Enhanced Surveillance for Adverse Events Following Immunization

Two Years of dTap Catch-Up Among High School Students in Yukon, Canada (2004, 2005)

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ABSTRACT

Background: To address the increasing age of pertussis cases, Yukon replaced the Grade 9 tetanus/diphtheria/inactivated polio booster with diphtheria/tetanus/acellular pertussis (dTap) and implemented a dTap catch-up program for Grade 12 students. The program began in June 2004, making Yukon one of the first Canadian jurisdictions to introduce dTap within five years of a tetanus booster. We implemented enhanced surveillance to monitor adverse events following immunization (AEFI) to determine whether students receiving dTap ≥ 3 to < 5 years after their last tetanus booster were at increased risk of severe AEFI.

Methods: Students completed a self-administered AEFI questionnaire one week post-dTap vaccination. Public health professionals contacted students reporting severe AEFI. Health care providers were requested to report AEFI. Symptom rate, severity and duration were compared between students receiving dTap ≥ 3 to < 5 years after their last tetanus booster and those receiving it ≥ 5 years later.

Results: The ≥ 3 to < 5 years group was more likely than the ≥ 5 years group to report pain at the injection site (70.6% vs. 61.5%, $p=0.038$) and less likely to report injection site redness (10.0% vs. 17.3%, $p=0.022$), injection site swelling (8.9% vs. 16.4%, $p=0.013$), decreased energy (10.0% vs. 17.1%, $p=0.023$), body aches (2.2% vs. 7.2%, $p=0.014$) and sore joints (3.3% vs. 10.1%, $p=0.004$). Severe AEFI did not differ between the groups (3.3% vs. 5.6%, $p=0.232$). Health care professionals reported no AEFI.

Conclusions: Results suggest no increased risk of severe AEFI among students receiving dTap ≥ 3 to < 5 years after their last tetanus booster.

MeSH terms: Diphtheria-Tetanus-acellular Pertussis vaccines; pertussis; vaccines; Arthus reaction; immunization programs; immunization schedule

La traduction du résumé se trouve à la fin de l'article.

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Pertussis incidence among adolescents and adults has been rising throughout Yukon. This trend has also been observed in other jurisdictions,¹⁻⁴ and is likely due to a combination of increased physician awareness, waning vaccine-induced immunity and low efficacy (50-60%) of the adsorbed whole-cell vaccine used from the early 1980s to the mid 1990s.^{1,4,5}

Infection with *Bordetella pertussis* is an important cause of respiratory disease in adolescents and adults,⁶⁻⁸ placing them at risk of severe complications and hospitalization.^{6,8} Infected adolescents and adults can also transmit pertussis to others, including those at high risk of severe morbidity and mortality.^{8,9}

To mitigate the upward trend in the age of pertussis cases in Yukon, in the spring of 2004 the routine Grade 9 tetanus/diphtheria/inactivated polio (TdIPV) booster was replaced with a new adolescent/adult vaccine for diphtheria/tetanus/acellular pertussis (dTap), AdacelTM.

To increase the proportion of young adults in Yukon protected against pertussis, a three-year (2004-2006) catch-up program was initiated for Grade 12 students. Since no monovalent pertussis vaccine was available in Canada, Grade 12 students were offered one dose of dTap, meaning that Grade 12 students would receive a tetanus toxoid booster approximately three years after they received their Grade 9 TdIPV booster.

The National Advisory Committee on Immunization recommends that tetanus toxoid "not be given routinely to a patient who has received a booster dose in the preceding five years",¹⁰ as it may put the patient at increased risk of severe local, or Arthus-type, reaction.⁵ However, the Yukon three-year dTap catch-up program was seen as a one-time "rescue" program whose benefits of enhanced pertussis protection outweighed the possible risk of adverse events following immunization (AEFI).

Since Yukon was one of the first Canadian jurisdictions to administer dTap to a cohort of students < 5 years after their last tetanus toxoid, Yukon implemented enhanced surveillance for AEFI in 2004 and 2005 in order to:

1. monitor the rate and nature of adverse events following AdacelTM vaccination of Grade 9 and Grade 12 students; and

TABLE I
Demographic Features of Participants by Time Since Last Tetanus Toxoid

	≥3 to <5 Years Since Last Tetanus Toxoid (n=180)		≥5 Years Since Last Tetanus Toxoid (n=444)		Statistical Comparison of Groups
	#	%	#	%	
Grade					Chi-square=516.0, p<0.001 *
9	0	0.0	402	90.5	
12	178	98.9	23	5.2	
Other	2	1.1	19	4.3	Chi-square=9.5, p=0.023 *
School					
School A	46	25.6	132	29.7	
School B	69	38.3	134	30.2	
School C	34	18.9	123	27.7	
Other	31	17.2	55	12.4	H=366.3, p<0.001 *
Age					
Mean	17.5		14.7		

* Statistically significant difference (p<0.05)

- compare rates and severities of AEFI among students who received tetanus toxoid component ≥3 to <5 years previously to those who received tetanus toxoid component ≥5 years previously to determine whether the former group was at increased risk of severe AEFI.

METHODS

Information about the dTAP catch-up program (including the rationale for the program, benefits of the vaccine, reasons to defer or not receive the vaccine, expected reactions and instructions on how to treat minor reactions) and consent forms were provided to all Grade 9 and 12 students in Yukon. Forms requested consent for vaccination and, for those vaccinated, consent to participate in a follow-up questionnaire. Informed consent was accepted from guardians or students aged 16 years and older.

Vaccination clinics were held at high schools for students returning completed consent forms and who did not have relative or absolute contraindications for dTAP. Vaccination was either not provided or deferred for students who: received tetanus booster <3 years previously, had confirmed pertussis since 1996, had a fever on the day of the vaccination clinic, or had a history of either severe oropharyngeal swelling that limited breathing or hives in response to any previous vaccine. In 2004, all vaccines had the same lot number; two different lot numbers were used in 2005 with no significant difference in the distribution of lot numbers between the comparison groups. The public health nurses assigned to each school administered vaccine to students in both grades.

Seven days post vaccination, students were asked to complete a self-administered adverse events questionnaire (AEQ) during class time. The AEQ was a 14-item questionnaire, asking about demographics, symptoms following vaccination, severity of symptoms, missed school, and whether medical attention was obtained. To gauge the size of reactions, students completing the AEQ received packages containing two OreosTM cookies, each 46mm in diameter.

In 2004, the vaccination program was implemented in the last few weeks of school and most Grade 12 students were asked to complete the AEQ on their own time, one week after immunization.

To ensure any severe AEFI was reported, primary healthcare providers were notified and requested to report AEFI to Yukon Communicable Disease Control.

Community health centres adapted student lists to include demographic and vaccination history from vaccination records. The AEQ and class list data were entered into EpiData,¹¹ linked non-nominally and analyzed using EpiInfo software.¹²

Comparing AEFI

The proportion of respondents developing each adverse reaction was compared between those who received tetanus toxoid ≥3 to <5 years previously (Shortened Interval Group, SIG) and those who received it ≥5 years previously (Recommended Interval Group, RIG), using odds ratios and Fisher's exact tests. Symptom severity was compared between the two groups using Chi-square analysis, odds ratios and Fisher's exact tests. The level of significance was 0.05; 95% confidence intervals (CI) were calculated.

Comparing severe AEFI

Severe AEFI were defined as self-reported:

- absence from school due to symptoms related to vaccination;
- one or more of: erythema or swelling ≥OreoTM cookie size, fever, or marked limitation of arm movement; and/or,
- medical attention for symptoms following vaccination.

Public health professionals conducted follow-up telephone interviews with students who reported severe AEFI to validate AEQ responses by asking detailed questions about reasons for missed school, type of medical attention received and severity of symptoms.

RESULTS

Over two years, 323 (58%) students in the SIG and 580 (76%) students in the RIG were vaccinated. Of these, 110 (34%) and 444 (77%) in the SIG and RIG, respectively, completed the AEQ.

Table I outlines respondent demographics by time since last tetanus booster. The SIG was significantly older than the RIG. The RIG was mostly comprised of Grade 9 students and the SIG, Grade 12 students, although occasional overlap occurred. The immunization records contained data on gender for only 216 (35%) of respondents.

AEFI

The SIG was more likely than the RIG to report pain at the injection site (Table II). However, the SIG was less likely to report injection site redness, injection site swelling, decreased energy, body aches, and sore joints. There were no significant differences in reported symptom severity between groups.

TABLE II

Reports of Adverse Events by Time Since Last Tetanus Toxoid

Symptom or Severity of Symptom	≥3 to <5 Years Since Last Tetanus Toxoid (n=180)		≥5 Years Since Last Tetanus Toxoid (n=444)		Statistical Comparison of Groups
	#	%	#	%	
Any Redness at Injection Site	18	10.0	77	17.3	OR=0.53 (0.30-0.95), p=0.022 OR=2.58 (0.29-58.43), p=0.684
Smaller than an Oreo™	17	9.4	66	14.9	
Larger than an Oreo™†	1	0.6	6	1.4	
Upper arm†	0	0.0	3	0.7	OR=0.49 (0.26-0.90), p=0.013 Chi-square=0.29, p=0.865
Entire arm†	0	0.0	1	0.2	
Any Swelling	16	8.9	73	16.4	
Smaller than an Oreo™	10	5.6	46	10.4	
Larger than an Oreo™	4	2.2	20	4.5	
Upper arm	2	1.1	6	1.4	OR=1.48 (1.00-2.20), p=0.038 Chi-square=0.31, p=0.858
Entire arm	0	0.0	0	0.0	
Any Pain at Injection Site	127	70.6	273	61.5	
Mild	70	38.9	140	31.5	
Moderate	51	28.3	112	25.2	OR=0.87 (0.60-1.25), p=0.420 Chi-square=0.51, p=0.775
Severe	3	1.7	8	1.8	
Any Limitation of Arm Movement	73	40.6	194	43.7	
Mild	31	17.2	85	19.1	OR=0.53 (0.30-0.95), p=0.023 OR=0.52 (0.19-1.38), p=0.155 OR=0.58 (0.30-1.10), p=0.072 Chi-square=0.81, p=0.668
Moderate	36	20.0	89	20.0	
Marked	4	2.2	7	1.6	
Any Decreased Energy	18	10.0	76	17.1	
Any Fever	6	3.3	27	6.1	OR=0.29 (0.08-0.88), p=0.014 OR=0.19 (0.01-2.62), p=0.283
Any Headache	15	8.3	59	13.3	
Mild	6	3.3	30	6.8	
Moderate	6	3.3	19	4.3	
Severe	3	1.7	8	1.8	OR=0.30 (0.11-0.76), p=0.004 OR=1.65 (0.22-15.02), p=0.683
Any Body Aches	4	2.2	32	7.2	
Mild	1	0.6	19	4.3	
Moderate†	2	1.1	8	1.8	
Severe†	1	0.6	3	0.7	OR=0.68 (0.30-1.47), p=0.286 OR=2.89 (0.38-21.94), p=0.332 OR=1.07 (0.27-3.91), p=1.000
Any Sore Joints	6	3.3	45	10.1	
Mild	4	2.2	23	5.2	
Moderate†	1	0.6	17	3.8	
Severe†	1	0.6	2	0.5	
Nausea	10	5.6	35	7.9	
Vomiting	3	1.7	4	0.9	
Diarrhea	4	2.2	9	2.0	

* Statistically significant difference (p<0.05).

† Due to small sample size, these categories were collapsed during statistical analyses comparing symptom severities between groups.

TABLE III

Reports of Severe Adverse Events Following Immunization (AEFI) by Time Since Last Tetanus Toxoid

Severe AEFI	≥3 to <5 Years Since Last Tetanus Toxoid (n=180)		≥5 Years Since Last Tetanus Toxoid (n=444)		Statistical Comparison of Groups
	#	%	#	%	
Self-reported Severe AEFI *	18	10.0	69	15.5	OR=0.60 (0.33-1.08), p=0.070
Validated Severe AEFI *	6	3.3	25	5.6	OR=0.58 (0.21-1.53), p=0.232
Absence from school	1	0.6	0	0.0	OR=undefined, p=0.288
Injection site redness ≥Oreo™ cookie size	1	0.6	7	1.6	OR=0.35 (0.02-2.83), p=0.449
Injection site swelling ≥Oreo™ cookie size	4	2.2	17	3.8	OR=0.57 (0.16-1.84), p=0.314
Fever	4	2.2	21	4.7	OR=0.46 (0.13-1.44), p=0.148
Marked limitation of arm movement	2	1.1	3	0.7	OR=1.65 (0.19-12.22), p=0.629
Medical attention for AEFI	0	0.0	0	0.0	n/a

* Severe AEFI are defined as:

- absence from school due to symptoms related to vaccination
- one or more of: erythema or swelling ≥Oreo™ cookie size, fever, or marked limitation of arm movement, and/or,
- medical attention for symptoms following vaccination.

Severe AEFI

Eighteen (10%) members of the SIG and 69 (16%) members of the RIG self-reported severe AEFI (Table III). Public health follow-up found that some respondents misinterpreted measures of symptom severity on the AEQ. Of the 87 reports of severe AEFI, 24 were found to be unrelated to dTap and 32 were re-coded to mild or moderate. Six (3.3%) students in the SIG and 25 (5.6%) in the RIG were found to truly experience severe AEFI. The proportion experiencing severe AEFI did not differ significantly

between the two groups. In all instances, symptoms resolved without further complication within 2 hours to 12 days.

None of the students reported being seen by a medical professional for symptoms. One student reported visiting the emergency room for pain at the injection site, but left without receiving medical care; symptoms resolved within 24 hours. Two called medical providers and were satisfied with the advice received by phone. Health care professionals did not report any AEFI among vaccinated students.

Other factors

Participants completed the AEQ 1 to 37 days post immunization (mean=8.8, median=7.0). The SIG (44%) was more likely than the RIG (25%) to complete the AEQ more than 7 days after vaccination (p<0.001). Those completing their AEQs late were less likely than those completing it on time to report redness at the injection site, limitations of arm movement and headache (Table IV). The time between vaccination and AEQ completion did not confound or interact with the relationship

TABLE IV

Reports of Adverse Events by Time Between Vaccination and Adverse Events Questionnaire (AEQ) Completion

Symptom	Completed AEQ ≥ 7 Days After Vaccination (n=435)		Completed AEQ >7 Days After Vaccination (n=189)		Statistical Comparison of Groups
	#	%	#	%	
Redness at Injection Site	80	18.4	15	7.9	OR=0.38 (0.20-0.71), p<0.001 *
Swelling at Injection Site	69	15.9	20	10.6	OR=0.62 (0.35-1.09), p=0.075
Pain at Injection Site	281	64.4	119	63.0	OR=0.92 (0.63-1.34), p=0.644
Limitation of Arm Movement	200	46.0	67	35.4	OR=0.64 (0.44-0.93), p=0.014 *
Decreased Energy	66	15.2	28	14.8	OR=0.96 (0.57-1.59), p=0.856
Fever	28	6.4	5	2.6	OR=0.39 (0.13-1.10), p=0.050
Headache	60	13.8	14	7.4	OR=0.49 (0.25-0.93), p=0.018 *
Body Aches	28	6.4	8	4.2	OR=0.63 (0.26-1.48), p=0.250
Sore Joints	36	8.3	15	7.9	OR=0.93 (0.47-1.82), p=0.820
Nausea	33	7.6	12	6.3	OR=0.80 (0.38-1.67), p=0.531
Vomiting	5	1.1	2	1.1	OR=1.11 (0.12-8.72), p=1.000
Diarrhea	10	2.3	3	1.6	OR=0.67 (0.14-2.72), p=0.763

* Statistically significant difference (p<0.05).

between time since last tetanus toxoid and reports of these symptoms. There were no significant differences in reported symptom severity between those completing their AEQs late and those completing them on time.

Public health professionals noted an increase in nausea, vomiting and diarrhea in the community during the 2005 vaccination program (Personal communication, C. Hemsley, Communicable Disease Control Officer, Yukon, 15/04/2005). Upon telephone follow-up, six students indicated onset of gastro-intestinal symptoms temporally inconsistent with vaccination or unvaccinated friends or family experiencing similar gastro-intestinal symptoms.

DISCUSSION

AEFI

Enhanced surveillance of AEFI during dTap catch-up in Yukon found that students receiving dTap ≥ 3 to <5 years since their last tetanus toxoid booster were more likely than those receiving it ≥ 5 years after their last tetanus booster to report pain at the injection site, but less likely to report redness, swelling, decreased energy, body aches and sore joints. The rates of adverse events reported for both groups were within the ranges observed elsewhere.^{13,14}

Severe AEFI

Follow-up with students reporting severe AEFI revealed that, in many cases, the adverse event was less severe than initially reported. Other reported indicators (i.e., missed school) were unrelated to dTap. Overall, 31 respondents experienced severe AEFI. There was no association between

experiencing severe AEFI and time since last tetanus toxoid.

Other factors

We expected the group with the shortened interval between tetanus boosters to be more likely to report symptoms or severe AEFI; however, this was not our finding. This may be explained by possible differences in reporting behaviours between younger and older students (younger students may have been more likely to report adverse events). We could not control for the differences in age in our two groups because, in general, Grade 9 students received their previous tetanus toxoid booster in Kindergarten and Grade 12 students received tetanus toxoid in Grade 9.

The observed differences in participation rates between the two groups within each school were not expected and may be attributable to other unassessed factors, such as socio-economic status or social desirability/peer pressure. These factors may also be related to the probability of reporting AEFIs.

The differing treatment of the Grade 12 students in 2004 may have resulted in recall bias, either by providing these students with a list of symptoms to consider for a week before completing the AEQ or by allowing these students to complete their AEQs at any time following vaccination. However, Grade 12 students did not consistently report more or fewer symptoms than Grade 9 students.

The community experienced increased gastro-intestinal symptoms during the 2005 vaccination program and it appeared that enteric viruses were responsible for some of the symptoms reported.

Despite collecting surveillance data over two years, the relatively small sample size may have led to less precise comparisons. However, the sample size was large enough to detect differences in individual symptoms. No difference was detected in incidence of severe adverse events between the two groups; the group of primary interest (students with a shortened interval between tetanus boosters) tended to report fewer severe reactions. As these results were based on enhanced surveillance following a public health campaign, we were not able to control all factors that may have confounded the associations of primary interest. Further research is required to support the findings of this surveillance project.

CONCLUSIONS

Adverse events were generally mild in the two groups. Students who received dTap ≥ 3 to <5 years after their last tetanus toxoid booster did not experience increased risk of severe AEFI. There was no significant difference in the severity of symptoms reported by the two groups and there was no significant difference in the proportion of respondents in either group experiencing severe AEFI. Enhanced surveillance confirmed that the benefits of this rescue program outweighed the possible risk of severe AEFI.

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RÉSUMÉ

Contexte : Afin de remédier à l'augmentation de l'âge des cas de coqueluche, le gouvernement du Yukon a décidé de remplacer le vaccin de rappel antitétanique/antidiphthérique/antipoliomyélitique inactivé, administré aux élèves de 9^e année, par un vaccin contre la diphthérie, le tétanos et la coqueluche acellulaire (dTCa) et de mettre en place un programme de rattrapage « dTCa » à l'intention des élèves de 12^e année. Le programme a débuté en juin 2004, faisant du gouvernement du Yukon l'un des premiers au Canada à introduire l'administration du vaccin dTCa au cours des cinq années suivant l'administration d'un vaccin de rappel contre le tétanos. Des moyens de contrôle accrus ont été institués afin de surveiller l'apparition de manifestations postvaccinales indésirables (MAPI) et de déterminer si les élèves recevant le vaccin dTCa ≥ 3 à < 5 ans après leur dernière injection de rappel contre le tétanos étaient plus à risque de présenter des MAPI graves.

Méthode : Les élèves ont rempli un questionnaire sur les MAPI une semaine après avoir reçu le vaccin dTCa, et des professionnels de la santé publique ont communiqué avec ceux rapportant des MAPI graves. Les professionnels de la santé ont été tenus de signaler les MAPI. Les symptômes (fréquence, gravité et durée) des élèves ayant reçu le vaccin dTCa ≥ 3 à < 5 ans après leur dernière injection de rappel contre le tétanos ont été comparés à ceux des élèves ayant reçu le vaccin ≥ 5 ans plus tard.

Résultats : Le groupe dont le délai était de ≥ 3 à < 5 ans était plus susceptible de signaler une douleur au point d'injection que le groupe dont le délai était ≥ 5 ans (70,6 % contre 61,5 %, $p=0,038$) et moins susceptible de signaler une rougeur (10 % contre 17,3 %, $p=0,022$) et une enflure au point d'injection (8,9 % contre 16,4 %, $p=0,013$), une baisse d'énergie (10 % contre 17,1 %, $p=0,023$), des courbatures (2,2 % contre 7,2 %, $p=0,014$) et des douleurs articulaires (3,3 % contre 10,1 %, $p=0,004$). Il n'y avait pas de différence entre les deux groupes en ce qui a trait aux MAPI graves (3,3 % contre 5,6 %, $p=0,232$). Les professionnels de la santé n'ont signalé aucune MAPI.

Conclusion : Les résultats indiquent qu'il n'y a pas de risque accru de MAPI graves chez les élèves qui reçoivent le vaccin dTCa ≥ 3 à < 5 ans après leur dernière injection de rappel contre le tétanos.

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