i>	<i>4,696,079</i>	<i>2,029,078,771</i>	<i>243.78</i>	<i>1.40</i>	<i>31.93</i>
2004	46,419	51,921	51,260	153,682	0	520,029	51,718,372	89.26	1.10	0.00
2005	81,406	88,483	87,526	262,428	1	721,023	158,312,115	112.90	1.08	11.30
2006	109,592	115,614	114,287	342,658	1	762,911	166,587,346	143.65	1.04	8.65
2007	124,890	133,831	132,278	396,561	5	827,366	174,867,912	150.95	1.06	37.36
2008	325,570	346,735	340,205	1,019,550	8	1,730,917	300,895,830	188.09	1.04	23.07
2009	322,449	350,258	342,505	1,026,464	13	1,859,088	409,916,836	173.44	1.06	37.12
2010	282,664	314,470	308,924	925,683	11	1,747,044	391,689,895	161.80	1.09	34.98
2011	205,932	221,596	217,530	650,936	13	1,606,955	357,500,002	128.15	1.06	58.67
2012	5,246	5,419	5,338	15,998	0	219,115	17,590,463	23.94	1.02	0.00
<i>15-20 Days Post-Vaccination †</i>	<i>1,128,139</i>	<i>1,603,767</i>	<i>1,575,770</i>	<i>9,421,156</i>	<i>124</i>	<i>4,696,079</i>	<i>2,029,078,771</i>	<i>240.23</i>	<i>1.40</i>	<i>77.32</i>
2004	45,947	51,386	50,731	303,757	5	520,029	51,718,372	88.35	1.10	97.30
2005	80,625	87,586	86,642	518,756	4	721,023	158,312,115	111.82	1.07	45.67
2006	108,588	114,511	113,194	677,563	11	762,911	166,587,346	142.33	1.04	96.06
2007	123,660	132,479	130,937	784,149	18	827,366	174,867,912	149.46	1.06	135.87
2008	321,842	342,602	336,171	2,012,057	22	1,730,917	300,895,830	185.94	1.04	64.21
2009	318,514	345,822	338,197	2,023,706	20	1,859,088	409,916,836	171.33	1.06	57.83
2010	279,024	310,189	304,720	1,822,663	30	1,747,044	391,689,895	159.71	1.09	96.72
2011	199,041	213,838	209,904	1,246,901	14	1,606,955	357,500,002	123.86	1.05	65.47
2012	5,183	5,354	5,274	31,604	0	219,115	17,590,463	23.65	1.02	0.00

Table 4b. Summary of Incident Influenza Vaccination and Seizures in the MSDD between September 1, 2004 and March 31, 2012 by Year, Ages 2 Years - < 5 Years

	New Users	Total Vaccinations	New Episodes	Days at Risk	New Seizure Events	Eligible Members	Member-Days	New Users/ 1K Eligible Members	Episodes/ User	New Events/ 1M Vaccinations
LAIV										
<i>1-3 Day Post-Vaccination*</i>	433,924	560,244	560,175	1,678,654	26	4,699,540	2,044,249,871	92.33	1.29	46.41
2004	140	142	142	424	0	521,339	52,433,386	0.27	1.01	0.00
2005	302	313	313	937	0	723,012	159,566,379	0.42	1.04	0.00
2006	655	674	674	2,022	0	765,819	168,202,849	0.86	1.03	0.00
2007	10,321	10,535	10,533	31,579	0	830,414	176,660,169	12.43	1.02	0.00
2008	111,611	115,155	115,138	345,076	6	1,736,880	304,112,424	64.26	1.03	52.10
2009	148,176	153,106	153,087	458,928	11	1,863,323	412,719,376	79.52	1.03	71.85
2010	151,179	162,142	162,124	485,892	5	1,750,519	393,843,546	86.36	1.07	30.84
2011	113,929	116,899	116,886	349,966	4	1,609,134	359,048,074	70.80	1.03	34.22
2012	1,271	1,278	1,278	3,830	0	219,237	17,663,668	5.80	1.01	0.00
<i>15-20 Days Post-Vaccination †</i>	427,779	552,135	552,067	3,300,711	34	4,699,540	2,044,249,871	91.03	1.29	61.58
2004	137	139	139	833	0	521,339	52,433,386	0.26	1.01	0.00
2005	297	308	308	1,844	0	723,012	159,566,379	0.41	1.04	0.00
2006	650	669	669	4,012	0	765,819	168,202,849	0.85	1.03	0.00
2007	10,224	10,432	10,430	62,412	1	830,414	176,660,169	12.31	1.02	95.86
2008	110,380	113,857	113,840	681,346	9	1,736,880	304,112,424	63.55	1.03	79.05
2009	146,731	151,588	151,570	907,768	9	1,863,323	412,719,376	78.75	1.03	59.37
2010	149,504	160,289	160,271	959,134	8	1,750,519	393,843,546	85.41	1.07	49.91
2011	110,774	113,587	113,574	675,784	7	1,609,134	359,048,074	68.84	1.03	61.63
2012	1,259	1,266	1,266	7,578	0	219,237	17,663,668	5.74	1.01	0.00

* Does not include seizures on day of vaccination

† Does not include seizures 0-14 days post-vaccination

Table 5a. Summary of Incident Influenza Vaccination and Seizures in the MSDD between September 1, 2004 and March 31, 2012 by Influenza Season, Ages 6 Months - < 5 Years

		Total Vaccinations	New Episodes	Days at Risk	New Seizure Events	New Events/ 1M Vaccinations
TIV (not high dose, not intradermal)						
<i>0-1 Day Post-Vaccination</i>						
2004-2005	JUL-JUN	180,800	178,482	356,891	4	22.12
	OCT-JAN	162,332	160,203	320,359	4	24.64
2005-2006	JUL-JUN	198,310	196,482	392,882	3	15.13
	OCT-JAN	183,890	182,193	364,320	3	16.31
2006-2007	JUL-JUN	262,495	259,925	519,737	11	41.91
	OCT-JAN	245,134	242,736	485,371	10	40.79
2007-2008	JUL-JUN	286,636	283,775	567,385	18	62.80
	OCT-JAN	258,161	255,572	510,999	17	65.85
2008-2009	JUL-JUN	839,424	826,759	1,653,063	28	33.36
	OCT-JAN	721,349	710,406	1,420,519	22	30.50
2009-2010	JUL-JUN	806,661	793,982	1,587,519	32	39.67
	OCT-JAN	540,986	532,180	1,064,205	16	29.58
2010-2011	JUL-JUN	778,683	769,212	1,537,931	41	52.65
	OCT-JAN	594,669	587,176	1,174,097	31	52.13
2011-2012	JUL-MAR	444,419	438,209	875,818	36	81.00
	OCT-JAN	311,866	307,198	613,999	27	86.58

Table 5a. Summary of Incident Influenza Vaccination and Seizures in the MSDD between September 1, 2004 and March 31, 2012 by Influenza Season, Ages 6 Months - < 5 Years

		Total Vaccinations	New Episodes	Days at Risk	New Seizure Events	New Events/ 1M Vaccinations
TIV (not high dose, not intradermal)						
<i>14-20 Days Post-Vaccination*</i>						
2004-2005	JUL-JUN	178,868	176,572	1,232,719	29	162.13
	OCT-JAN	160,608	158,501	1,106,474	25	155.66
2005-2006	JUL-JUN	196,018	194,219	1,355,369	22	112.23
	OCT-JAN	181,814	180,144	1,257,042	21	115.50
2006-2007	JUL-JUN	259,566	257,021	1,794,015	44	169.51
	OCT-JAN	242,367	239,993	1,675,102	40	165.04
2007-2008	JUL-JUN	283,419	280,583	1,958,064	52	183.47
	OCT-JAN	255,313	252,746	1,763,638	44	172.34
2008-2009	JUL-JUN	828,103	815,619	5,688,372	118	142.49
	OCT-JAN	711,794	701,000	4,887,857	103	144.70
2009-2010	JUL-JUN	795,707	783,231	5,462,329	99	124.42
	OCT-JAN	533,755	525,093	3,659,858	71	133.02
2010-2011	JUL-JUN	767,707	758,385	5,287,029	109	141.98
	OCT-JAN	586,393	579,014	4,034,976	88	150.07
2011-2012	JUL-MAR	423,143	417,193	2,877,617	54	127.62
	OCT-JAN	292,473	288,034	1,976,008	35	119.67

* Does not include seizures 0-13 days post-vaccination

Table 5b. Summary of Incident Influenza Vaccination and Seizures in the MSDD between September 1, 2004 and March 31, 2012 by Influenza Season, Ages 2 Years - < 5 Years

		Total Vaccinations	New Episodes	Days at Risk	New Seizure Events	New Events/ 1M Vaccinations
TIV (not high dose, not intradermal)						
<i>1-3 Day Post-Vaccination*</i>						
2004-2005	JUL-JUN	175	175	523	0	0.00
	OCT-JAN	161	161	481	0	0.00
2005-2006	JUL-JUN	302	302	904	0	0.00
	OCT-JAN	268	268	802	0	0.00
2006-2007	JUL-JUN	704	704	2,112	0	0.00
	OCT-JAN	640	640	1,920	0	0.00
2007-2008	JUL-JUN	12,337	12,335	36,981	0	0.00
	OCT-JAN	11,742	11,740	35,198	0	0.00
2008-2009	JUL-JUN	118,904	118,887	356,312	6	50.46
	OCT-JAN	91,360	91,348	273,770	4	43.78
2009-2010	JUL-JUN	151,899	151,880	455,318	11	72.42
	OCT-JAN	82,217	82,209	246,486	6	72.98
2010-2011	JUL-JUN	166,914	166,895	500,208	5	29.96
	OCT-JAN	111,238	111,227	333,432	3	26.97
2011-2012	JUL-MAR	109,009	108,997	326,296	4	36.69
	OCT-JAN	59,539	59,532	178,100	2	33.59

Table 5b. Summary of Incident Influenza Vaccination and Seizures in the MSDD between September 1, 2004 and March 31, 2012 by Influenza Season, Ages 2 Years - < 5 Years

		Total Vaccinations	New Episodes	Days at Risk	New Seizure Events	New Events/ 1M Vaccinations
TIV (not high dose, not intradermal)						
<i>15-20 Days Post-Vaccination †</i>						
2004-2005	JUL-JUN	171	171	1,025	0	0.00
	OCT-JAN	157	157	941	0	0.00
2005-2006	JUL-JUN	298	298	1,784	0	0.00
	OCT-JAN	264	264	1,580	0	0.00
2006-2007	JUL-JUN	699	699	4,192	0	0.00
	OCT-JAN	635	635	3,808	0	0.00
2007-2008	JUL-JUN	12,220	12,218	73,129	1	81.83
	OCT-JAN	11,628	11,626	69,577	1	86.00
2008-2009	JUL-JUN	117,568	117,551	703,537	9	76.55
	OCT-JAN	90,384	90,372	540,741	9	99.58
2009-2010	JUL-JUN	150,394	150,376	900,641	9	59.84
	OCT-JAN	81,559	81,552	488,275	5	61.31
2010-2011	JUL-JUN	165,043	165,024	987,609	10	60.59
	OCT-JAN	110,106	110,095	658,640	10	90.82
2011-2012	JUL-MAR	105,742	105,730	628,794	5	47.28
	OCT-JAN	56,842	56,835	336,052	3	52.78

Table 5b. Summary of Incident Influenza Vaccination and Seizures in the MSDD between September 1, 2004 and March 31, 2012 by Influenza Season, Ages 2 Years - < 5 Years

		Total Vaccinations	New Episodes	Days at Risk	New Seizure Events	New Events/ 1M Vaccinations
LAIV						
<i>1-3 Day Post-Vaccination*</i>						
2004-2005	JUL-JUN	58,042	57,270	171,708	0	0.00
	OCT-JAN	51,390	50,690	151,992	0	0.00
2005-2006	JUL-JUN	87,328	86,416	259,101	1	11.45
	OCT-JAN	82,688	81,826	245,357	1	12.09
2006-2007	JUL-JUN	123,233	121,840	365,309	1	8.11
	OCT-JAN	118,259	116,935	350,611	1	8.46
2007-2008	JUL-JUN	132,867	131,266	393,516	5	37.63
	OCT-JAN	122,948	121,468	364,152	5	40.67
2008-2009	JUL-JUN	364,271	357,271	1,070,699	10	27.45
	OCT-JAN	321,231	315,109	944,398	10	31.13
2009-2010	JUL-JUN	345,918	338,402	1,014,190	13	37.58
	OCT-JAN	227,428	222,204	666,002	11	48.37
2010-2011	JUL-JUN	330,173	324,474	972,346	12	36.34
	OCT-JAN	256,212	251,725	754,405	10	39.03
2011-2012	JUL-MAR	186,495	182,914	547,091	10	53.62
	OCT-JAN	130,013	127,342	380,596	5	38.46

Table 5b. Summary of Incident Influenza Vaccination and Seizures in the MSDD between September 1, 2004 and March 31, 2012 by Influenza Season, Ages 2 Years - < 5 Years

LAIV		Total Vaccinations	New Episodes	Days at Risk	New Seizure Events	New Events/ 1M Vaccinations
<i>15-20 Days Post-Vaccination †</i>						
2004-2005	JUL-JUN	57,454	56,689	339,471	6	104.43
	OCT-JAN	50,871	50,178	300,438	6	117.95
2005-2006	JUL-JUN	86,442	85,544	512,163	4	46.27
	OCT-JAN	81,879	81,030	485,124	4	48.85
2006-2007	JUL-JUN	122,093	120,709	722,563	13	106.48
	OCT-JAN	117,161	115,846	693,441	12	102.42
2007-2008	JUL-JUN	131,493	129,904	777,959	18	136.89
	OCT-JAN	121,722	120,252	720,145	16	131.45
2008-2009	JUL-JUN	359,921	353,028	2,112,875	24	66.68
	OCT-JAN	317,507	311,474	1,863,953	22	69.29
2009-2010	JUL-JUN	341,561	334,166	1,999,741	17	49.77
	OCT-JAN	224,608	219,474	1,312,643	11	48.97
2010-2011	JUL-JUN	325,761	320,139	1,915,082	30	92.09
	OCT-JAN	252,840	248,416	1,485,709	24	94.92
2011-2012	JUL-MAR	179,042	175,591	1,041,302	12	67.02
	OCT-JAN	123,264	120,703	712,555	7	56.79

* Does not include seizures on day of vaccination

† Does not include seizures 0-14 days post-vaccination