

# Tetanus Immunization Shortage in the United States

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The purpose of this study is to determine the effect of the tetanus immunization shortage on EDs and the EPs understanding of the prioritization of persons needing tetanus immunization. A survey consisting of questions about knowledge of the tetanus shortage, prioritization of immunizations, incidence of tetanus infections, and understanding of CDC recommendations was mailed to a random sample 20% of the US ED medical directors. The results of the survey were input into the SPSS program (SPSS, version 10, Chicago, IL). The survey was returned by 618 of the 1,375 (44.9%) ED medical directors in the United States. Almost all (97.2%, 601 of 617) were notified about the tetanus shortage and 58.3% (360 of 617) reported a shortage. A total of 42.2% (199 of 472) gave tetanus toxoid (TT), instead of tetanus and diphtheria toxoids adult type (dT) when indicated. Only 11.6% of those surveyed (56 of 482) established a patient callback system. Routine vaccination was stopped in 37.5% of the reporting hospitals, most often for adults and children (57.5%, 69 of 120). Twelve hospitals (1.9%) reported they had an increase in tetanus. Although 87.5% of the respondents (539 of 616) stated they were familiar with the CDC's prioritization for tetanus immunization, only 1.8% (11 of 616) got the prioritization correct. Although EM directors uniformly know about and are experiencing the tetanus shortage, few correctly reported the tetanus immunization priority. Few EDs had a patient callback system. (*Am J Emerg Med* 2003;21:298-301. © 2003 Elsevier Inc. All rights reserved.)

The US Public Health Service learned of an expected shortage of tetanus immunizations late in 2000.<sup>1</sup> This tetanus shortage began in March 2001 and was expected to last 12 to 18 months.<sup>2</sup> The tetanus shortage was caused by reduction in the number of manufacturers of tetanus toxoid. Although Aventis Pasteur has increased their production to meet the current need, it was anticipated that it would take months to increase the amount of vaccine to meet this need.<sup>3</sup>

The number of tetanus cases has steadily decreased in the last 20 years from a high of almost 200 cases in 1969 to a low of 35 cases reported, in 2000.<sup>4,5</sup> The effects of a tetanus shortage on the possibility of tetanus elimination in the United States are unknown.

The purpose of this study is to determine the effect on EM of the tetanus immunization shortage in the United States. The study also evaluates EPs understanding of the prioritization of persons needing tetanus immunization.

## METHODS

A survey tool consisting of questions about knowledge of the tetanus vaccine shortage, prioritization of immunizations, incidence of tetanus infections, and CDC information was developed and trialed on a group of EPs.<sup>5</sup> The survey did not address the physicians' knowledge about tetanus-prone wounds or diphtheria-related illnesses. The revised survey was mailed to a random sample of ED medical directors of 20% of hospitals in the United States. The hospital list was obtained from a web site related to the American Hospital Association.<sup>6</sup> The survey was remailed to the nonresponders 6 weeks after the first. The results of the survey were input into the SPSS program (SPSS, version 10, Chicago, IL). Nationwide analysis was performed to determine statistical significance of any regional differences using the CDC standard regions.<sup>7</sup>

## RESULTS

The survey was returned by 618 of 1375 (44.9%) ED medical directors in the United States (Table 1). Twenty-four percent (146 of 618) were urban, 33.3% (206 of 618) were suburban, 42.1% (260 of 618) were rural hospitals, and 42.5% (114 of 268) considered themselves teaching hospitals. Almost all (97.4%, 601 of 618) were notified about the tetanus shortage, most frequently (57.1%, 344 of 603) by the hospital pharmacy. Medical directors were least frequently notified of the tetanus shortage by the hospital's infectious disease service (0.8%, 5 of 603) or by hospital administration (0.7%, 5 of 603). Twenty-one were informed by other means such as CNN (2), journal (1), or drug distributor (1). Fifty-nine percent experienced a shortage that lasted 3 months (21.4%).

The shortage was seen most often with tetanus and diphtheria toxoids adult type (dT) (53.5%), tetanus toxoid (TT) (3.5%), and both dT and TT (43.2%). Only 43.8% gave TT instead of dT when indicated. Routine tetanus vaccination was stopped in 39.5% of the reporting hospitals, most often for adults and children (62.0%). Only 10.5% of those surveyed established a patient callback system to administer the vaccination when the vaccine becomes available.

Seven hospitals stated that they were familiar with an increase in the number of cases of tetanus that occurred since the shortage. Although 90.2% of the respondents stated they were familiar with the CDC's prioritization of immunization for tetanus, only 1.8% got the prioritization correct. (Table 2).

One-way analysis of variance demonstrated the number of correct answers to CDC's priority with EDs experiencing a shortage ( $f = 2.435$ ,  $df = 5$ ,  $P = .034$ ), but not with volume or number of operating beds ( $P < .05$ ). No rela-

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TABLE 1. Results

Type of Hospital	No.	Percent
Urban	146/610	23.9
Suburban	206/610	33.8
Rural	260/610	42.6
Teaching or nonteaching		
Teaching	114/268	42.5
Nonteaching	154/268	57.5
Informed of nationwide tetanus shortage		
Yes	601/617	97.4
No	16/617	25.9
How did you learn of the tetanus shortage?		
Hospital pharmacy	344/603	57.0
Multiple	178/603	29.5
State health department	30/603	5.0
Other	21/603	3.5
County health department	9/603	1.5
Federal government	8/603	1.3
Hospital infectious disease service	5/603	0.8
Hospital administration	4/603	0.7
Mortality and Morbidity Weekly Report	4/603	0.7
Has your ED experienced a shortage of tetanus in 2000/2001?		
Yes	360/617	58.3
No	257/617	41.7
Was the shortage dT, TT, or both dT and TT?		
dT	197/366	53.8
TT	16/366	4.4
Both	153/366	41.8
Did you give TT instead of dT during the shortage?		
Yes	199/472	42.2
No	232/472	49.2
Unknown	41/472	8.7
Was there a patient callback system?		
Yes	56/483	11.6
No	393/483	81.4
Unknown	33/483	6.8
Did your institution stop routine tetanus vaccination?		
Yes	229/610	37.5
For children	2/120	1.7
For adults	49/120	40.8
For adults and children	69/120	57.5
No	311/610	51.0
Unknown	70/610	11.5
Are you familiar with an increase in the number of tetanus cases?		
Yes	12/617	1.9
No	605/617	98.1

tionship was found between increased tetanus cases and those EDs experiencing a shortage of tetanus, ED volume, type of notification, or number of operating beds ( $P < .05$ ).

There were no differences found in the regions of the United States for shortage notification, callback system,

correct answers, or increased cases (Table 3). There was a correlation with the region and experience a shortage of tetanus (Pearson correlation coefficient .085  $P = .035$ ), stopping routine immunizations (Pearson correlation coefficient .083,  $P = .042$ ) and familiarity of CDC recommendations (Pearson correlation coefficient .085,  $P = .035$ ).

## DISCUSSION

This study demonstrates that medical directors have general knowledge concerning the recent tetanus shortage. Most of the reporting hospitals throughout the country are experiencing a shortage of tetanus toxoid-containing material. However, it is a concern that they do not know the priority of immunization nor have established a patient callback system.

The responsibility for notification of the ED medical directors about critical level or shortage of drug and vaccine supplies is unknown. This study did not attempt to determine the appropriate responsibility for notification or the means of notification. It would be best if the hospital phar-

TABLE 2. Results

	No.	Percent
Are you familiar with the CDC's recommendation for use of dT?		
Yes	539/616	87.5
No	77/616	12.5
Is the rank correct?		
Yes	11/616	1.8
No	605/616	98.2
How many correct responses?		
0	349	56.9
1	129	21.0
2	64	10.4
3	29	4.7
4	31	5.1
5	0	0
6	11	1.8
	Correct Rank	No. 1 Rank
Persons traveling to a country where the risk of diphtheria is high	65/459	65
Persons requiring tetanus vaccination for prophylaxis in wound management	45/583	450
Persons who have received <3 doses of vaccine containing dT	198/468	21
Pregnant women and persons at occupational risk for tetanus-prone injuries who have not been vaccinated with dT within the last 10 years	115/466	27
Adolescents who have not been vaccinated with a vaccine containing dT within the preceding 10 years	116/470	16
Adults who have not been vaccinated with dT within the preceding 10 years	137/476	22

**TABLE 3.** Regional Analysis\*

	No.	Notified of a Shortage	Experienced a Shortage†	Callback System	Correct Rank	More Cases
Northeast	102/615	100/102	58/102	12/74	1/101	2/102
Midwest	159/615	154/158	73/158	13/115	6/158	2/156
South	188/615	180/188	124/188	18/155	1/188	7/188
West	166/615	164/166	102/166	12/135	2/165	1/166

\*No significance was found in regional analysis of the responses noted except for a correlation of the region and experience a shortage of tetanus.

†(Pearson correlation coefficient .085,  $P = .035$ ).

macy notify all those who use a medication or vaccine that is in critically low supply or shortage. The hospital pharmacy should be responsible for educating the physicians about the priority for the use of the current stockpile of tetanus immunizations and the plan to call patients back. A number of other critical medications have been noted to also be in short supply for hospitals in the United States.<sup>8</sup> A similar problem occurred in 1985 when there was also a shortage of United States because 2 of the 3 manufacturers had ceased production.<sup>9</sup> In that situation, pediatricians were notified by the CDC to delay routine immunizations of children and they were then notified to restart immunizations.<sup>11</sup>

The CDC recommends that healthcare providers record the names of patients who need a tetanus booster and to contact them when the booster is available.<sup>12</sup> They also recommend deferral of routine booster doses of tetanus and diphtheria toxoid for adolescents and adults.<sup>13</sup> It is essential that the medical directors establish a callback system when they are unable to give tetanus prophylaxis. The manufacturer has distributed a kit to assist clinicians in keeping track of patients who had deferral of tetanus immunizations.<sup>14</sup> The Postgraduate Institute for Medicine mailed a letter to educate healthcare professionals on the priority of dT vaccination.<sup>15</sup> EDs routinely call back patients for radiology or laboratory recalls. However, this situation is different for the tetanus shortage because the recall can come weeks or months after the initial ED visit.

Although some medical directors stated that there was an increase of tetanus in their institution, it is uncertain whether this shortage will lead to an increased number of tetanus cases nationwide. Because the inoculation period can take over 1 month, it is too early to make such a determination.<sup>16</sup> Tetanus immunization is recommended every 10 years in adults unless the wound is thought to be tetanus-prone.<sup>16</sup> Even though many adults in the United States are not adequately protected against diphtheria, the incidence of diphtheria in the United States has been low for a number of years.<sup>17</sup> The incidence of diphtheria would also be suspected to increase in those populations who have not received a dT booster.

This study demonstrates the need for medical directors to understand the protocol for dealing with patients who need tetanus immunizations when there is a lack of tetanus toxoid. It is not surprising that ED medical directors are not familiar with the correct priority of tetanus immunization because most EPs rarely treat patients who are traveling to an area endemic for diphtheria (Appendix 1). However, it

behooves the medical directors to educate their staff concerning the CDC protocol for the relevant priorities.

The CDC and the FDA have provided testimony to the United States Senate Committee on Governmental Affairs as to the respective organization's role in maintaining the supply of childhood vaccines.<sup>18,19</sup> The FDA has reduced the need for duplicative efforts by manufacturers, and the CDC monitors state ordering and distribution, modification of recommendations, and vaccine stockpiling. The monitoring of immunization supplies statewide can reduce the problem of maldistribution noted in this study. The CDC maintains a web page on the current vaccine shortages, providing expected duration and temporary change from routine recommendation.<sup>20</sup>

## POSTSCRIPT

The shortage of tetanus vaccine is officially over.<sup>21</sup> It took approximately 11 months for Aventis to increase their production of Td. The CDC recommends that healthcare providers contact those patients who had their immunizations delayed to bring them up to date.<sup>21</sup>

## Limitations and Future Questions

This study is limited by those who did not respond to the survey as well as those who had incomplete responses. It is uncertain if the nonresponders would have answered the questions any different. Direct observation would be the preferred means to obtain information about the true impact of the tetanus shortage on healthcare institutions. The incidence of new cases of tetanus was not confirmed by those who noted such. The survey did not inquire about the number of additional diphtheria cases, but these cases are presumed to be increased. Future study of the incidence of the tetanus that was caused by or related to the shortage would be valuable. We assumed, but did not question, the EPs knowledge of the management of the tetanus-prone wounds.

## CONCLUSION

Emergency medical directors have general knowledge concerning the recent tetanus shortage but not the approach to the shortage. It is important for these emergency directors and their staff to understand the protocol for tetanus immunization during this time of shortage.

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## REFERENCES

1. Centers for Disease Control and Prevention: Update on the supply of tetanus and diphtheria toxoids and of diphtheria and tetanus toxoids and acellular pertussis vaccine. *MMWR* 2001;50:198-190
2. Furste W: Tetanus: A new threat. *J Trauma* 2001;51:416-417
3. Centers for Disease Control and Prevention: Deferral of routine doses of tetanus and diphtheria toxoids for adolescents and adults. *MMWR* 2001;50:418-420
4. Centers for Disease Control and Prevention: Tetanus surveillance: United States 1995–1997. *MMWR* 1998;47:1-11
5. Centers for Disease Control and Prevention: Summary of provisional cases of selected notifiable diseases, United States, cumulative week ending December 30, 2000. *MMWR* 2000;49:1167
6. Medical-Net, Inc: Hospital Select–Hospital Locator [http://www.hospitalselect.com/curb\\_db/owa/sp\\_hospselect.hosp\\_data](http://www.hospitalselect.com/curb_db/owa/sp_hospselect.hosp_data). Accessed June 2001
7. Centers for Disease Control and Prevention: <http://cdc.gov>. Accessed July 7, 2002
8. American Society of Health-System Pharmacists: Drug product shortages management resource center. <http://www.ashp.org/shortage>. Accessed October 25, 2001
9. Centers for Disease Control and Prevention: Diphtheria–tetanus–pertussis vaccine shortage. *JAMA* 1985;253:1540-1541
10. Centers for Disease Control and Prevention: Diphtheria–tetanus–pertussis vaccine shortage—United States. *JAMA* 1985;253:22-23
11. Centers for Disease Control and Prevention: Reinstatement of regular diphtheria–tetanus–diphtheria vaccine schedule. *MMWR* 1985;34:231-232
12. Centers for Disease Control and Prevention: Shortage of tetanus and diphtheria toxoids. *MMWR* 2000;49:1029-1030
13. Centers for Disease Control and Prevention: Notice to readers: Deferral of routine booster doses of tetanus and diphtheria toxoids for adolescents and adults. *MMWR* 2002;50:1159
14. Doutre, WH, Important news about the shortage of tetanus vaccine. July 2001
15. Decker M: Deferral of routine booster doses of tetanus toxoids for adolescents and adults. June 2001
16. Carden DL: Tetanus, in Tinitnalli JE, Ruiz E, Krome RL (eds): *Emergency Medicine: A Comprehensive Study Guide*. New York, McGraw-Hill, 1996
17. US Department of Health and Human Services: Diphtheria, tetanus, and pertussis: Recommendations for vaccine use and other preventative measures recommendations of the Immunization Practices Advisory Committee. *MMWR* 1991;40:1-28
18. Centers for Disease Control and Prevention: FDA's role in maintaining the supply of childhood vaccines: Testimony before the committee on governmental affairs United States Senate. <http://www.cdc.gov/nip/news/testimonies/vac-shortages-FDA-6-12-2002.htm>. Accessed July 14, 2002
19. Centers for Disease Control and Prevention: Protecting our kids: What is causing the current shortage in childhood vaccines? Testimony before the Committee on Governmental Affairs United States Senate. <http://www.cdc.gov/nip/news/testimonies/vac-shortages-walt-6-12-2002.htm>. Accessed July 14, 2002
20. Centers for Disease Control and Prevention: Current vaccine shortages. <http://www.cdc.gov/nip/news/shortages.default.htm>. Accessed July 14, 2002
21. Centers for Disease Control and Prevention: Resumption of routine schedule for tetanus and diphtheria toxoids. *MMWR* 2002;51:529-530

## APPENDIX 1. Tetanus Immunization Priority

1. Persons traveling to a country where the risk of diphtheria is high
2. Persons requiring tetanus vaccination for prophylaxis in wound management
3. Persons who have received <3 doses of vaccine containing dT
4. Pregnant women and persons at occupational risk for tetanus-prone injuries who have not been vaccinated with dT within the last 10 years
5. Adolescents who have not been vaccinated with a vaccine containing dT within the preceding 10 years
6. Adults who have not been vaccinated with dT within the preceding 10 years

Data from Centers for Disease Control and Prevention: Deferral of routine doses of tetanus and diphtheria toxoids for adolescents and adults. *MMWR* 2001;50:418-420