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Preventable Mix-ups of Tuberculin and Vaccines

Reports to the US Vaccine and Drug Safety Reporting Systems

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Abstract

Background: Errors involving the mix-up of tuberculin purified protein derivative (PPD) and vaccines leading to adverse reactions and unnecessary medical management have been reported previously.

Objectives: To determine the frequency of PPD-vaccine mix-ups reported to the US Vaccine Adverse Event Reporting System (VAERS) and the Adverse Event Reporting System (AERS), characterize adverse events and clusters involving mix-ups and describe reported contributory factors.

Methods: We reviewed AERS reports from 1969 to 2005 and VAERS reports from 1990 to 2005. We defined a mix-up error event as an incident in which a single patient or a cluster of patients inadvertently received vaccine instead of a PPD product or received a PPD product instead of vaccine. We defined a cluster as inadvertent administration of PPD or vaccine products to more than one patient in the same facility within 1 month.

Results: Of 115 mix-up events identified, 101 involved inadvertent administration of vaccines instead of PPD. Product confusion involved PPD and multiple vaccines. The annual number of reported mix-ups increased from an average of one event per year in the early 1990s to an average of ten events per year in the early part of this decade. More than 240 adults and children were affected and the majority reported local injection site reactions. Four individuals were hospitalized (all recovered) after receiving the wrong products. Several patients were inappropriately started on tuberculosis prophylaxis as a result of a vaccine local reaction being interpreted as a positive tuberculin skin test. Reported potential contributory factors involved both system factors (e.g. similar packaging) and human errors (e.g. failure to read label before product administration).

Conclusions: To prevent PPD-vaccine mix-ups, proper storage, handling and administration of vaccine and PPD products is necessary.

The US Institute of Medicine has identified medical errors as an important cause of injuries.[1] Medication errors involving mix-ups in the use of drugs and biological products including vaccines, are not uncommon, especially among products with similar names or appearances and indications.[2-5] Incidents involving inadvertent administration of vaccines instead of tuberculin purified protein derivative (PPD) products have been previously reported, mostly in health newsletters.[6-17] The US FDA in collaboration with the Centers for Disease Control and Prevention (CDC) conducted a review of mix-up errors between vaccine and PPD products reported to the US Vaccine Adverse Event Reporting System (VAERS) and the Adverse Event Reporting System (AERS, also referred to as MedWatch). The objectives of this review were to characterize and determine the frequency of PPD-vaccine mix-up events, describe adverse events and products involved in inadvertent administration of vaccine or PPD and delineate potential contributory factors by systematically evaluating medication errors reported to two national post-marketing databases.

Methods

We reviewed VAERS reports from 1990 to 2005 and AERS reports from 1969 to 2005. VAERS, a spontaneous reporting system for adverse events following administration of US-licensed vaccines, is jointly administered by the FDA and CDC and was formed in 1990.[18,19] AERS is a computerized information database, consisting of spontaneous reports, designed to support the FDA's post-marketing safety surveillance programme for all approved drug and therapeutic biological products.[20]

We searched free text fields for the terms 'tuberculin', 'Mantoux', 'TB Test' and 'PPD' to identify potential mix-up error events in the VAERS database. We identified, using the following free text terms: 'error', 'vaccine', 'inadvertent' and 'instead', AERS reports of possible errors and/or adverse events associated with PPD-vaccine mix-ups, and then reviewed the corresponding detailed line listings. We extracted from the error reports information on vaccine or PPD product administered (e.g. brand name, manufacturer, etc.), route of administration, type of healthcare provider, number of persons affected, demographics, type of adverse event, date of administration and onset of adverse events, health outcome (e.g. hospitalization), type of healthcare setting (e.g. school clinics, correctional facilities, etc.), contributory factors, detection of mix-ups, type of reporter and geographic location.

We defined a mix-up error event as an incident in which a single patient or a cluster of patients inadvertently received vaccine instead of a PPD product, or received a PPD product instead of vaccine. A cluster is defined as inadvertent administration of PPD or vaccine products to more than one patient in the same facility within 1 month.

Results

From 1969 through 2005, 115 mix-up error events were reported from 37 states in the US. Our search strategy identified no mix-up error reports before 1990. The annual number of reported mix-ups increased from an average of one event per year in the early 1990s (1990–4) to an average of 12 events per year during 2000–4 (figure 1). Of these error events, 101 involved inadvertent administration of vaccine instead of tuberculin PPD (76 single-case events and 25 clusters) and 14 involved inadvertent administration of tuberculin PPD instead of vaccine (all single-patient events). There were no reports of event clusters after inadvertent adminis-

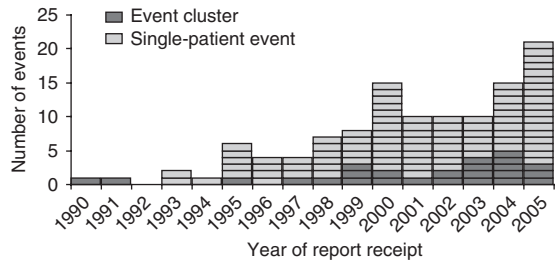

Fig. 1. Distribution of vaccine and purified protein derivative (PDD) mix-up error events by year of report receipt in the US Vaccine Adverse Event Reporting System and the Adverse Event Reporting System. In some reports, the vaccine or PDD administration date is not the same as the report receipt date (e.g. of 21 mix-up events reported in 2005, 12 occurred before 2005). An 'event cluster' is defined as inadvertent administration of PDD or vaccine products to more than one patient in the same facility within 1 month.

Table I. Inadvertent administration of vaccines instead of tuberculin purified protein derivative (PPD)

Vaccine administered	Number of events	
	single-patient	event cluster (number of patients)
Tetanus and diphtheria toxoids for adult use[a]	26	13 (82)
Pneumococcal polysaccharide 23-valent[a]	16	3 (18)
Inactivated influenza[a]	15	1 (multiple)
Tetanus toxoid[a]	6	5 (31)[b]
Hepatitis B[a]	5	0
Diphtheria and tetanus toxoids and pertussis[c]	3	1 (2)
Measles, mumps, rubella	2	0
Diphtheria and tetanus toxoids for paediatric use	1	1 (16)
Inactivated polio	1	0
Varicella	1	0
Hepatitis A	0	1 (2)

a Source: multiple manufacturers; some manufacturers' products are not currently available in the US market.

b Number of patients derived from three clusters. Two clusters did not specify the number of patients involved.

c Diphtheria and tetanus toxoids and pertussis, diphtheria and tetanus toxoids and acellular pertussis, and diphtheria and tetanus toxoids and pertussis/haemophilus b conjugate vaccines.

tration of PPD instead of vaccines. Clusters occurred in hospitals (n = 6), private physician clinics (5), nursing homes (4), correctional facilities (3), school and university health clinics (2), home healthcare settings (2), public health departments (1) and social service agencies (1). One cluster report did not provide information about the healthcare setting. Only a few reports provided information about how the mix-up was detected; examples included notice of unusual pattern of 'large injection site reaction' (false-positive tuberculin skin tests [TSTs]) in low tuberculosis (TB) risk populations, 'cellulitis' at the injection site and reading of product packaging label and lot numbers after administration leading to recognition of the error.

Multiple vaccine products (n = 27) from different manufacturers were involved in the mix-up error events. Some of the reported vaccines are not currently available in the US market. The three vaccines most commonly administered instead of tuberculin PPD were tetanus diphtheria toxoids (Td), pneumococcal polysaccharide 23-valent (PPV) and inactivated influenza for single-patient events; and Td, tetanus toxoid (TT) and PPV for events cluster (table I). Table II describes products involved in the inadvertent administration of PPD instead of vaccines. The two reported tuberculin PPD products, which are used for TSTs, were Tubersol® [1] (Sanofi Pasteur Limited, Toronto, ON, Canada) and Aplisol® (Parkedale Pharmaceuticals, Rochester, MI, USA). The three vaccines most commonly reported as those intended for administration were Td, TT and inactivated influenza. For mix-up error reports that provided information on the professional background of PPD or vaccine administrators, health professionals involved in inadvertent PPD or vaccine administration included nurses (40 events), medical/physician assistants (6), physicians (3) and a pharmacist (1).

More than 240 adults and children (median age and range in years: 29 and 1–80) were affected in these 115 mix-up error events. Most of the reported adverse events were local injection site reactions, including pain, oedema, pruritus, induration, warmth and erythema. The median time from injection to onset was <1 day (range: 0–5 days). In some event clusters, an unspecified number of patients were started on isoniazid as a result of a vaccine local reaction having been interpreted as a positive TST.

Four individuals were hospitalized: (i) a 42-year-old female developed 'serum sickness-like' illness

1 The use of trade names is for product identification purposes only and does not imply endorsement.

Table II. Inadvertent administration of tuberculin purified protein derivative (PPD) instead of vaccines

Product administered	Product intended	Number of single-patient events
Aplisol®	Inactivated influenza[a]	2
Aplisol®	Tetanus diphtheria toxoids for adult use[a]	2
Aplisol®	Tetanus toxoid[a]	2
Aplisol®	Diphtheria and tetanus toxoids and pertussis	1
Tubersol®	Inactivated influenza[a]	1
Tubersol®	Pneumococcal 7-valent conjugate	1
Tubersol®	Tetanus diphtheria toxoids for adult use[a]	1
Tubersol®	Tetanus toxoid[a]	1
PPD unspecified	Hepatitis B	2
PPD unspecified	Tetanus diphtheria toxoids for adult use[a]	1

a Multiple manufacturers; some manufacturers' products are not currently available in the US market.

after inadvertent intradermal administration of pneumococcal vaccine; (ii) a male of unspecified age developed fever, hypotension, syncope, nausea, vomiting and muscle weakness after inadvertent administration of PPD instead of Td; (iii) a 26-year-old male was hospitalized because of dyspnoea and diagnosed with mild asthma after inadvertent intramuscular administration of PPD mixed with hepatitis B vaccine; and (iv) a 14-year-old male experienced an exacerbation of asthma after inadvertent intramuscular administration of PPD instead of Td. All four individuals recovered.

The majority of reports did not provide information on contributory factors to the mix-up errors. For those few reports that provided such information, factors potentially contributing to the mix-up error events included similarities in packaging (11 events), storage of vaccine and PPD products side by side in the refrigerator (3), similar product name abbreviations (i.e. pneumococcal vaccine PPV and tuberculin PPD) [2], pharmacies dispensing and manufacturers distributing the wrong products (2), understaffing and unfamiliarity with vaccine or TST administration (2), use of syringe containing wrong product during concomitant administration of vaccine and PPD products (1) and failure to verify the right product by persons administering TST (1). Product confusion as a result of similar packaging was reported only between Tetanus and Diphtheria Toxoids for Adult Use (Sanofi Pasteur Inc., Swiftwater, PA, USA) and Tubersol® (Sanofi Pasteur Limited, Toronto, ON, Canada). Cited packaging similarities included stylized carton, vial labelling, and vial size and shape. The reported corrective actions taken by healthcare facilities as a result of PPD-vaccine mix-up errors included physical separation of vaccine and tuberculin PPD products in different locations, use of auxiliary labelling (e.g. string tag, name sticker) and review of stocking procedures with staff.

Discussion

Our review showed that the number of vaccine and PPD mix-up errors reported to VAERS and AERS in the early 2000s was more than ten times the number of errors reported in the early 1990s. Higher reporting does not necessarily mean that these mix-up events are increasing in frequency. Several health newsletter articles published since 2000[7-17] may have stimulated reporting by health professionals. If frequency of the events has increased, potential causes include increased availability of vaccine products and/or changing patterns in TST.

There were relatively few reports of intramuscular or subcutaneous administration of PPD instead of vaccines. One possible explanation is that the detection of inadvertent administration of PPD might be less likely because re-examination of a vaccination site (in contrast to TB screening with PPD, which requires examination by health professionals 48–72 hours after administration)[21,22] is not a routine practice. Local injection site reactions following vaccination are common,[23] and their presence alone

therefore would be unlikely to raise suspicion of a medical error.

In the few reports that described contributory factors, both system failures and human errors were potentially implicated in confusion between vaccines and PPD products. Similar product labelling and packaging was reported among multidose vials of tetanus-containing vaccine and PPD products from the same manufacturer. In addition, these products may be stored in the same refrigerator at healthcare facilities, potentially prompting the 'confirmation bias' phenomenon, in which the health professional relies on familiar evidence (e.g. the colour or shape of the vial) and overlooks contrary evidence (e.g. the writing on the container).[3,24] Communication failures such as prescribing errors involving product names and abbreviations (e.g. PPV vs PPD; DTP [diphtheria, tetanus and pertussis] vs PPD; tetanus vs tuberculin) might also have contributed to the mix-up errors. It is noteworthy that many instances of misadministration of vaccine instead of PPD occurred in clusters at healthcare facilities where mass screening for latent TB infection (LTBI) might be a routine practice. Medical errors associated with increased workload or high patient volume settings have been described in the medical literature and might account for these errors in mass screenings.[25-27]

Mix-ups between vaccine and PPD product can lead to several types of errors: diagnostic (e.g. error or delay in diagnosis), treatment (e.g. avoidable delay in treatment or in responding to an abnormal test) or preventive (failure to provide prophylactic treatment).[28] Inadvertent administration of vaccine instead of PPD might lead to false-negative TST and consequently misdiagnosis or delayed diagnosis of LTBI and active TB disease. Although this was not observed in any of the reports, untreated LTBI can progress to active TB disease in susceptible people and delayed diagnosis of TB disease can propagate TB transmission.[29-31] On the other hand, a false-positive TST as a result of injection site reaction can lead to inappropriate diagnostic testing and unnecessary initiation of TB prophylaxis, as well as unnecessary utilization of public health resources in epidemiological investigations.[6,10,24] Drugs recommended for the treatment of LTBI such as isoniazid and pyrazinamide/ethambutol have adverse effects including, rarely, fatal hepatotoxicity.[32-34] Inadvertent administration of PPD instead of vaccine might put individuals at risk for vaccine-preventable diseases including tetanus, diphtheria, pneumococcal disease, hepatitis B and influenza. These adverse outcomes can be prevented or minimized by correcting the factors contributing to the mix-up errors involving vaccines and tuberculin PPD.

To prevent or minimize medication errors involving vaccine and PPD mix-ups, multiple interventions targeting both system and human factors can be taken. The Institute for Safe Medication Practices (ISMP) recommends administrative actions such as purchasing vaccines or PPD products from different manufacturers and improving storage practice of vaccines and tuberculin PPD (i.e. physical separation in the same refrigerator, auxiliary labelling of cartons or containers with alert stickers).[7-9,13,15,35,36] For those facilities that possess bar code scanning technology, such scanning could help prevent errors made during pharmacy dispensing of products or during vaccine or PPD administration.[37] In addition, health professionals should always carefully read labels, record the product name and lot number before each TST administration or vaccination and avoid using medical abbreviations when prescribing vaccines or TST by spelling out the product name. In 2006 and 2007, ISMP reported that the company, Sanofi Pasteur, made labelling changes (e.g. colour change for product package, addition of product abbreviations on the labels, etc.) for its tuberculin PPD, and some vaccine products. An evaluation of their effect on mix-ups would be useful.[35,36]

This study has several limitations. VAERS is not specifically designed for medical error reporting and is subject to the limitations of passive surveillance. These include under-reporting, incomplete case ascertainment, incomplete report information and absence of denominator data on number doses administered for calculating incidence rates. In addition, a causal relationship between the inadvertent administration and reported adverse events (such as those

leading to hospitalizations) can not be determined. Nonetheless, VAERS has played a useful role with regard to surveillance for medication errors in the immunization process, such as overdose, improper vaccination interval and wrong route of administration.[5] The FDA's AERS database shares the same limitations as VAERS. The capture of medical error information may be enhanced by taking into account reports from other non-federal systems.[38,39]

Conclusions

In summary, we observed increased reporting of mix-up errors involving misadministration of vaccines and PPD during the past 15 years, despite efforts to alert health professionals to such problems and to disseminate information on preventive measures through multiple communication channels. Although the error events reported here involve a small (although probably under-reported) proportion of the millions of vaccines and TSTs administered each year, these errors have potential public health implications and can be prevented. Health professionals should consider mix-up errors between vaccine and tuberculin PPD products as a possible explanation when dealing with unexplained clusters of positive TST results.

Clinicians and other healthcare providers in the US are encouraged to report cases of inadvertent administration of vaccines and PPD to VAERS, http://vaers.hhs.gov or telephone 1-800-822-7967 (following vaccine administration), and the FDA's MedWatch Program http://www.fda.gov/medwatch or telephone 1-800-FDA-1088 (following PPD administration), even when they do not result in adverse outcomes. Reporters are encouraged to provide information about associated adverse events, potential contributory factors and suggestions to prevent such errors.

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