Voluntarily reported unintentional injections from epinephrine auto-injectors

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Background: Epinephrine auto-injectors provide life-saving prehospital treatment for individuals experiencing anaphylaxis in community settings.
Objective: To determine the number, demographics, and associated circumstances and outcomes of unintentional injections from epinephrine auto-injectors.
Methods: We searched the databases of the American Association of Poison Control Centers and the Food and Drug Administration's Safety Information and Adverse Event Report System for these incidents as reported by members of the public and by health care professionals.
Results: From 1994 to 2007, a total of 15,190 unintentional injections from epinephrine auto-injectors were reported to US Poison Control Centers, 60% of them from 2003 to 2007. Those unintentionally injected had a median age of 14 years (interquartile range, 8-35), 55% were female, and 85% were injected in a home or other residence. Management was documented in only 4101 cases (27%), of whom 53% were observed without intervention, 29% were treated, 13% were neither held for observation nor treated, and 4% refused treatment. In contrast, from 1969 to 2007, only 105 unintentional injections from epinephrine auto-injectors were reported to MedWatch. Forty percent of these occurred during attempts to treat allergic reactions. Injuries resulting in permanent sequelae were rarely reported to either US Poison Control Centers or to MedWatch.
Conclusion: The number of reported unintentional injections from epinephrine auto-injectors increased annually from 1994 to 2007. To prevent these unintentional injections, improved epinephrine auto-injector design is needed, along with increased vigilance in training the trainers and in training and coaching the users, as well as efforts to increase public awareness of the role of epinephrine auto-injectors in the first-aid treatment of anaphylaxis in the community. (J Allergy Clin Immunol 2010;125:419-23.)

Key words: *Epinephrine auto-injector, adrenaline auto-injector, anaphylaxis, acute allergic reaction, unintentional injection, needle stick injury, sharps injury*

Epinephrine is the drug of choice for the treatment of anaphylaxis.[1-3] Epinephrine auto-injectors are a key component in the first-aid treatment of anaphylaxis in the community.[4,5] Ideally, they should be simple and safe to use, but studies have demonstrated that they are not.[6-8]

People in the community who are at risk for anaphylaxis, or who care for children or other at-risk individuals, require training and regular coaching in the use of epinephrine auto-injectors. Such training is not necessarily provided, and when it is, it cannot be assumed that the physician or other health care professional providing it knows how to demonstrate the use of an epinephrine auto-injector correctly and safely.[6-9]

Unintentional injections from epinephrine auto-injectors have been reported infrequently in the medical literature in the past.[10] In a systematic review, we described a total of 69 cases published in peer-reviewed journals between 1989 and 2008 and noted that most cases were reported between 2002 and 2008.[11] In addition, 2 recent abstracts suggested that the rate of occurrence of unintentional injections from epinephrine auto-injectors might be increasing.[12,13]

The purpose of this study was to estimate the number of unintentional injections from epinephrine auto-injectors occurring each year in the United States and to describe the demographics of those unintentionally injected and the associated circumstances and outcomes. We hypothesized that unintentional injections from epinephrine auto-injectors have been increasing over time across all age groups. We tested this hypothesis by reviewing reports of such injections to US Poison Control Centers (PCCs) from 1994 to 2007 and reports to the US Food and Drug Administration (FDA) from 1969 to 2007.

METHODS

The study protocol was approved by the Institutional Review Board at Virginia Commonwealth University. The databases used to investigate reports of unintentional injections from epinephrine auto-injectors were the American Association of Poison Control Centers' (AAPCC) databases, specifically the Toxic Exposure Surveillance System up to and including 2005, and the National Poison Data System after 2005. We also searched the FDA's Adverse Event Reporting System (AERS) database.

PCCs (AAPCC database)

We accessed the AAPCC database for reports collected from 1994 through 2007 as logged by each of the 61 PCCs. These PCCs use the Poisindex

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Abbreviations used
AAPCC: American Association of Poison Control Centers
AERS: Adverse Event Reporting System
FDA: US Food and Drug Administration
IQR: Interquartile range
PCC: US Poison Control Center

(Micromedex, Denver, Co) database to find information about drugs and other substances by using product names and codes. Case records in the PCCs databases reflect the information voluntarily reported by a member of the public or a health care professional who telephones to report an exposure to a substance and seek medical advice. This information is uploaded to the AAPCC's national databases. The PCCs are staffed by nurses, pharmacists, and other health care professionals who are available to assist callers 24 hours a day, 365 days of the year. The AAPCC is not able to verify the accuracy of every report made to member PCCs. Collection of data is not standardized. Additionally, because reporting is voluntary, some exposures may go unreported to PCCs; therefore, the AAPCC database does not necessarily include all national exposures to a given substance or product.[14]

We searched the AAPCC database by EpiPen product distribution code. We did not include Twinject, an epinephrine auto-injector available in the United States since 2005, in the search because, to date, no product code for it is available in the AAPCC database.

We supplemented the information from the AAPCC database by contacting 6 geographically diverse PCCs (Southeast, Mid-Atlantic, Northeast, Central, Southwest, and Northwest) in order to retrieve specific information that was not uniformly available from all of the PCCs. This included the anatomical location of the unintentional injection (finger, thumb, hand, etc.); specific treatment, if any; and whether the unintentional injection occurred during an attempt to aid someone having an acute systemic allergic reaction.

MedWatch and the FDA AERS database

In addition, we accessed the FDA's AERS database, version 2.0.1, which supports the FDA postmarketing surveillance program known as MedWatch. This AERS database captures and monitors adverse events and medication errors occurring with approved drugs and medical devices prescribed, dispensed, or used by health care professionals and the medical product-using public.[15] Reports are received through telephone calls, faxes, e-mails, and letters. Those posted to the website since 1996 are available for public review.

We searched for and captured additional information about epinephrine auto-injector safety from the AERS database as reported from 1969 through the end of 2007. Key words used in the search included *EpiPen*, *Twinject*, *epinephrine auto-injector*, *epinephrine autoinjector*, *adrenaline auto-injector*, and *adrenaline autoinjector*.

Statistical analysis

All descriptive analyses were performed using STATA 10.0 (StataCorp, College Station, Tx). Data are presented as proportions (with 95% CI) or medians (with interquartile range [IQR]).

RESULTS

Reports to PCCs (AAPCC database)

From 1994 to 2007, PCCs received 15,951 telephone calls about exposures to epinephrine auto-injectors. After application of specific exclusion criteria (see this article's Fig E1 in the Online Repository at www.jacionline.org), we identified 15,190 telephone calls relating to unintentional injections from epinephrine auto-injectors (Fig 1).

The number of reports of unintentional injections increased annually during the 14 years studied ($P < .001$). This increase was noted across all age groups ($P < .001$; Fig 1). Over 60% of unintentional injections were reported from 2003 to 2007 inclusive. Two-thirds of the unintentional epinephrine injections were from EpiPen auto-injectors, while one-third were from EpiPen Jr auto-injectors.

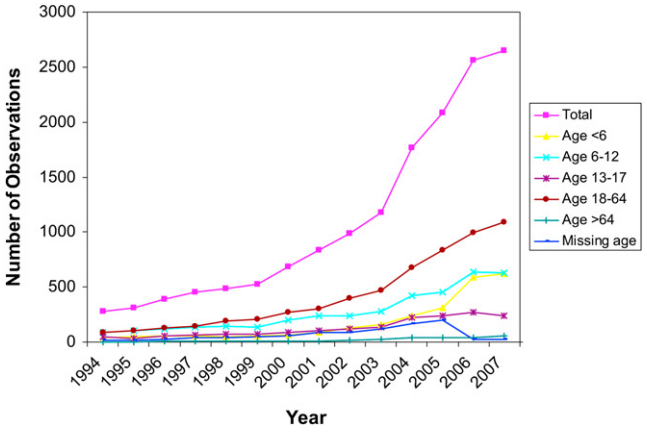

FIG 1. Reports of 15,190 unintentional injections from epinephrine auto-injectors were found in the AAPCC database from 1994 to 2007, inclusive. The graph shows the number of reports by year. Ages are in years.

The median age of those unintentionally injected was 14 years (range, 0-89 years; IQR, 8-35 years), with only 2% occurring in people older than age 65 years. A slight majority of the unintentional injections occurred in females. Most of the unintentional injections occurred in a home or other residence (Table I). Almost half of those unintentionally injected (44%) were managed on site or at a non-health care facility, 31% were referred to a health care facility by their primary care physician, and 23% with an unintentional injection were already en route to a health care facility at the time the PCC was called.

Documentation of the management of the unintentional injections from epinephrine auto-injectors was available for only 4101 (27%) of the cases due to the voluntary nature of the reporting system and the incomplete information available. In these 4101 cases, 49% of the clinical effects were described as "minor," 20% were described as "minimal clinical effects, not followed," and 15% were described as "moderate" (Table I). In the 27% of cases where management was documented in a health care facility, approximately half (54%) of the patients were treated by observation alone without any intervention; 29% had treatment provided, although the nature of the treatment was not known; 13% were neither held for observation nor treated; and 4% refused treatment. In all, only 7.8% of the 15,190 unintentional injections were treated (29% of the 4101 cases where management in a health care facility was documented).

The findings in the 6 geographically diverse PCCs were similar to those in the full AAPCC database. In addition, the regional PCC data provided unique information about the body site where the unintentional injections occurred: 76%, finger or thumb; 14%, hand or palm; 6%, leg or thigh; and 4%, other. The treatment provided was most commonly observation (42%), comfort care (35%), warm soaks or compresses (19%), or nitroglycerin paste applications (15%), with fewer than 10% receiving phentolamine injections. Although PCC personnel did not specifically ask those contacting them how

TABLE I. Characteristics of unintentional injections from epinephrine auto-injectors: AAPCC database

Variable	No. (%)
Type of epinephrine auto-injector*	
EpiPen	3,460 (66)
EpiPen Jr	1,752 (34%)
Age of person unintentionally injured* (y)	
0-5	2,500 (18)
6-11	3,815 (27)
12-17	1,767 (12)
18-65	5,893 (41)
>65	263 (2)
Sex	
Female	8,390 (55)
Location where unintentional injection occurred*	
Home or other residence	12,968 (85)
Other (school, workplace, public area†)	2,091 (15)
Severity	
No effects	977 (6)
Minor effect‡	7,372 (49)
Minimal clinical effect, not followed§	3,088 (20)
Moderate effect‖	2,247 (15)
Major effect¶	27 (0.2)
Other#	1,479 (10)

*Numbers do not add up to 15,190 because the reporting system was voluntary, and the reports did not necessarily include this information.
†For example, park, amusement park.
‡Signs and symptoms minimally bothersome, generally resolve rapidly with no residual disability.
§No follow-up made because patient was expected to experience no more than a minor effect.
‖More pronounced or prolonged than minor effect, treatment usually indicated.
¶Significant signs or symptoms.
#Not followed, judged as nontoxic exposure; or unable to follow, judged as potentially toxic exposure; or unrelated effects.

TABLE II. How the unintentional injections occurred as reported to MedWatch (N = 105)

Description of how the unintentional injection occurred	No. (%)
Person was trying to inject self or another person having an allergic reaction	42 (40)
Person was trying to inspect, familiarize himself/herself with, or was holding, an epinephrine auto-injector when it "accidentally fired"	14 (13)
Person was disposing of an epinephrine auto-injector	12 (11)
Person was participating in an epinephrine auto-injector training session or demonstrating how to use an auto-injector	8 (8)
Person reached into an enclosed space, eg, purse, pencil case, diaper bag and was unintentionally injected	7 (7)
Child was playing with an auto-injector	4 (4)
Person found an epinephrine auto-injector and mistook it for a writing tool such as a highlighter	2 (2)
Person was trying to find out why an epinephrine auto-injector apparently failed to fire	1 (1)
Information about the incident was not available	15 (14)

the unintentional injection occurred, 4% of the PCC cases were reported to involve injection into a digit during an attempt at self-administration or an attempt to aid someone having an allergic reaction. For most of these cases, the outcome in the person experiencing the allergic reaction was not described.

Half of the unintentional injections from epinephrine auto-injectors occurred in children 17 years of age or younger. In this subgroup of young patients, 70% of the unintentional injections were from the EpiPen containing 0.3 mg epinephrine, and 30% were from the EpiPen Jr containing 0.15 mg epinephrine.

Reports to MedWatch and the FDA AERS database

From 1969 to 2007, a considerably longer period than encompassed in the AAPCC database, the preliminary AERS database query returned only 403 reports. Eight of these reports were made before October 31, 1997, and 395 were made after November 1, 1997. After applying primary and secondary exclusion criteria, we selected only reports in which an epinephrine auto-injector was considered to be a suspect medication and in which the unintentional injection from an epinephrine auto-injector had occurred in the United States. This resulted in 105 reports that met the predetermined criteria (see this article's Fig E2 in the Online Repository at www.jacionline.org).

In these 105 reports, the median age was 34 years (range, 2-72 years; IQR, 24-44 years). Almost three-quarters of those unintentionally injected were female, and more than one third were health care professionals. Two of those unintentionally injected were reported to develop severe local vasoconstriction and degloving injury, resulting in amputation of a digit. Of the 105 reports, 90 (86%) contained information about how the incident occurred. Of these, 40% of those unintentionally injected were attempting to treat an allergic reaction, either in themselves or in someone else. Outcomes in those who might have received a decreased epinephrine dose, or no dose, were not described. The circumstances surrounding the unintentional injections are listed in Table II.

Prospective surveillance instrument

Based on the results of this study, the investigators developed a surveillance instrument for collection of detailed information about unintentional injections of epinephrine from auto-injectors. The instrument is intended for use in a prospective trial in selected PCCs (see this article's Table E1 in the Online Repository at www.jacionline.org).

DISCUSSION

The number of unintentional injections from epinephrine auto-injectors has been underreported previously in the medical literature.[10,11] Here we observe that it appears to be increasing, in parallel with the increased rate of occurrence of anaphylaxis[16-24] and the high[25,26] and increasing[21] dispensing rates for epinephrine auto-injectors. During the 14-year period studied, more than 15,000 unintentional injections from epinephrine auto-injectors were reported to the PCCs. The number of unintentional injections increased steadily year by year, especially between 2003 and 2006. Despite this, underreporting might have occurred; for example, there might have been reporting bias against phoning in about unintentional injections that led to little or no injury, and health care professionals inadvertently self-injecting epinephrine during training sessions might not have reported the incidents due to embarrassment.

Most of those unintentionally injected were not treated in a health care facility after contact with PCCs. Although adverse outcomes were not reported in a consistent manner, serious injury and permanent sequelae appeared to be rare. The necessity for routine intervention after injection of epinephrine 1 mg/mL (1:1,000) into a digit has recently been queried.[27]

The PCC database and the AERS database have limitations as surveillance tools because the PCCs and the MedWatch system are based entirely on voluntary reporting, likely underestimate the number of incidents, and do not provide any mechanism for capturing missing or additional information. During PCC telephone calls, a basic template is used for recording information; however, the centers do not use a uniform template, and to some extent, the details captured depend on the specific needs, questions, and comments of the callers.

Similarly, in the MedWatch reporting system, when information is received through telephone calls, faxes, e-mails, or letters, a basic template is used for entering it into the AERS database, but the voluntary nature of the reporting system means that different people contacting MedWatch might focus on different aspects of the unintentional injection and the resulting injury, if any.

The investigators have therefore developed a surveillance instrument suitable for trial use in selected PCCs for systematic collection of information about unintentional injections of epinephrine from auto-injectors. Surveillance might help to obtain insight into the so-called "lost dose hazard," defined as the outcome of the anaphylaxis episode in a patient whose epinephrine dose is either completely lost when unintentionally injected into another person, or partially lost due to profound vasoconstriction and delayed absorption from a digit or other small body space unintentionally self-injected.[11]

When more comprehensive information about unintentional injections from epinephrine auto-injectors is available based on surveillance, the next step will be to develop a protocol for triaging patients who have been injured following such unintentional injections. As there is no consensus with regard to management of the unintentional injuries,[11] it should eventually be possible to perform randomized controlled trials of various treatment modalities. These might include trials of local warming with soaks or compresses versus local application of nitroglycerin paste, or trials of various treatment regimens involving local injections of the α-adrenergic blocker phentolamine with or without lidocaine.

The FDA has issued guidance to the medical device industry regarding incorporation of human factors engineering principles into improving the design and safety of medical devices.[28,29] This will lead to the development of epinephrine auto-injectors that are more intuitive to use and have intrinsically improved safety features.

In the meantime, there should be increased vigilance with regard to prevention of unintentional injections from epinephrine auto-injectors. This should focus on 3 areas:

1. Training the trainers—specifically, the health care professionals such as physicians, nurses, pharmacists, and others who instruct patients and caregivers in how to use epinephrine auto-injectors.[6-9]
2. Training and regularly coaching those who carry and use epinephrine auto-injectors in the community on when and how to use them correctly and safely.
3. Increasing public awareness of the role of epinephrine auto-injectors in the first-aid treatment of anaphylaxis in the community.

We thank Kirk L. Cumpston, DO, for assistance.

Clinical implications: The number of unintentional injections from epinephrine auto-injectors is increasing annually. This trend will be reversed by improved epinephrine auto-injector design and by increased vigilance in training and coaching the users.

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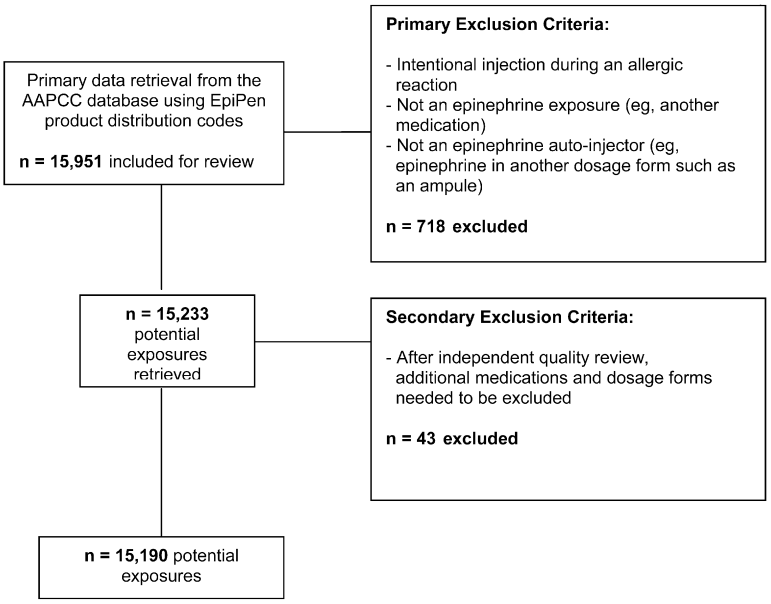

FIG E1. Outline of the strategy used to search reports to PCCs (AAPCC database).

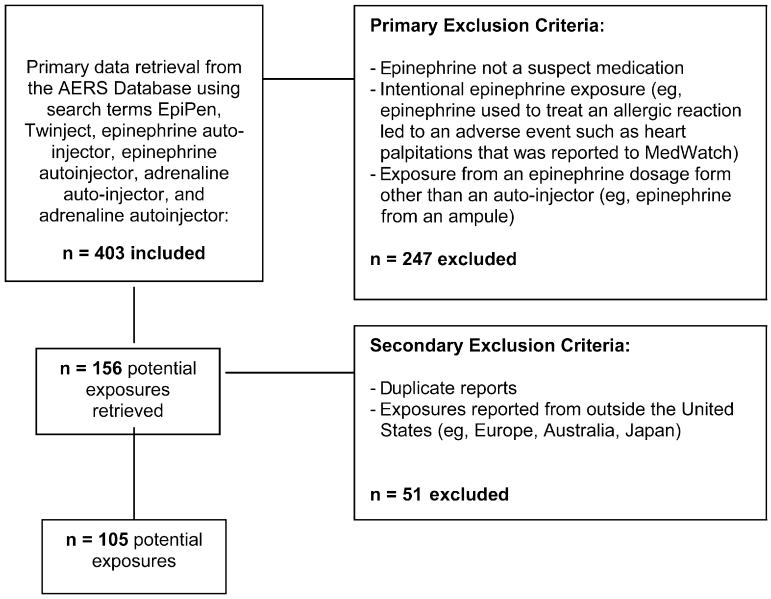

FIG E2. Outline of the strategy used to search reports to MedWatch (FDA AERS database).

TABLE E1. Instrument for surveillance of voluntarily reported unintentional injections from epinephrine auto-injectors

Person reporting the unintentional injection (please check one):
- Self (person who was unintentionally injected) _____
- Parent _____
- Health care professional _____
- Other, please describe _____

Age of person who received the unintentional injection: _____ years

Sex of person who received the unintentional injection:
- Female _____ Male _____

Weight of person who received the unintentional injection (_____ kg; ____ lbs)

Body part injected (please check one):
- Finger _____
- Thumb _____
- Hand _____
- Other (please describe) _____

Epinephrine auto-injector and dose (please check one)
- EpiPen 0.3 mg _____
- EpiPen 0.15 mg _____
- Twinject 0.3 mg _____
- Twinject 0.15 mg _____
- Other, please state name of auto-injector and dose _____
- Expiry date, if known _____

Where did the unintentional injection occur? (please check one)
- Home _____
- Work _____
- School _____
- Restaurant _____
- Health care facility _____
- Other, please describe _____

How did the unintentional injection occur? (please check one)
- Trying to inject self during an allergic reaction _____
- Trying to inject someone else having an allergic reaction _____
- Familiarizing self with how to use epinephrine auto-injector _____
- Using epinephrine auto-injector in training session _____
- Trying to dispose of auto-injector _____
- Reaching into enclosed space, eg. purse, where auto-injector was stored _____
- Child playing with auto-injector ____
- Other, please describe _____

Did the injured body part look/feel normal? Yes _____ No _____

If no, please check all that apply:
- Pale _____
- Blue/purple _____
- Cold _____
- Numb _____
- Painful _____
- Tingling sensation _____
- Other, please describe _____

Did the caller see the injured area? Yes _____ No _____

Were there any symptoms elsewhere in the body? Yes _____ No _____

If yes, please check all that apply:
- Palpitations _____
- Tremor _____
- Headache _____
- Dizziness _____
- Other, please describe _____

Was the injured person assessed in a health care facility? Yes _____ No _____

If yes, check all that apply:
- Examined by a physician _____
- Radiograph (x-ray) _____
- Doppler ultrasound _____
- Surgeon consulted _____
- Other, please describe _____

Was treatment given in a health care facility? Yes _____ No _____

If yes, check all that apply:
- Warm compresses or warm soaks _____

(*Continued*)

TABLE E1. (*Continued*)

Massage _____
Nitroglycerin paste _____
Phentolamine injection _____
Lidocaine injection _____
Antibiotic _____
Other treatment, please describe _____
If the injured person was seen in a health care facility, was he/she admitted? Yes _____ No _____
Did the unintentional injection occur during the treatment of an allergic reaction? Yes ___ No ___
If yes, what happened to the person having the allergic reaction? (check one)
Recovered without getting any epinephrine from the auto-injector _____
Recovered after getting a partial epinephrine dose from the auto-injector _____
Recovered after getting an epinephrine injection from another auto-injector _____
Allergic reaction got worse _____
Died from the allergic reaction _____
Caller does not know what happened _____