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Research Paper

New Combined Tetanus-Diptheria-Acellular Pertussis Vaccines for Adults

Primary Care Physician Attitudes and Preferences

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KEY WORDS

pertussis, Tdap, physician attitudes, adult vaccines

ABBREVIATIONS

ACIP	US Advisory Committee on Immunization Practices
AMA	American Medical Association
CDC	Centers for Disease Control and Prevention
FP	family physician
IM	general internist
OB/GYN	obstetrician/gynecologist
Td	tetanus-diptheria
Tdap	tetanus-diptheria-acellular pertussis
US	United States

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ABSTRACT

Availability of combined tetanus-diphtheria-acellular pertussis (Tdap) vaccines for adults offers a new pertussis prevention strategy for the US. Successful uptake of Tdap vaccine will depend partly on the attitudes and practices of primary care physicians, including their experience with Td boosters. We conducted a mail survey in August 2005 of a national random sample of 399 family physicians (FPs) and 399 general internists (IMs) to assess practices related to Td boosters, clinical experience with pertussis, and attitudes toward a potential Tdap vaccine recommendation for adults. The response rate was 49% (52% FPs, 46% IMs). Among 336 eligible respondents, half reported having clinical experience with pertussis. Most (81%) would recommend Tdap vaccine for their adult patients, and 73% support targeting adults likely to come in close contact with infants. Attitudes toward a potential Tdap vaccine recommendation differed by whether providers stock and administer Td boosters. We conclude that adult primary care providers in the US are likely to recommend Tdap vaccine to their adult patients, in concordance with recent national recommendations. Future research should assess the extent to which barriers impede adoption of Tdap vaccine recommendations.

INTRODUCTION

Pertussis is an acute coughing illness that remains endemic in the United States despite routine childhood pertussis vaccination. Reported pertussis cases have increased steadily since 1976. This increase has disproportionately affected adults,[1,2] who are susceptible to pertussis after childhood vaccine-induced immunity wanes. In 2004, 25,827 pertussis cases were reported in the United States, of which 7,008 (27%) were among adults.[1]

Physicians frequently do not recognize signs of pertussis in adolescents and adults,[3] yet the health and economic consequences of pertussis can be substantial.[4] In addition, addressing pertussis outbreaks using conventional approaches to interrupting disease transmission may be hindered by factors such as clustering of cases in hard-to-reach adult populations.[5] Furthermore, infants, especially those who have not yet received the routine three-dose primary series of childhood diphtheria-tetanus-pertussis vaccine, are particularly vulnerable to severe complications and death from pertussis,[6] and often become infected through exposure to adults with pertussis.[7]

Vaccinating adults against pertussis is therefore an appealing pertussis control strategy. In June 2005, a combined tetanus-diphtheria-acellular pertussis (Tdap) vaccine was licensed in the US for persons aged 11–64 years,[8] the first vaccine with a pertussis component licensed for use in US adults. Tdap vaccine has been shown to induce immune responses adequate to protect against pertussis (as well as tetanus and diphtheria) and has an overall safety profile similar to that of tetanus-diphtheria (Td) vaccine.[8,9]

Understanding the current practices of primary care physicians related to routine Td vaccination for adult patients has important implications for adoption of Tdap vaccine recommendations. In 2003, almost half (48%) of all physician office visits by adults were made to primary care physicians; of these, 48% of visits were made to general practice/family physicians (GPs/FPs), 33% to general internists (IMs), and 18% to general obstetricians/gynecologists (OB/GYNs).[10] Adult Td vaccination practices have not been well defined for these groups of physicians. Serologic and survey data indicate that US adults are undervaccinated with Td, and that rates of coverage decline with increasing age.[11,12] In addition, studies of adult vaccination practices have found specialty-based differences in influenza and pneumococcal immunization practices;[13,14] similar differences may exist for Td, and potentially for Tdap vaccine as well.

We surveyed FPs and IMs to characterize their current Td booster vaccination practices, perceived barriers to Td vaccination, clinical experience with pertussis, and their preferences regarding potential Tdap vaccine recommendations for adults. Results of a similar survey of OB/GYNs are published elsewhere.[15] In October 2005, these data were presented to the US Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention (CDC), to inform its deliberations regarding recommendations for use of Tdap vaccine among adults. Now that the ACIP has recommended that adults aged 19-64 years receive Tdap vaccine to replace the next Td booster,[16] our findings present an assessment of likely challenges to adoption of the adult Tdap vaccine recommendation by family physicians and general internists.

METHODS

Sample. We drew a national random sample of 399 FPs and 399 IMs from the American Medical Association (AMA) Masterfile through a contracted vendor. The AMA Masterfile, a database of all licensed US physicians, is the most comprehensive physician listing in the United States, and includes both AMA members and non-members. The sampling frame included all allopathic and osteopathic physicians self-described as a family physician or general internist in office-based, direct patient care. Excluded were physicians with any subspecialty board listing, physicians 70 years of age or older, physicians in residency training, and physicians employed at federal government (i.e., Veterans Affairs, military) medical facilities.

Based on our prior studies of physician behavior regarding immunizations,[13,17] this sample size and an anticipated response rate of 50% was expected to generate an analytic sample that would give us 80% power to detect a 10% difference in the practice behaviors reported by FPs and IMs, with a two-tailed α-level of 0.05.

The Institutional Review Boards of the University of Michigan Medical School and CDC approved this study.

Instrument. We developed a two-page, 15-item survey instrument, accompanied by a one-page "fact sheet" regarding pertussis and the recently licensed Tdap vaccine (available from the corresponding author). Survey items addressed physicians' experience with Td vaccination; clinical experience with diagnosing pertussis; perspectives on Tdap vaccine for all adults; perspectives on a potential Tdap vaccine recommendation targeted to adults in close contact with young infants; and practice characteristics.

We pilot-tested the survey instrument and fact sheet with a convenience sample of FPs and IMs to ensure clarity and ease of administration. We made minor refinements based on pilot test feedback.

Survey administration. To meet the timeframe of the ACIP, we fielded only one mailing of the survey in August 2005. Survey packets contained a cover letter explaining the purpose of the study, the fact sheet and survey form, and a $5 cash incentive.

Data analysis. We generated univariate frequencies for each variable and then performed chi-square analyses to examine associations between variables, with a two-tailed α-level of 0.05 as the threshold for statistical significance. All analyses were conducted using SAS® version 8.2 (SAS Institute, Cary, NC).

RESULTS

Sample characteristics. Of 798 physicians in the study sample, 20 were excluded (8 FPs, 12 IMs) because mailing materials were returned as undeliverable. Surveys were returned by 383 (204 FPs, 179 IMs) of the remaining 778 physicians, for an overall response rate of 49% (52% FPs, 46% IMs). A total of 47 respondents (13 FPs, 34 IMs) were ineligible because they indicated they were not providing outpatient primary care to adults ≥19 years, leaving 336 respondents (191 FPs, 145 IMs) in the group for final analyses. Based on a limited set of demographic variables available, the only difference between respondents and non-respondents was that respondents were more likely to be board certified.

Of the 336 eligible respondents, 63% were in private practice, 15% in hospital-affiliated outpatient practice, 9% in practice networks (including managed care organizations), and the remainder in other settings. With regard to practice size, 20% were in solo practice, 39% in small group practices (2–5 physicians), and 41% in practices with more than five physicians. Practice ownership/affiliation and size did not differ by physician specialty.

Current Td immunization patterns. The practices of almost all respondents (92%) stock Td boosters, though the proportion was significantly higher among FPs (96%) than IMs (87%, $p < 0.01$).

Almost all respondents (93%) said they "routinely" administer Td vaccine for wound management; FPs were more likely to do so (97%) compared to IMs (86%, $p < 0.0001$). The majority (68%) said they "routinely" administer Td boosters for routine health maintenance when indicated, while 24% do so "sometimes" and 8% "rarely/never," with no significant difference by specialty.

When asked to estimate the proportion of their adult primary care patients that are up-to-date on Td boosters, 43% of respondents said that <50% of their patients are up-to-date, 40% said that 50%–75% of their patients are up-to-date, and 17% reported that >75% of their patients are up-to-date. There was no difference by specialty.

Barriers to Td immunization. From a list of potential barriers to adult Td vaccination, respondents were asked to identify which were major barriers in their practice. The most commonly cited major barriers were "recordkeeping/knowing who needs a Td booster" (51%), being too busy or having other priorities at visits (42%), and patient reluctance/refusal (42%). Less often cited were reimbursement or insurance coverage issues (24%), vaccine supply (11%), a preference for limiting Td boosters to wound management (5%), and other, miscellaneous reasons (4%); the remaining 9% said there were no major barriers to adult Td vaccination in their practice. The only barrier that differed by specialty was recordkeeping, with FPs more likely to cite this barrier (56%) than IMs (44%, $p < 0.05$).

Clinical experience with pertussis. One of every two respondents (51%) said they had never diagnosed pertussis in their practice in a patient of any age. Of the remainder, 37% had diagnosed pertussis 1-5 times and 12% more than 5 times. FPs were more likely than IMs to have ever diagnosed pertussis (55% vs 42%, $p < 0.01$).

Physician attitudes regarding Tdap vaccine to prevent pertussis among adults. Half (50%) of respondents "agree" or "strongly agree" with the statement, "pertussis among adults is a serious enough disease to warrant administering a vaccine that includes an acellular pertussis component (Tdap), rather than Td, to adults." Another 37% were "neutral" and 13% "disagree" or "strongly disagree." Extent of agreement that pertussis in adults is serious enough to warrant administering Tdap vaccine differed significantly by physician specialty, current Td booster practices, and clinical experience with pertussis in a patient of any age (Table 1).

When asked to anticipate an ACIP recommendation to replace Td with Tdap vaccine for adults, 81% of respondents said they would recommend Tdap vaccine for all of their adult patients, when

Table 1 **Differences in agreement that Tdap vaccine is warranted to protect adults from pertussis by respondent characteristics and practices.**

Respondent Characteristics and Practices	"Pertussis Among Adults is Serious Enough to Warrant Administering Tdap Vaccine" Strongly Agree / Agree % (N)		Neutral / Disagree / Strongly Disagree % (N)		P-Value
Specialty					
FP	58%	(111)	42%	(80)	< 0.001
IM	40%	(57)	60%	(87)	
Practice currently stocks Td boosters					
Yes	52%	(160)	48%	(146)	< 0.05
No	31%	(8)	69%	(18)	
Administer Td for routine health maintenance, when indicated					
Routinely	55%	(120)	45%	(100)	< 0.05
Sometimes/Rarely/Never	42%	(44)	58%	(60)	
No. of times have diagnosed pertussis					
Never	38%	(65)	62%	(104)	< 0.0001
1-5 times	55%	(68)	45%	(56)	
>5 times	83%	(35)	17%	(7)	

FP, family physicians; IM, general internists.

Table 2 **Differences in predicted willingness to recommend Tdap vaccine for adults by respondent characteristics, practices, and attitudes.**

Respondent Characteristics, Practices, and Attitudes	Would You Recommend Tdap Vaccine for Adults if Recommended by ACIP? % (N) Yes		No/Unsure		P-Value
Specialty					
FP	82%	(154)	18%	(34)	NS
IM	79%	(112)	21%	(30)	
Administer Td for routine health maintenance, when indicated					
Routinely	85%	(187)	15%	(33)	< 0.01
Sometimes/Rarely/Never	71%	(71)	29%	(29)	
No. of times have diagnosed pertussis					
Never	77%	(128)	23%	(38)	NS
1-5 times	83%	(101)	17%	(21)	
>5 times	88%	(37)	12%	(5)	
Tdap vaccine for adults is warranted					
Agree/Strongly Agree	93%	(155)	7%	(12)	< 0.0001
Neutral/Disagree/Strongly	68%	(110)	32%	(52)	

FP, family physicians; IM, general internists; NS, not significant ($p > 0.05$)

indicated; another 18% were unsure and 1% said they would not. Predicted willingness to recommend Tdap vaccine differed significantly by physicians' current approach to administering Td boosters and extent of agreement that Tdap vaccine is warranted to address pertussis disease in adults (Table 2).

The majority (71%) of respondents anticipated stocking Tdap vaccine. Three-quarters of respondents whose practices currently stock Td boosters anticipated stocking Tdap vaccine, compared to 25% of those who do not currently stock Td vaccine ($p < 0.0001$).

At the time the study was conducted, the retail price for Tdap vaccine was not yet known. Given the scenario that Tdap vaccine was expected to cost $20 more than Td vaccine, respondents were asked to anticipate the extent to which the additional cost would be a barrier to recommending and stocking Tdap vaccine for adults. With regard to recommending Tdap vaccine, 28% cited cost as "a strong barrier," 49% "a slight barrier" and 23% "not a barrier." The extent to which cost was perceived as a barrier to recommending Tdap vaccine did not differ by specialty, but did vary by several other variables (Table 3).

With regard to stocking Tdap vaccine, 44% reported that cost will be "a strong barrier," 40% "a slight barrier" and 16% "not a barrier." The extent to which cost was perceived as a barrier to stocking Tdap vaccine did not differ by specialty, but differed by several other variables in a similar pattern as for recommending Tdap vaccine (results not shown). In addition, more respondents (73%) from practices that do not stock Td boosters cited cost as "a strong barrier" to stocking Tdap vaccine, compared to 42% of those from practices that do stock Td boosters ($p < 0.05$).

Physician attitudes regarding Tdap vaccine to prevent pertussis among infants. The majority (73%) of respondents "agree" or "strongly agree" with the statement, "INFANT pertussis is a serious enough disease to warrant administering Tdap vaccine to adults (other than pregnant women) in your practice who are likely to come in contact with infants ≤6 months of age (e.g., expectant fathers, grandparents, day care workers)." Another 19% were "neutral" and 8% "disagree" or "strongly disagree." Extent of agreement with this statement did not differ by physician specialty or current Td booster practices. There was variation by clinical experience with pertussis, with significantly higher levels of agreement among those who have diagnosed pertussis compared to those who have never diagnosed pertussis ($p < 0.005$).

However, when asked how capable their practice would be in identifying persons other than mothers likely to come in close contact with infants ≤6 months of age, only 28% of respondents said their practice would be "capable" or "very capable" of doing so. The majority (54%) rated their practice as "somewhat capable" of doing so, while 20% did not think their practice would be capable of doing so. FPs were more likely than IMs to feel that their practice was "capable" or "very capable" of identifying these adults (34% vs 21%, $p < 0.05$).

Assuming that the ACIP were to target a Tdap vaccine recommendation to adults likely to come in close contact with infants

Table 3 **Differences in attitudes regarding cost as a barrier to recommending Tdap for adults.**

	Extent that Cost of Tdap is a Perceived Barrier to Recommending Tdap for Adults % (N)						
Among Respondents Reporting…	**Strong Barrier**		**Slight Barrier**		**Not a Barrier**		**P-Value**
Major barrier to routine adult Td vaccination:							
Recordkeeping / knowing who needs Td booster							
Yes	32%	(53)	51%	(84)	17%	(27)	< 0.05
No	23%	(38)	47%	(75)	30%	(48)	
Major barrier to routine adult Td vaccination:							
Reimbursement / insurance coverage							
Yes	40%	(32)	37%	(30)	23%	(19)	< 0.05
No	24%	(59)	53%	(129)	23%	(56)	
No. of times have diagnosed pertussis							
Never	31%	(51)	49%	(79)	20%	(33)	< 0.01
1-5 times	30%	(37)	49%	(60)	21%	41%	
> 5 times	7%	(3)	52%	(22)	(25)	(17)	
Tdap vaccine for adults is warranted							
Agree/Strongly Agree	21%	(35)	53%	(88)	26%	(43)	< 0.05
Neutral/Disagree/Strongly Disagree	35%	(56)	45%	(73)	20%	(32)	
Favor stocking Tdap vaccine if recommended for adults by ACIP							
Yes	21%	(47)	53%	(120)	26%	(59)	< 0.001
No/Unsure	42%	(40)	42%	(40)	16%	(16)	
Would recommend Tdap vaccine if recommended by ACIP							
Yes	21%	(55)	53%	(138)	26%	(22)	< 0.0001
No/Unsure	54%	(34)	35%	(67)	11%	(7)	

≤6 months of age, 89% of respondents (94% FPs, 83% IMs, p < 0.01) said that adult primary care providers have a role in promoting Tdap vaccination among this group of adults. The majority also see a Tdap vaccine promotion role for pediatricians (74%), public health providers (67%), and obstetricians (59%). Almost all (95%) also felt that adult primary care providers have a role in administering Tdap vaccine to this group of adults, with the majority also seeing a role for public health providers in administering Tdap vaccine (64%). Less than half felt that obstetricians (41%) and pediatricians (37%) should bear some responsibility for administering Tdap vaccine to adults anticipating close contact with young infants.

DISCUSSION

Against a backdrop of increasing pertussis morbidity among adults[1,2] and persistent pertussis morbidity and mortality among infants too young to receive primary pertussis vaccination themselves,[6,18] the US ACIP voted in October 2005 to recommend that adults aged 19-64 years receive a single dose of Tdap vaccine to replace their next Td booster dose, if they have not received Tdap vaccine previously.[16] The ACIP also recommended that the following adults receive a dose of Tdap vaccine: (1) adults in close contact, or anticipating close contact, with an infant <12 months of age (e.g., parents, grandparents <65 years of age, childcare providers, healthcare personnel), and (2) health-care personnel with direct patient contact. For these adults, intervals as short as two years since the last Td booster dose are recommended, although shorter intervals may be used.

This national survey, conducted prior to the ACIP recommendation, indicates a strong willingness among adult primary care physicians to support the recommendation. Whether this support will translate into successful implementation of the recommendation, with a corresponding reduction in pertussis disease among adults and children, is not yet known.

Given that Tdap vaccine will be administered in place of a Td booster, issues related to Td vaccination will likely affect implementation of the Tdap vaccine recommendations. Despite a longstanding recommendation for adults to receive a Td booster every ten years, less than three-quarters of respondents say that they routinely administer Td boosters for routine health maintenance and most estimate that less than 75% of their adult patients are up-to-date on Td boosters. This finding is consistent with national survey data showing that less than two-thirds of all adults report being vaccinated against tetanus in the past ten years.[11] In addition, physician-reported barriers to Td vaccination will likely be issues for Tdap vaccine as well. The most commonly cited barrier was knowing who needs a Td booster; whether giving Tdap vaccine at an interval shorter than ten years (as short as two years) will impact this barrier is unknown, and should be monitored as the recommendation is implemented.

The additional cost of Tdap vaccine is another consideration identified by many physicians. As respondents were asked to assume in the survey, the private sector cost of Tdap vaccine is close to $20 higher than the cost of Td vaccine.[19] Cost as a barrier was more pronounced for stocking Tdap vaccine compared to recommending Tdap vaccine, implying that access to Tdap vaccine may become an issue if physicians refer their patients to public health providers to receive the vaccine. From a societal perspective, a recent study indicates that one-time adult Tdap vaccination may not be cost effective at conventionally accepted thresholds.[20] However, a reanalysis, presented at the October 2005 meeting of the ACIP, used estimated incidence data for adult pertussis generated from active, prospective surveillance, and concluded that adult Tdap vaccination would likely be cost-effective.[21]

Importantly, most respondents supported Tdap vaccination for adults expected to come in close contact with infants, and also felt that primary care providers have a role in promoting and administering Tdap vaccine to this group of adults. However, less than one-third of respondents believed their practices were readily able

to identify these adults. To reach this group of adults successfully, all relevant practitioners - primary care physicians, obstetricians, pediatricians, and public providers - will need to play an active role in promoting Tdap vaccination.

Of some concern, only one-half of respondents reported having any clinical experience with pertussis. Whether this accurately reflects the extent of actual pertussis cases presenting to these physicians or, alternatively, indicates a degree of underrecognition of pertussis among the respondents could not be determined from this survey. To address the potential for underrecognition of pertussis, provider education regarding the new Tdap vaccine recommendation for adults could include information on the disease burden and clinical presentation of pertussis. Importantly, although those with experience with pertussis were more likely to agree that Tdap vaccine for adults is warranted, experience with pertussis was not associated with respondents' predicted willingness to recommend Tdap vaccine to their adult patients.

There were a few notable differences by physician specialty regarding anticipated Tdap vaccine practices. For example, FPs were more likely than IMs to stock Td, to have diagnosed pertussis, and to believe that the pertussis disease burden in adults warrants the Tdap vaccine recommendation. Despite these contrasts, there was no difference by specialty in predicted adherence to the Tdap vaccine recommendations.

The main limitation of studies utilizing mailed surveys is the possibility of response bias. Those who responded to the survey may be more interested in vaccination issues; at the same time, non-respondents may not as actively endorse adult immunizations. Based on a limited set of demographic variables available, the only statistically significant difference between respondents and non-respondents was that respondents were more likely to be board certified; the meaning of this finding is unclear. Our overall response rate is consistent with those of other published studies of US physician behavior,[22,23] suggesting that our sample was neither more nor less likely to answer questions about immunization practices than about other topics. In addition, the response rate is favorable compared to other studies of immunization attitudes and practices among adult primary care providers,[14,24,25] particularly considering that we were limited to one mailing of the survey in order to meet the timeframe for ACIP deliberations. However, given the potential for response bias, we would hypothesize that the estimates of physician adherence to Tdap vaccine recommendations are likely the upper limits of future national patterns, both overall and within specialties.

In conclusion, this study indicates that adult primary care providers are likely to recommend Tdap vaccine in place of a Td booster to their patients, and support targeting those expected to come in close contact with infants, as recently recommended by the ACIP. Barriers to uptake of the new Tdap vaccine recommendations include low levels of familiarity with pertussis disease and concerns about the cost of the vaccine that may lead physicians not to stock or recommend the vaccine. The extent to which barriers will impede adoption of the new Tdap vaccine recommendations should continue to be monitored, concomitant with efforts to track adult pertussis immunization rates and levels of pertussis disease among adults and children.

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